Integrated Islet Distribution Program
City of Hope

STANDARD OPERATING PROCEDURE (SOP)
Standardized Packing of IIDP Shipping Container Used for Research Islet Distribution and the Return of Packaging Materials
(*For IIDP Centers)*
Version: SHP-001-07

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1.0 Objective

1.1 The goal of the Integrated Islet Distribution Program (IIDP) is to develop a uniform standardized shipping method among all the subcontracted IIDP centers that will result in minimal loss of quality or quantity of shipped islets (as compared to control islets remaining at the IIDP center). The objective of this Standard Operating Procedure (SOP) is to establish a standardized method for packing and shipping research quality islets to approved investigators.

1.2 This SOP was developed based on results from preliminary studies conducted by the Islet Cell Resource Consortium (ICR) and commissioned by the original IIDP Project Officer (PO), and External Evaluation Committee (EEC). It is the prototype for standardization and will be modified as future methods are tested and approved by the PO, the Scientific Officer (SO) and EEC.

2.0 Scope and Applicability

2.1 This SOP applies to the IIDP Coordinating Center (CC) and to any center using funds from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that provides islets for basic research studies to IIDP approved investigators.

2.2 This SOP will require participation from all participating IIDP centers.

3.0 Responsibilities

3.1 It is the responsibility of the IIDP CC to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.

3.2 It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.

3.3 It is the responsibility of each approved investigator receiving islets through the IIDP to cooperate in returning the shipping boxes and shipping materials to the center supplying the islets.

4.0 Definitions

4.1 Integrated Islet Distribution Program (IIDP): The IIDP is a contracted program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK PO, SO, the EEC and the CC at City of

Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

4.2 IIDP Coordinating Center (CC): Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Research Information Sciences at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.

4.3 Approved Investigators: Researchers who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the EEC.

4.4 Islet Allocation System (IA): This is the online system administered by the IIDP to allow fair distribution of basic science islets to approved investigators. This interactive system used by the IIDP Centers and the Approved Investigators tracks not only the distribution of islets but the return of the shipping materials to the IIDP centers.

5.0 Materials

5.1 The IIDP will provide each center with the following equipment necessary for shipments:

Company/Manufacturer Name	Order#	Item Description
TipTemp	TLCSEN 364A	Ascending and descending disposable temperature indicators
Aremco Scientific	Thermosafe -Model #355	14”x14”x14 5/6” OD Thermosafe container
Haemonetics (was SEBRA)	THER1290	Ambient temperature packs
Cryopack	TCP 22	Small ambient temperature packs
Taylor Packaging	1093	Durasorb Underpads
Taylor Packaging	BW/rolls	Bubble Wrap 1/2 “x 12”x125’/ Roll
Bioexpress	C-3317-5	50 ml centrifuge tubes
Origen	EV120	EVO Origen Bags (120 ml optimum volume)
Bioexpress	191306043	Quart Ziplock Bags
Mediatech	99-603-CV	Connaught Medical Research Laboratories (CMRL)1066
Gemini Bio Products	100106	Fetal Bovine Serum (FBS) HI-BenchMark

Gemini Bio Products	100512	Human AB Serum (ABS)HI- LOT # H15M03A
COH Pharmacy/APP	NDC# 63323-543-02 Product # 504302	Heparin - Preservative Free 5000 USP units/.5ml – 2ml vial
Cellgro, Inc	61-277RG	Ciprofloxacin Hydrochloride – 5 gm bottle
COH Printing	NA	IIDP Labels for Outside Boxes

5.2 Supplies provided by the IIDP Centers:

5.2.1. Islets for distribution
5.2.2 Completed FedEx Shipping Labels and Return Labels to your center
5.2.3 Islet Allocation Tissue Shipment Forms for appropriate recipients
5.2.4 Packing tape for sealing boxes
5.2.5 Markers for labeling vessels
5.2.6 Supplies for transferring islets

6.0 Procedures

6.1 **Receipt of Supplies**
The majority of supplies should be stored in appropriate dry, temperature-controlled environments (room temperature 16-28°C).

6.1.1 The TipTemp Tempasure disposable indicators should be stored at 4°C until use. *Note: Extra care should be taken in handling the TipTemp Tempasure disposable indicators. They will register color changes if handled improperly after activation and come in contact with temperatures exceeding 29°C or below 15°C. (See Attachment 8.1)*

6.1.2. Haemonetics Ambient Gel Packs can be stored at room temperature (16-28°C) *Note: Per J. Hertzel from SEBRA Development, the phase change (frozen solid to liquid) for the ambient gel packs occurs at 19.6°C ±1°C. Charging to solidity is not necessary for proper temperature control. Solidity is only required if packs are needed to cool contents (see 6.2.1 below*).

6.1.3 The Connaught Medical Laboratory (CMRL 1066), the Heparin, and the Ciprofloxacin (Cipro) should be stored between 2 and 8° C upon receipt.

6.1.4 The Fetal Bovine Serum (FBS) and the AB serum should be stored at -5 to -20° C. *(The FBS should be thawed and aliquoted into 50 ml conical tubes and refrozen upon receipt of the 500ml bottles. One conical can be thawed each*

time a bottle of CMRL is prepared, reducing the need for continual freeze/thaw of the FBS.)

6.2 **Media Preparation**

Origen EV120 tissue culture bags are the standardized shipping vessel to be used for the IIDP distribution program. Each bag can hold up to 20,000 IEQs. The bag should be filled with 120 ml of shipping media regardless of the number of IEQs. CMRL 1066, without sodium bicarbonate is the base media provided by the IIDP for islet distribution. Additives provided by the IIDP include FBS or ABS to be used at 10% v/v, Heparin to be used at 10u/ml, and Cipro to be used at 10mg/ml. The following instructions should be followed for media preparation.

6.2.1 Obtain a 500ml bottle of CMRL 1066. Remove 51 ml from the bottle and discard.

6.2.2 Add 50ml of either FBS or ABS to the CMRL 1066. (*The choice of using FBS or ABS was based on the cGMP rules of the specific facilities.)*

6.2.3 Add 0.5 ml of Heparin (10u/ml) to the media bottle.

6.2.4 Add 0.5 ml of Cipro (10mg/ml) to the media bottle.

6.2.5 Use CMRL Complete (base media plus all additives) at 120 ml per Origen EV120 bag.

6.3 **Packing Instructions**

Carefully read and follow the packing instructions below. *Note: Care should be taken to limit the packaged time prior to Fed Ex pick up.*

6.3.1 A minimum of 6 Ambient Gel Packs per shipment should be readied for shipment. If extreme temperatures are expected during shipment route, additional packs may be added to help stabilize the shipment. **Note: as of May 9th, 2012 Haemonetics is no longer producing the Sebra Thermasure Ambient Gel Packs. Please see section 6.3.1.4 for instructions to substitute the Sebra Thermasure Ambient Gel Packs with the Cryopack Phase 22 pouches.*

6.3.1.1 For shipments where expected temperatures are below 5°C (41°F) gel packs should be warmed to 25-28°C before packing. *Note: The Ambient Gel Packs may be placed in or run under warm running water or placed in a 37*°C *incubator until target temperature is met. The contents of the Ambient Gel Packs will be completely liquid at*

this point. (See page 13 of Sebra Thermasure Manual for details- Attachment 8.2).

6.3.1.2 For shipments where expected temperatures are above 30°C (86°F) gel packs should be refrigerated before shipment to allow contents of gel packs to become slushy before packing. *Note: Ambient Gel Packs may be placed in the refrigerator (for less than an hour) or the -20°C freezer (for less than 30 minutes) several hours to lower the temperature to between 18-21°C to attain a semi-solid consistency. (Actual refrigeration time may vary depending on initial room storage temperature at your laboratory.)*

6.3.1.3 For shipments where no extreme temperatures are expected, the gel packs, can be packed directly from room temperature storage or after a brief time in the freezer or refrigerator until a slightly slushy consistency is attained. (20-24°C). *(Again, actual refrigeration time may vary depending on initial room storage temperature at your laboratory.) Note: Gel packs should never be used above or below the shipping temperature ranges we are trying to maintain (15-29°C).*

6.3.1.4 If a center finds themselves short of the standard number of Thermasure Ambient Gel Packs (6) per shipping box, on Thermasure pack may be substituted with four (4) Cryopack Phase 22 gel pouches, place together to cover approximately the same area as the single Thermasure pack. **Note: As many as possible Thermasure Gel Packs should be used in each shipping box, only using the Cryopack Phase 22 pouches when necessary. The Cryopack Phase 22 pouches can be prepped the same as the Sebra Thermasure Ambient Gel Packs listed above.*

EXAMPLE: If there are 10 boxes to send out and a center has only 48 Thermasure Se bra Ambient Gels packs in stock, they should divide them in the following manner:

2 boxes with 4 Thermasure and 8 Cryopack Phase 22 pouches
8 boxes with 5 Thermasure and 4 Cryopack Phase 22 pouches
This will insure that each box has a majority of the standard Thermasure Ambient Gel Packs supplemented by the smaller Cryopack Phase 22 pouches.

6.3.2 Islets are to be counted and tested for quality control post culturing and prior to shipping. These results should be re-entered into the broadcast system

during confirmation of final shipping numbers. (Sterility testing can be done on the final preparation on the day of isolation.) Aliquot the appropriate amounts of islet equivalents (IEQs) into the Origen EV120 shipping bags as determined by the Islet Allocation System. Label islet vessels with Isolation Number, Amount of IEQs, and recipient PI name. ***Note: Islets must be cultured for at least 12 hours post isolation and must have a viability of greater than 80% and purity greater than 50% in order to be reimbursed by the IIDP.***

6.3.3 Gather the rest of the materials listed in 5.0 and prepare for packaging. Open one Thermosafe container and remove Styrofoam lid. Cushion bottom of the container with a layer of bubble wrap and one Durasorb Underpad for absorption if leaking should occur.

6.3.4 Place two (2) ambient temperature packs on top of the underpad.

6.3.5 Obtain TipTemp Tempasure indicator and activate per insert instructions (Pull tab out of the indicator) and tape onto the islet vessel.

Note: See Attachment 8.1. Handle disposable indicator with care in order to avoid triggering of high temperature indicator with body heat.

6.3.6 Place pre-loaded islet vessel into a quart bag and seal. Place on the two bottom ambient temperature packs.

6.3.7 Place two more Ambient Gel Packs next to the islet vessel, one on each side.

6.3.8 Place the final two Ambient Gel Packs on top of the islet vessel.

6.3.9 Pack more bubble wrap around the islets and packs to stabilize the package and avoid movement during shipping. Add a second Durasorb Underpad to the top of the contents for padding and leak protection.

6.3.10 Replace Styrofoam lid and place completed FedEx Return Material Shipping Label, Instruction Sheet for Material Return, and a Tissue Shipment Form on top before closing outside cardboard box. Secure outside box with packing tape and affix FedEx Shipping Label to outside.

6.4 **Return and Tracking of Shipping Boxes and Supplies**

The Islet Allocation System will help in the tracking and return of supplies to the Islet Isolation Centers from the Approved Investigators. The IIDP will be responsible for the cost of returning the Standardized Shipping Box and Supplies back to their center by

reimbursement for the shipping costs when an invoice and copies of the FedEx waybills are supplied to Cindy Palmer, Administrative Manager of the IIDP. The following is the course of events to be followed for all shipments within the United States:

(*Note: For international FedEx shipments please refer to SOP SHP-003-01.)*

6.4.1 The shipping center will enter the IEQs to be shipped (Confirm Recipient screen) and will enter both FedEx tracking numbers (Islet Tracking and Material Tracking) into the Islet Allocation System. In addition, the shipping center should process the shipment by using the on-line FedEx process and click the prompt to alert the recipient of the FedEx tracking number. This will help the recipient investigator follow their shipment through the Fed Ex system and free up time for the centers and the IIDP.

Note: If the investigator has picked up the islets at the distributing center then the center should check "Yes" in the "Direct Pickup" column and "Yes" under "Islets Shipped?" once they are picked up. The box under "Material Shipping Tracking #" will then say "NA" and no further tracking of supplies will be needed.

6.4.2 As soon as the center has entered the # IEQs shipped and indicated that the investigator will be shipped islets, the investigator's account will be set automatically to "ineligible". This will act like "on hold" preventing the investigator from receiving additional offers, open or targeted until the User Feedback Form has been completed and the shipping materials have been returned to the supplying Center.

6.4.3 The shipping center will include a return FedEx label for the investigator to easily send the shipping materials back using the tracking number created by the center. This will also serve as a receipt to use to invoice the IIDP for each return shipment of shipping material.

6.4.4 The investigators will have both FedEx tracking numbers listed in their History of Islet Offers table. Next to the two numbers, is a third column for "Date Materials Returned to Shipping Center". The investigators will enter a date when they send their materials back to the shipping center using the enclosed label and predetermined tracking number. An email will automatically be sent to the shipping center to alert them of the pending shipment.

Note: See Attachment 8.4 "User Guide for Broadcasting Staff 2010"and Attachment 8.5 "User Guide for Investigators 2010" for detailed reference.

6.4.5 As soon as possible, the investigator will complete the on-line User Feedback Form (UFF). A copy of this form will be automatically sent to the supplying center as well as the IIDP for tracking purposes.

6.4.6 Entering the "Date of Materials Returned to the Shipping Center" and Completion of the UFF will change the investigator's account status from "ineligible" to "eligible".

Note: See Attachment 8.6 "UFF User Guide for Broadcasting Staff" and Attachment 8.7 "UFF User Guide for Investigators" for detailed reference.

6.5 **Future Shipments**

The IIDP has supplied each shipping center with equipment to begin the Standardization of Shipping Containers. The IIDP will assist each center with helping to ensure that supplies are returned to the originating center through tracking of islet shipments through the Islet Allocation system.

6.5.1 The IIDP will help track the supplies at each by subtracting those needed per shipment from the originally provided. The IIDP Compliance Administrator (Barbara Olack) will be in charge of ordering all supplies for the individual centers and will coordinate needs through center representatives on a routine basis. If a special need arises, the shipping center representative should contact Barbara Olack at 618-539-3969, bolack@coh.org .

7.0 References

7.1 SEBRA website: http://www.sebra.com/thermasu.htm
7.2 Thermosafe website: http://www.polyfoam.com/content.cfm/cong_othersizes
7.3 Tip Temperature Products website: http://www.tiptemp.com/Product.aspx?ProductID=17344
7.4 Islet Shipping Container Evaluation (UW).ppt presented at the ICR SCM 5/26/07.
7.5 ICR SOP STDY-001-03.
7.6 ICR Shipping Study Subcommittee Minutes H:\ABCC\Subcommittees\Shipping: 8/3/07
7.7 *IATA Guidance Document, Infectious Substances* from the *50th Edition (2009) of the IATA Dangerous Goods Regulations (DGR)*
7.8 University of Wisconsin ITP SOP 001 (Islet Shipping) v3

8.0 Attachments

8.1 Tempasure Plus Handling Instructions

8.2 Ambient Pack Thermasure Instructions
8.3 *IATA Guidance Document, Infectious Substances IATA, 1/1/009*
8.4 User's Guide for Broadcasting Staff 2010
8.5 User's Guide for Investigators 2010
8.6 UFF User's Guide for Broadcasting Staff
8.7 UFF User's Guide for Investigators
8.8 User Instruction Sheet.
8.9 Minimum Required Assessments for Islet Distribution
8.10 Ciprofloxacin Stock Preparation

TEMPASURE PLUS Handling Instructions

The TEMPASURE+ combines the ability to accurately record both a critical descending cold temperature and a critical ascending hot temperature in a single miniature plastic housing.

Allow sensor to stabilize at product temperature. Pull safety TAB to activate sensor. Attach with self-adhesive backing.

Tempasure+ Activated ! Low & Hot Temp windows stays clear to indicate acceptable storage.

Permanent visual record of damaging high temp.

Permanent visual record of damaging low temp.

Permanent visual record of damaging high & low temp

Pre-Use Conditioning
To prevent premature response, the TEMPASURE PLUS indicators must be conditioned prior to removing the activation tab and activating the indicators. Condition indicators for a minimum of two hours in a suitable refrigerator, freezer or chamber at or below the temperature shown on the product.
Once conditioned and ready for use, the indicators can be maintained at any temperature below their trigger temperature.

Note: It is the indicator that must be cooled to the conditioning temperature that is going to be monitored. The product need only be maintained below its critical temperature.

Correct Surface Temperature During Indicator Activation
At the moment the TEMPASURE PLUS is activated by pulling the activation tab. The surface to which it is attached (carton, instruction card, product itself, etc.) must be at a temperature below the threshold temperature of the indicator. Otherwise, the heat from the carton or card could be enough to cause a premature triggering of the indicator.

Activation
After proper pre-use conditioning, the monitoring process is started by simply pulling the side tab off. The TEMPASURE PLUS is now set and will trigger if it exposed to a temperature above or below its trigger temperature (this depends on whether the product is an ascending or descending unit).

Storage
TEMPASURE PLUS Temperature indicators can be stored at 22°C (72°F) and 20-60% relative humidity prior to activation. Keep away from heat, such as, heating vents, hot pipes or direct sun.

Hot temperature indicator
Incorporated into the TEMPASURE PLUS is a single level, non-reversible temperature label. This label will change color from a white/silver to a dark silver/black when it is exposed to its trigger temperature.

You should be careful not to place your fingers on these labels, as it is possible to trigger them with the heat from your body.

IATA Dangerous Goods Regulations

50th Edition (English)
Effective 1 January 2009

ADDENDUM
Posted 23 December 2008

Users of the IATA Dangerous Goods Regulations are asked to note the following amendments and corrections to the 50th Edition, effective from 1 January 2009.

Where appropriate, changes or amendments to existing text have been highlighted (in yellow - PDF or grey - hardcopy) to help identify the change or amendment.

New or Amended State Variations (Section 2.9.2)

Amend **BEG (Belgium)**

Amend BEG-05 to read:

BEG-05 The following requirements apply to aircraft registered:

a) in Belgium no matter where they are operating; and

b) in a State other than Belgium and which are not required to operate under and in accordance with Annex III to Council Regulation (EC) NO. 3922/1991 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation ("EU-OPS"),when they are operating in Belgium:

Aircraft may only carry dangerous goods with the prior approval of the Civil Aviation Authority. Carriage of such goods must be in compliance with the ICAO Technical Instructions.

Application for a general or special authorisation must be submitted to:

Belgian Civil Aviation Authority
Operations Department-Dangerous Goods
CCN – 2nd Floor
Vooruitgangstraat 80 –Bus 5
B-1030 Brussels
Belgium

Telephone: + 32 2 277 43 58
Fax: +32 277 42 57
E-mail: koenraad.clerbout@mobilit.fgov.be

This variation does not apply:

a) to aircraft registered in a State other than Belgium and which are required to operate under and in accordance with EU-OPS providing an approval granted by such a State is held and a copy of this approval is submitted to the Belgian Civil Aviation Authority

b) unless otherwise specified in the ICAO Technical Instructions, to dangerous goods in the case of overflight of the Belgian territory by foreign operators, provided the operator has a permission from its State of Registry to carry dangerous goods in accordance with the provisions of these Instructions.

c) to the transport of Dry Ice (carbon dioxide, solid), UN 1845, when used for cooling purposes in combination with goods not subject to the ICAO Technical Instructions. All other requirements of these Instructions concerning the transport of Dry Ice remain applicable.

New or Amended Operator Variations (Section 2.9.4)

Amend **5X (United Parcel Service)**

5X-02 Shipments of Dangerous Goods in the UPS Small Package service with an origin and/or destination outside the USA, including shipments of Excepted Quantities, and Biological Substances, Category B, will be accepted by contract only. Combination packagings must be used and packages must not exceed 30 kg gross weight. When applicable, not more than three compatible different dangerous goods may be contained in one outer packaging (5.0.2.11). Other than specifically approved shipments of Dangerous Goods in Excepted Quantities, the following classes/divisions of Dangerous Goods are prohibited from UPS international small package service:

- Class 1 (Explosives)
- Division 2.3 (Toxic Gas)
- Division 4.2 (Spontaneously Combustible)
- Division 4.3 (Dangerous When Wet)
- Division 5.1 (Oxidizer)
- Division 5.2 (Organic Peroxide)
- Division 6.1—Substances requiring a “Toxic” label
- Division 6.2 (Infectious Substances, Category A)
- Class 7—Substances requiring a “Radioactive” White–I, Yellow–II, Yellow–III, or Fissile label.
  - — Radioactive Material, Excepted Package shipments are also prohibited.

Add new **BZ (BLUE DART AVIATION LTD)**

BZ-01 Dangerous goods falling under Class 1, explosives will not be accepted for carriage or handling by Blue Dart Aviation.

BZ-02 Dangerous goods in airmail will not be accepted.

BZ-03 Class 7, only the following radioactive materials will be accepted with effect from June 2009.

- Radioactive material in “excepted packages”;
- “Other form” radioactive material packaged in Type A packagings, not exceeding the A_2 values or Transport Index 10;
- The Shipper’s Declaration accompanying each shipment of radioactive material in categories I, II or III, must show the following endorsement “This radioactive material is intended for use in, or incidental to, research or medical diagnosis or treatment.”

BZ-04 Radioactive & fissile wastes will not be accepted for carriage

BZ-05 The shipper must provide a 24-hour emergency telephone number of a person/agency who is knowledgeable of the hazards, characteristics & actions to be taken in case in the case of an accident or incident concerning each of the dangerous goods being transported. This telephone number, including the country & area code, preceded by the word “Emergency Contact” of “24-Hour number” must be inserted in the Shipper’s Declaration for Dangerous Goods, in the “handling information” box.

A “24 hour” emergency telephone number is not required for shipments that do not require a Shipper’s Declaration for Dangerous Goods.

BZ-06 Prior clarification must be taken from the operator for sending shipments containing magnets under UN 2807. Refer to instructions under Packing Instruction 902.

BZ-07 Infectious substances, patient specimens, diagnostic specimens, clinical specimens & biological substances (human or animal) will only be accepted if assigned to UN 2814 or UN 2900, as appropriate. The only exceptions to this variation are:

- Dried blood spots, collected by applying a drop of blood onto absorbent material.
- Pathogen –free blood or blood components collected for transfusion or for the preparation of blood products to be used for human or animal transfusion or transplantation.
- Any tissue or organs intended for use in human or animal transplantation.

In these cases, the air waybill must bear a detailed description to enable identification as non regulated material (see Packing Instruction 602 & 8.2)

Amend **IJ (Great Wall Airlines)**

IJ-01 Only explosives of Division 1.4S packed for passenger and cargo aircraft will be accepted and these must be loaded in the lower deck of all aircraft.

IJ-02 Items with a primary or subsidiary risk of Division 2.1, ~~Class 3,~~ Class 4 and Class 5, when packed for Cargo Aircraft Only, will not be accepted for carriage.

Amend **LH (Deutsche Lufthansa / Lufthansa Cargo AG)**

Amend LH-03

LH-03 Infectious substances, UN 2814, UN 2900 and UN3373 will not be accepted in air mail.

Delete LH-07 to LH-13.

Amend **SQ (Singapore Airlines / Singapore Airlines Cargo)**

Amend SQ-06

SQ-06 UN3356 Oxygen Generator, Chemical will not be accepted.

Amend **US (US Airways)**

Amend US-01
US-01 US Airways will not accept shipments for carriage which contain articles and substances listed in these regulations and / or DOT Hazardous Materials Regulations, and revisions thereto, except for the following:

- Articles listed as not restricted or non-regulated in said regulations.
- Carbon dioxide, solid (Dry Ice) in individual packages with 5.5 pounds per package / 2.5 kilos or less cooling non-restricted contents.
- Environtainer - Unit Load Device equipment with Dry Ice cooling non-restricted contents.
- US Airways Company Material transported as aircraft replacement items.

ACKNOWLEDGEMENTS

Pg. xvii – Insert Dangerous Goods Board member as shown:

Mr. A. McCulloch, United Parcel Service, Louisville, USA

Section 1

Pg. 6 – In Table 1.5.A insert “x” into column 8 for row “Limitations”.

Section 2

Pg. 12 – Amend 2.3.2.2 as shown:

2.3.2.2 Wheelchairs/Mobility Aids with Non-spillable Batteries

Wheelchairs or other battery-powered mobility aids with non-spillable batteries (see Packing Instruction 806 and Special Provision A67), provided ~~that the battery is disconnected,~~ the battery terminals are protected from short circuits, e.g. by being enclosed within a battery container, and the battery is securely attached to the wheelchair or mobility aid (see 9.3.15.4 and Figure 9.3.G). Operators must ensure that wheelchairs or other battery-powered mobility aids are carried in such a manner so as to prevent unintentional operation and that the wheelchair/mobility aid is protected from being damaged by the movement of baggage, mail, stores or cargo.

~~***Note:***~~

~~*Wheelchairs/mobility aids with gel type batteries do not require the battery to be disconnected provided the battery terminals are insulated to prevent accidental short circuits.*~~

Pg. 14 – Amend Table 2.3.A as follows:

NO	YES	NO	YES	NO	**Wheelchairs or other battery-powered mobility devices with non-spillable batteries** (see Packing Instruction 806 and Special Provision A67), provided the battery terminals are insulated to prevent accidental short circuits, e.g. by being enclosed within a battery container, and the battery is securely attached to the wheelchair or mobility aid. Operators must ensure that wheelchairs or other battery-powered mobility aids are carried in such a manner so as to prevent unintentional operation and that the wheelchair/mobility aid is protected from being damaged by the movement of baggage, mail, stores or cargo. ~~***Note:***~~ ~~*Wheelchairs/mobility aids with gel type batteries do not require the battery to be disconnected provided the battery terminals are insulated to prevent accidental short circuits.*~~

Section 4

Pg. 214 – Add EQ Codes against UN 2478, Isocyanate solution, flammable, toxic, n.o.s.. For PG II add “E2” and for PG III add “E1”.

Pg. 214 – Add EQ Codes against UN 2206, Isocyanates solution, toxic, n.o.s.. For PG II add “E4” and for PG III add “E1”.

Pg. 222 – Add EQ Codes against UN 3336, Mercaptans, liquid, flammable, n.o.s.. For PG I add “E3”, for PG II add “E2” and for PG III add “E1”.

Pg. 247 – Add EQ Codes against UN 3259, Polyamines, solid, corrosive, n.o.s.. For PG I add “E0”, for PG II add “E2” and for PG III add “E1”.

Pg. 317 – Amend Special Provision A44 as follows:

A44 The entry chemical kits or first aid kits is intended to apply to boxes, cases, etc. containing small quantities of one or more compatible items of dangerous goods which are used for example for medical, analytical or testing or repair purposes. The only dangerous goods, which are permitted in the kits, are substances which may be transported as:

- excepted quantities as specified in Column F of Table 4.2, providing the inner packagings and quantities are as prescribed in ~~2.7.5.1~~Table2.7.A and ~~2.7.8.2~~2.7.5.1(a);
- limited quantities under ~~2.8.1~~ 2.8.2.1.

Pg. 320 – Amend Special Provision A99 as follows:

A99 Irrespective of the limit specified in Column L of the List of Dangerous Goods (Subsection 4.2), a lithium battery or battery assembly that has successfully passed the tests specified in the UN Manual of Tests and Criteria, Part III, sub-section 38.3 and that meets the requirements of Packing Instruction ~~903~~ 965 for lithium ion batteries, and Packing Instruction 968 for lithium metal batteries as prepared for transport may have a mass exceeding 35 kg G, if approved by the appropriate authority of the State of origin. A copy of the document of approval must accompany the consignment.

Pg. 322 – Amend Special Provision A123 as follows:

A123 This entry applies to Batteries, electric storage, not otherwise listed in Subsection 4.2 – List of Dangerous Goods. Examples of such batteries are: alkali-manganese, zinc-carbon, nickel-metal hydride and nickel-cadmium batteries. Any electrical battery or battery powered device, equipment or vehicle having the potential of a dangerous evolution of heat must be prepared for transport so as to prevent

(a) a short-circuit (e.g. in the case of batteries, by the effective insulation of exposed terminals; or, in the case of equipment, by disconnection of the battery and protection of exposed terminals) ~~is forbidden from transport~~; and

(b) accidental activation.

Pg. 322 – Amend Special Provision A130 as follows:

A130 When this material meets the definitions and criteria of other classes or divisions as defined in Section 3, it must be classified in accordance with the predominant subsidiary risk. Such material must be declared under the proper shipping name and UN number appropriate for the material in that predominant class or division, with the addition of the name applicable to this radioactive material according to Column B in Subsection 4.2 – List of Dangerous Goods, and must be transported in accordance with the provisions applicable to that UN number. In addition, all other requirements specified in ~~10.5.9 must apply, except 10.8.3.9.1, Step 3~~ 10.3.11 apply.

Pg. 325 – Amend Special Provision A163 as follows:

A163 (340) Chemical kits, first aid kits and polyester resin kits containing dangerous goods in inner packagings which do not exceed the quantity limits for excepted quantities applicable to individual substances as specified in Column F of Table 4.2 may be transported in accordance with 2.7. Division 5.2 substances, although not individually authorized as excepted quantities in Table 4.2, are authorized in such kits and are assigned Code E2 (see ~~2.7.1.1~~ 2.7.4.1).

Section 5

Pg. 330 – Amend 5.0.2.3 as follows:

Unless otherwise provided for, the UN specification packagings detailed in the packing instructions must meet the performance test requirements of the relevant packing group shown in Column ~~F~~ E of the List of Dangerous Goods for the particular article or substance.

Pg. 373 – Amend Packing Instruction 306 to add the following two new UN numbers:

INNER PACKAGINGS						
Desc.	**Glass, Earthenware**	**Plastic**	**Metal (not aluminium)**	**Aluminium**	**Glass ampoule**	**PPR (see below)**
Spec.	**IP1**	**IP2**	**IP3**	**IP3A**	**IP8**	
Unit	**L**	**L**	**L**	**L**	**L**	
UN 1250	1.0	F	1.0	F	0.5	5
UN 1305	1.0	F	1.0	F	0.5	5

Pp. 437/438 – Amend Packing Instruction 602 as follows:

This instruction applies to UN 2814 and UN 2900.

Packagings must meet the requirements of 6.5 and must be marked as required by ~~6.0.6~~ 6.5.3.1.

…

Substances consigned refrigerated or frozen (wet ice, prefrozen packs, Carbon dioxide, solid [dry ice]): Ice, Carbon dioxide, solid (dry ice) or other refrigerant must be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with ~~6.0.6~~ 6.5.3.1. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has dissipated. If ice is used, the outer packaging or overpack must be leak-proof. If Carbon dioxide, solid (dry ice) is used, the outer packaging or overpack must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

Pg. 511, 512, 514, 515, 517, 519 – Amend Part 1 of Packing Instructions 965 to 970 as follows:

General requirements

Cells and batteries must be packed in strong outer packagings that conform to 5.0.2.4, 5.0.2.6.1 and ~~5.2.12.1~~ 5.0.2.12.1.

Insert the following new text into Part 1 of Packing Instructions 965, 967, 968 and 970 as follows:

Overpacks

Individual packages each complying with the requirements of Part 1 may be placed in an overpack. The overpack may also contain packages of dangerous goods or goods not subject to these Regulations provided that there are no packages enclosing different substances which might react dangerously with each other. An overpack must be marked with the word "Overpack" and labelled with the lithium battery label (Figure 7.4.I), unless the label(s) on the package(s) inside the overpack are visible.

Any person preparing or offering cells or batteries for transport must receive adequate instruction on these requirements commensurate with their responsibilities.

Pg. 513 – Amend Packing Instruction 966 as follows:

Part 2

Part 2 requirements apply to each cell or battery type that has been determined to meet the criteria for assignment to Class 9.

Each cell or battery must:

1. Be of the type proven to meet the requirements of each test in the UN *Manual of Tests and Criteria*, Part III, subsection 38.3.
2. Incorporate a safety venting device or be designed to preclude a violent rupture under conditions normally incident to transport and be equipped with an effective means of preventing external short circuits.

Each battery containing cells or series of cells connected in parallel must be equipped with an effective means, as necessary, to prevent dangerous reverse current flow (e.g. diodes, fuses).

Additional requirements

- all lithium ion cells and batteries prepared for transport as Class 9 must be protected against short circuits;
- the completed package for the cells or batteries must meet Packing Group II packaging standards;
- ~~each completed package containing lithium cells or batteries must be marked and labelled in accordance with the applicable requirements of Section 7;~~
- the equipment and the packages of lithium cells or batteries must be placed in an overpack. The overpack must bear applicable marks and labels as set out in 7.1.4 and 7.2.7;
- for the purpose of this packing instruction, "equipment" means apparatus requiring the lithium batteries with which it is packed for its operation.

COMBINATION PACKAGINGS		
	Quantity per package Passenger aircraft	Quantity per package Cargo Aircraft Only
Quantity of lithium ion cells and batteries per overpack, excluding weight of equipment	5.0 kg	35.0 kg

OUTER PACKAGINGS

Type	Drums							Jerricans			Boxes						
Desc	Steel	Alum-inium	Ply-wood	Fibre	Plastic	Other metal	Steel	Alum-inium	Plastic	Steel	Alum-inium	Wood	Ply-wood	Recon-stituted wood	Fibre-board	Plastic
Spec	1A2	1B2	1D	1G	1H2	1N2	3A2	3B2	3H2	4A	4B	4C1 4C2	4D	4F	4G	4H1 4H2

Pg. 518 – Amend Packing Instruction 969 as follows:

Part 2

Additional requirements

- all lithium metal cells and batteries prepared for transport as Class 9 must be protected against short circuits;
- the completed package for the cells or batteries must meet Packing Group II packaging standards;
- ~~each completed package containing lithium cells or batteries must be marked and labelled in accordance with the applicable requirements of Section 7;~~
- the equipment and the packages of lithium cells or batteries must be placed in an overpack. The overpack must bear applicable marks and labels as set out in 7.1.4 and 7.2.7;
- for the purpose of this packing instruction, “equipment” means apparatus requiring the lithium batteries with which it is packed for its operation.

Lithium metal cells and batteries prepared for transport on Passenger Aircraft as Class 9:

- must be packed in rigid metal intermediate or outer packaging;
- cells and batteries must be surrounded by cushioning material that is non-combustible and non-conductive, and placed inside an outer packaging.

COMBINATION PACKAGINGS		
	Quantity per package Passenger aircraft	Quantity per package Cargo Aircraft Only
Quantity of lithium metal cells and batteries per overpack, excluding weight of equipment	5.0 kg	35.0 kg

OUTER PACKAGINGS

Type	Drums							Jerricans			Boxes						
Desc	Steel	Alum-inium	Ply-wood	Fibre	Plastic	Other metal	Steel	Alum-inium	Plastic	Steel	Alum-inium	Wood	Ply-wood	Recon-stituted wood	Fibre-board	Plastic
Spec	1A2	1B2	1D	1G	1H2	1N2	3A2	3B2	3H2	4A	4B	4C1 4C2	4D	4F	4G	4H1 4H2

Section 7

Pg. 576 – Revise requirements for lithium battery label as follows:

Colour: The border of the label must have red diagonal hatchings. Text and symbols black on a ~~white~~ contrasting background.

Section 10

Pg. 645 – In paragraph 10.3.11.1.3(b) and 10.3.11.1.3(c) amend “Table 10.3.C” to read “Table 10.3.D”.

Pg. 645 – Amend paragraph 10.3.11.1.5 as follows:

10.3.11.1.5 Empty Packages

An empty packaging which had previously contained radioactive material with an activity not exceeding the limit specified in the column headed "~~Instruments and Articles~~ Materials — Package Limits" in Table ~~10.3.C~~ 10.3.D may be classified as UN 2908, Radioactive material, excepted package empty packaging, provided that:

Appendix G.3

Pg. 815 – Add Austrian Airlines to the list of currently validated airlines.

Integrated Islet Distribution Program

ISLET DATA ENTRY SYSTEM

USER GUIDE for Broadcasting Staff 2010

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1.0. General Guidelines

1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Main Menu (e.g. access the Enter New Isolation data form). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for completing each section of the Enter New Isolation Data Form are presented in the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the Islet Allocation data entry screens are designed to be a 'single page' in which the data for each section of the IDES data form are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the IDES Data Form to capture the data.

1.2.2.1 Text Boxes

- Data must be typed in
- Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen – e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the

validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

(mm/dd/yy)

The system will automatically enter the forward slashes **(/)** as you enter the date.

1.3.1.2 Time Field Formats

(hh:mm)

The system will automatically enter the colon **(:)** as you enter the time.

1.3.1.3 Date Field Ranges

06/04/2010 (mm/dd/yy)

The system will display a message that the date is out of range and that the latest date that may be entered is the current date.

1.3.1.4 Numeric Field Formats

Percent of Trapped Islets (xxx.xxx)

This is one example of a numeric field format within the ICP Data Form.

1.3.1.5 Numeric Field Ranges

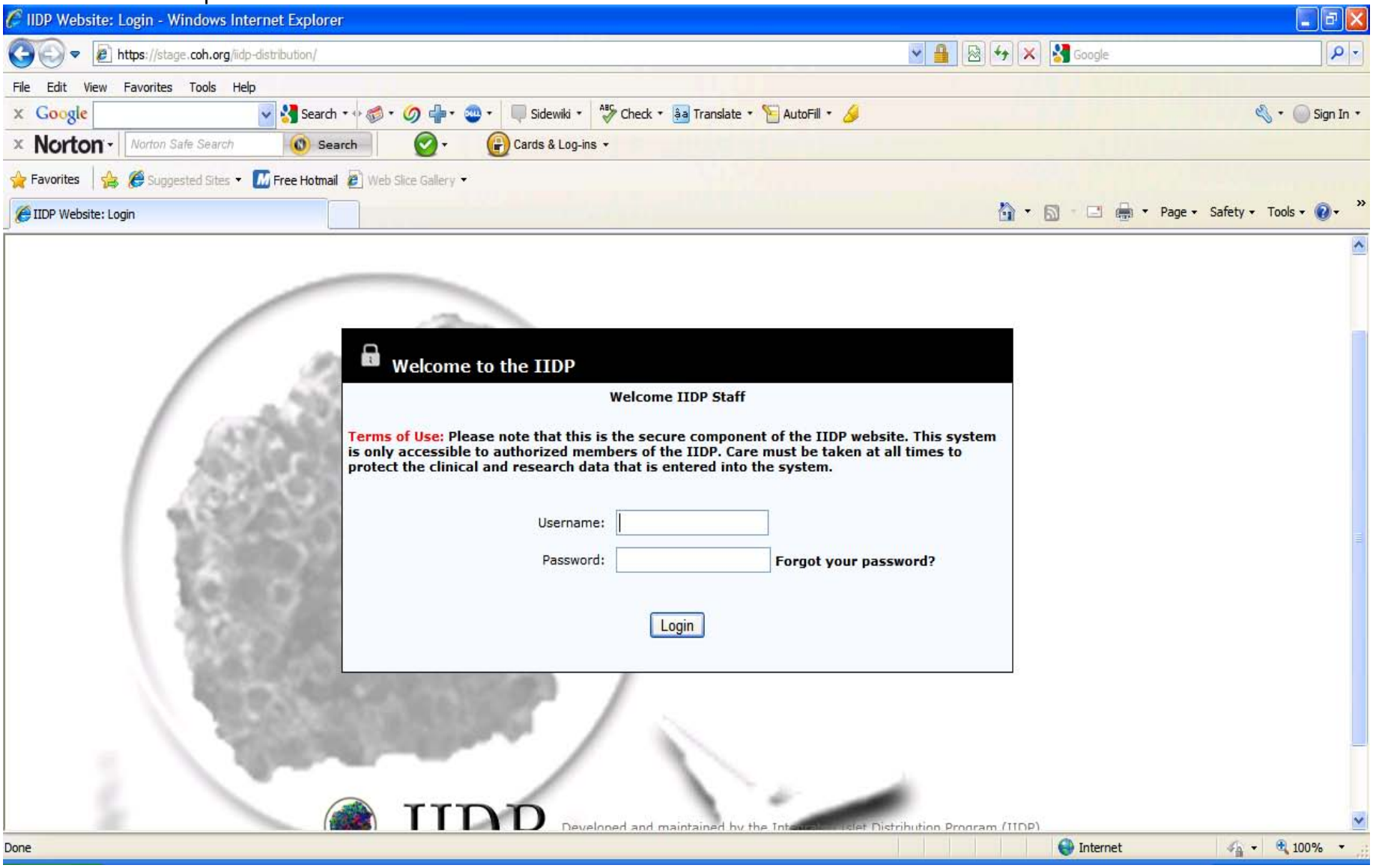
Acceptable Numeric Value → Percent of Trapped Islets 75.34 % (xxx.xxx)

Numeric Value Out of Range → Percent of Trapped Islets 110.93 % (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

2.0 Login to the Islet Data Entry System (IDES)

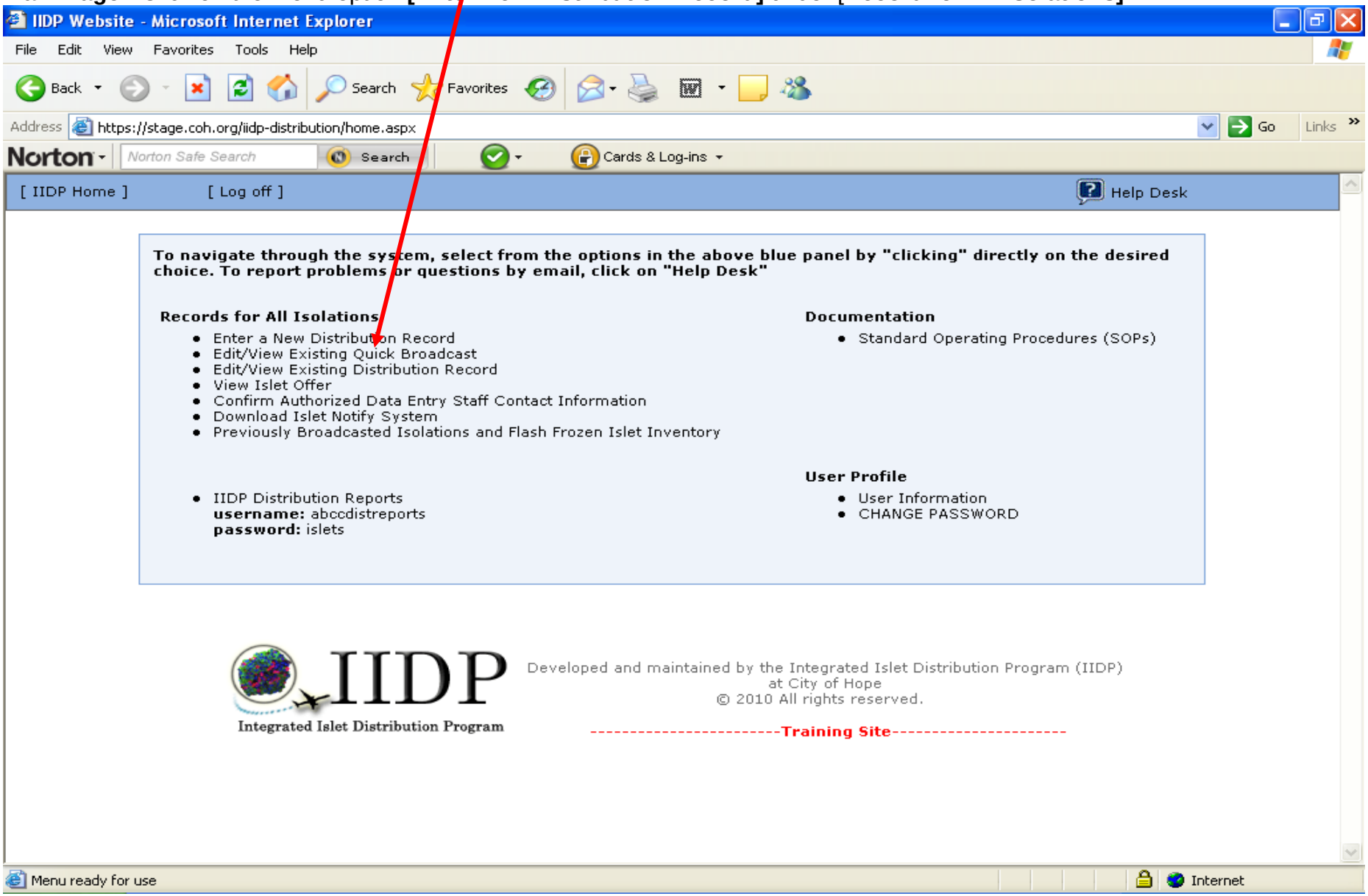
Login Screen - The system displays the login screen. Enter your username and password and then click on Login. IIDP assigns the username and password.



Main Page for the Islet Data Entry System (IDES) - Click on **[IIDP Home]** at any time to return to the Main Page.

3.0 New Process Options – Quick Broadcast or Complete a Distribution Record

Main Page - Click on the menu option **[Enter New Distribution Record]** under [**Record for All Isolations**].

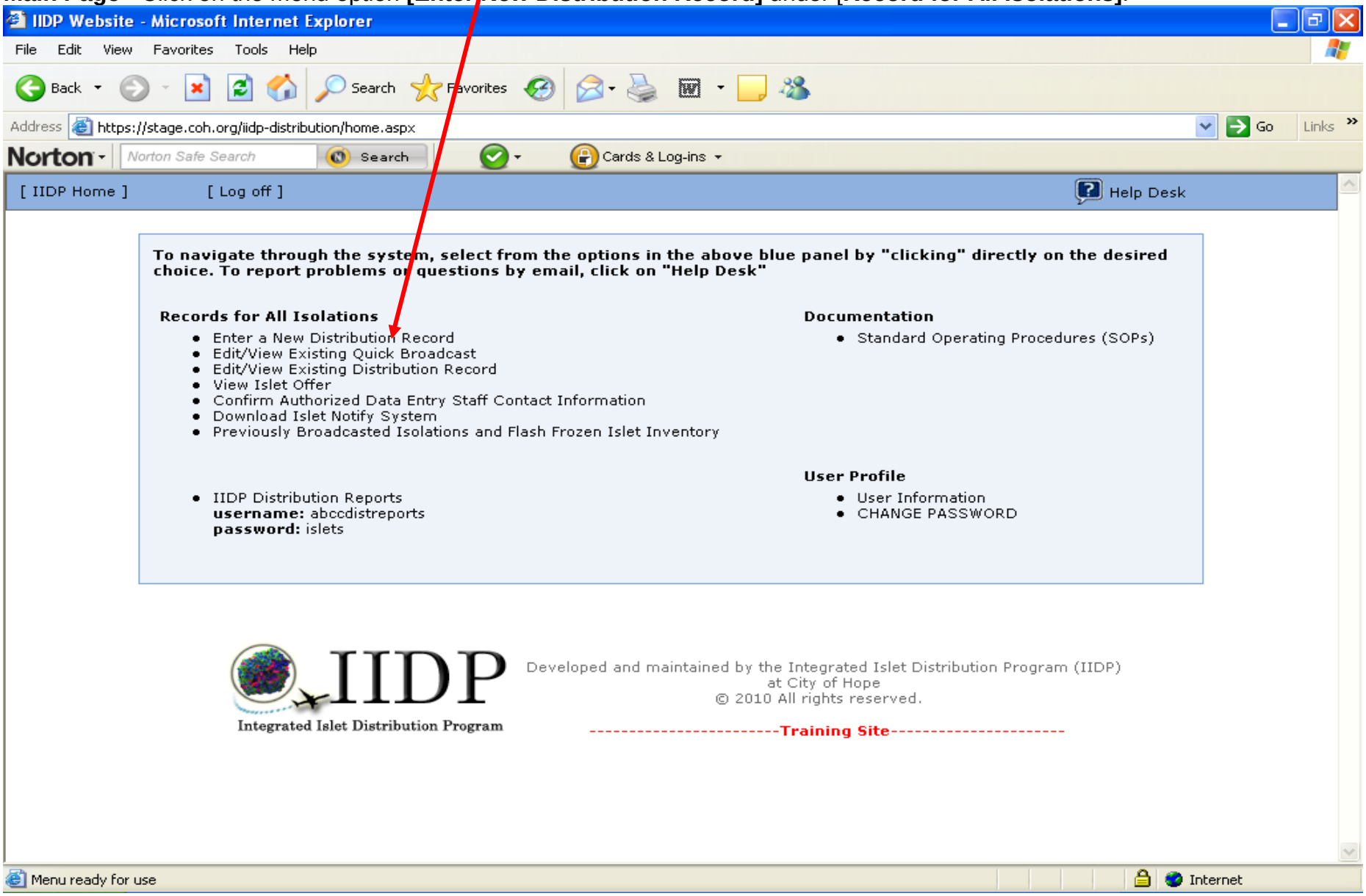


The system will then display the screen to select whether to broadcast an isolation or to complete a distribution record.

Click on **[Quick Broadcast]** to broadcast an isolation OR click on **[Complete a Distribution Record]** to complete a distribution record.

4.0 Broadcast an Isolation – Quick Broadcast

Main Page - Click on the menu option **[Enter New Distribution Record]** under [**Record for All Isolations**].

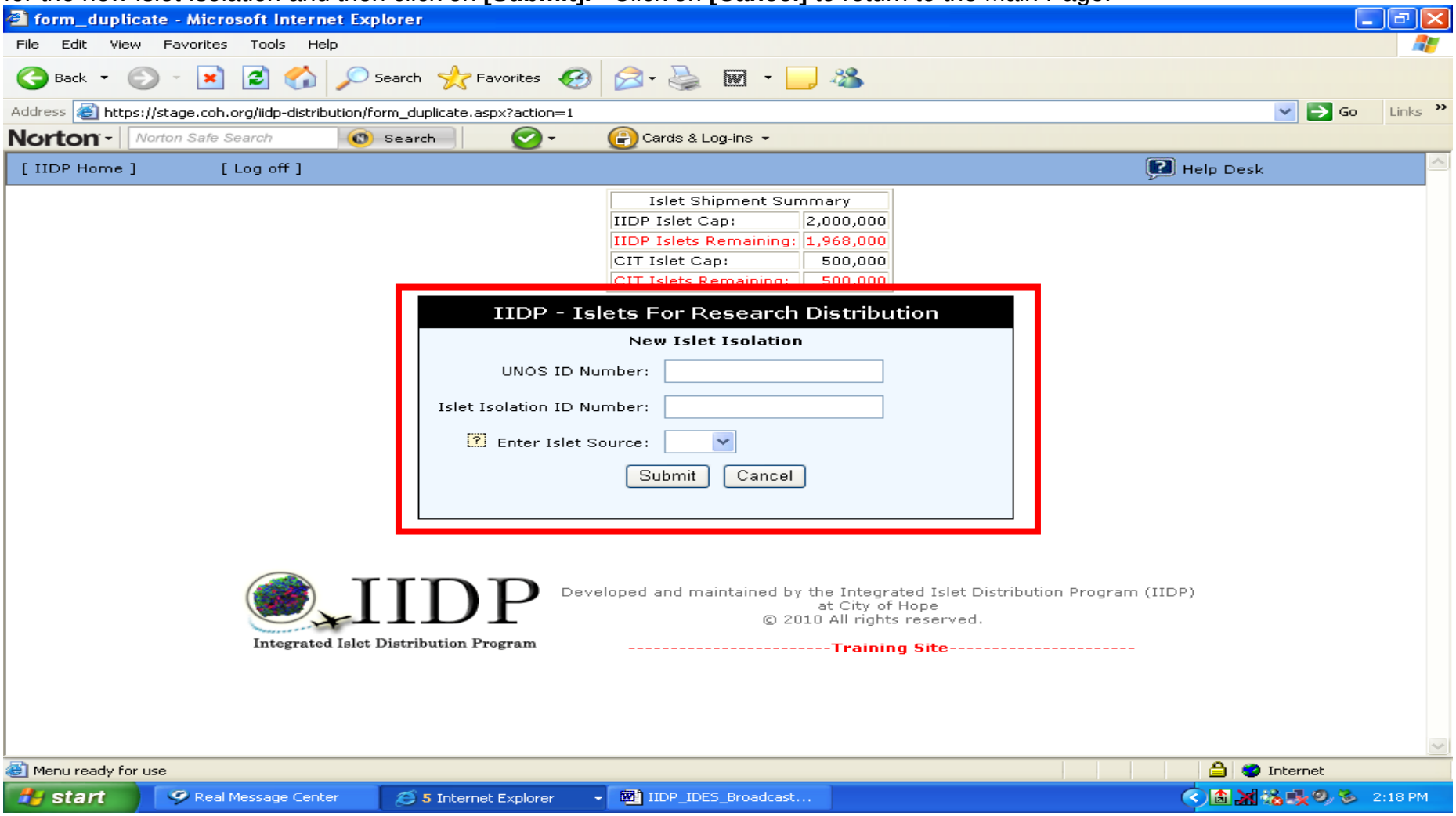


The system will then display the screen to select whether to broadcast an isolation or to complete a distribution record.

Click on **[Quick Broadcast]** to broadcast an isolation.

The system will display the UNOS ID and Islet isolation ID screen.

UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit].** Click on **[Cancel]** to return to the Main Page.

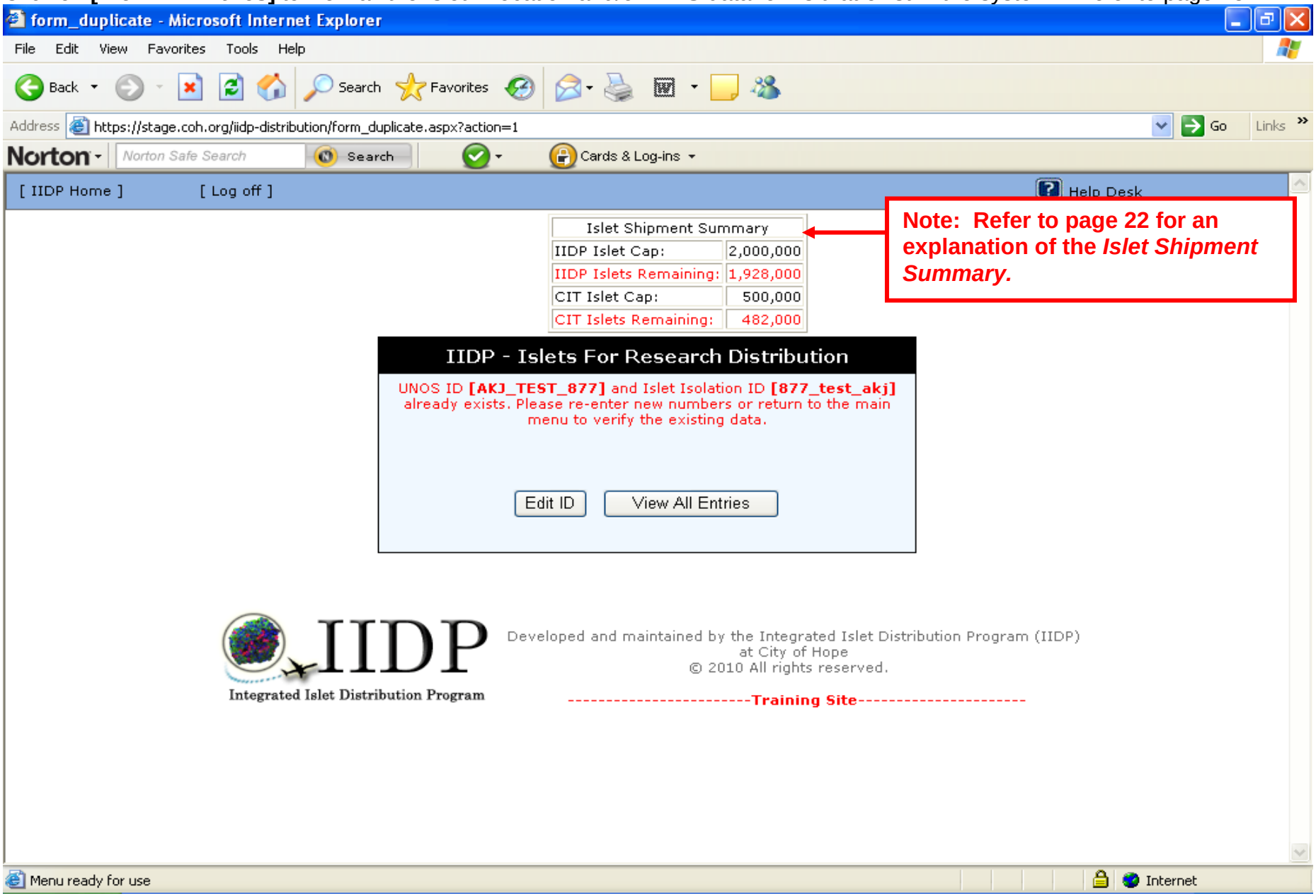


The system will compare the newly entered ID numbers with existing ID numbers in the system to prevent duplication of IDES data forms.

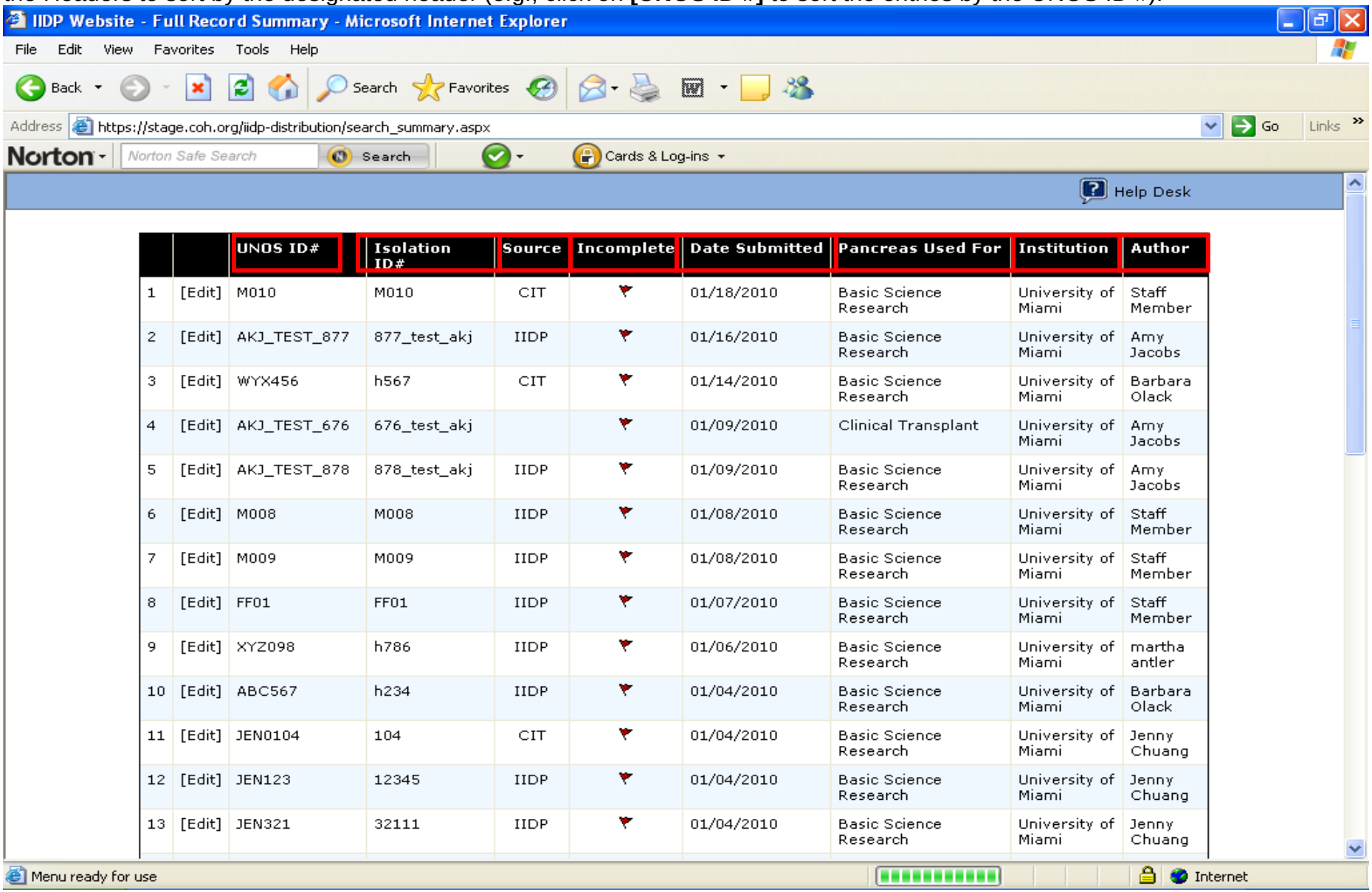
If the system finds a match with existing ID number(s), the system will display a message that the ID number(s) entered match existing ID number(s) – Refer to page 12.

If the system does not find a match, the system will display the Quick Broadcast Detail Summary screen – refer to page 15.

Click on **[Edit ID]** to re-enter the UNOS ID number and the Isolation ID number – Refer to page 11.
OR
Click on **[View All Entries]** to view all the Islet Allocation and/or IDES data forms that exist in the system – Refer to page 13.



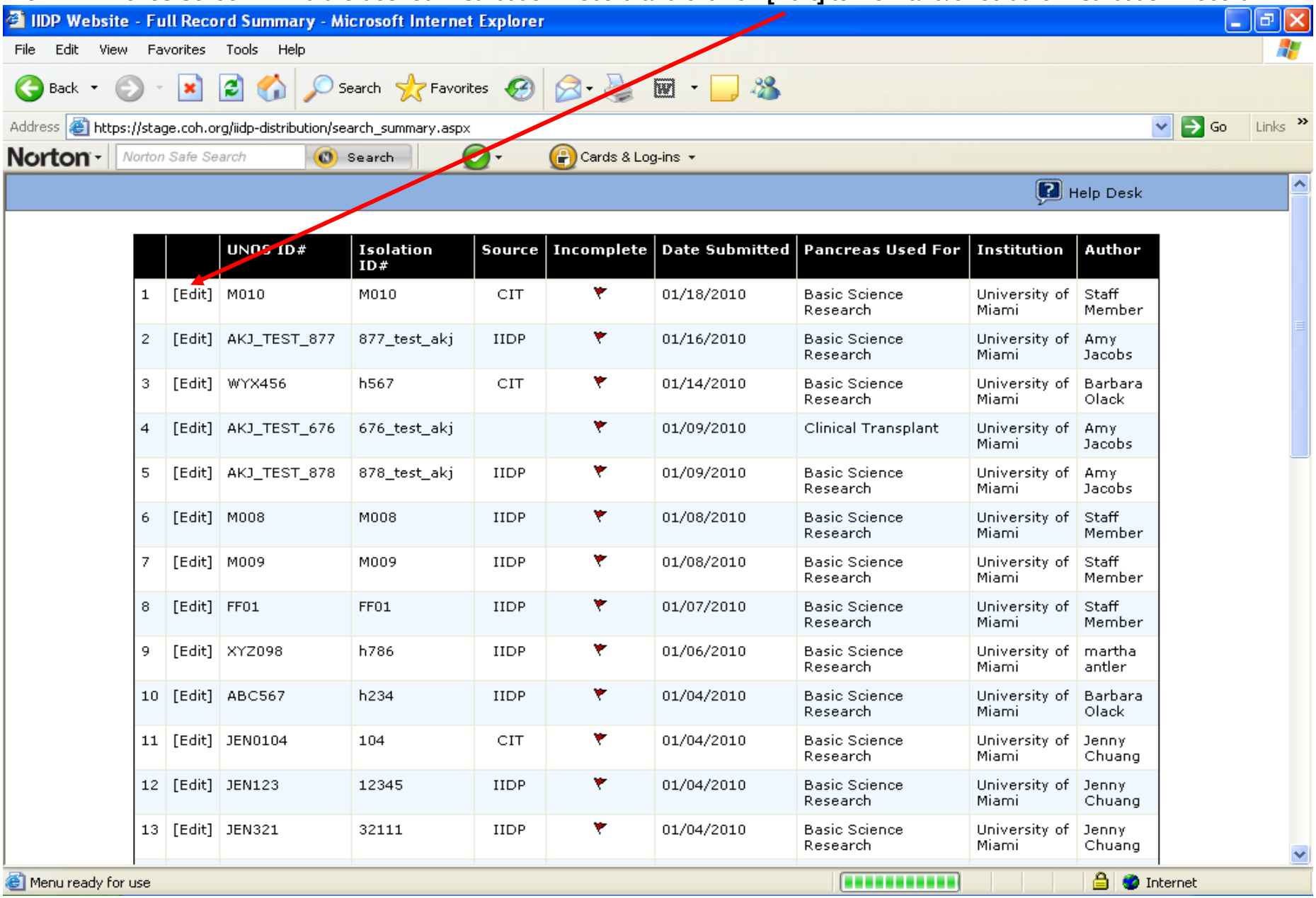
View All Entries screen - This system displays all of the Distribution Records entered for your specific institution. Click on any of the Headers to sort by the designated header (e.g., click on **[UNOS ID #]** to sort the entries by the UNOS ID #).



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	M010	M010	CIT		01/18/2010	Basic Science Research	University of Miami	Staff Member
2	[Edit]	AKJ_TEST_877	877_test_akj	IIDP		01/16/2010	Basic Science Research	University of Miami	Amy Jacobs
3	[Edit]	WYX456	h567	CIT		01/14/2010	Basic Science Research	University of Miami	Barbara Olack
4	[Edit]	AKJ_TEST_676	676_test_akj			01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs
5	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
6	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
7	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
8	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
9	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
10	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
11	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
12	[Edit]	JEN123	12345	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
13	[Edit]	JEN321	32111	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang

NOTE: In these examples screens, because it is from the training site (identical to the production ('real') site) all of the IDES data forms entered from the University of Miami. However, in the production ('real') site, users of each institution will only be able to see IDES data forms for their institution.

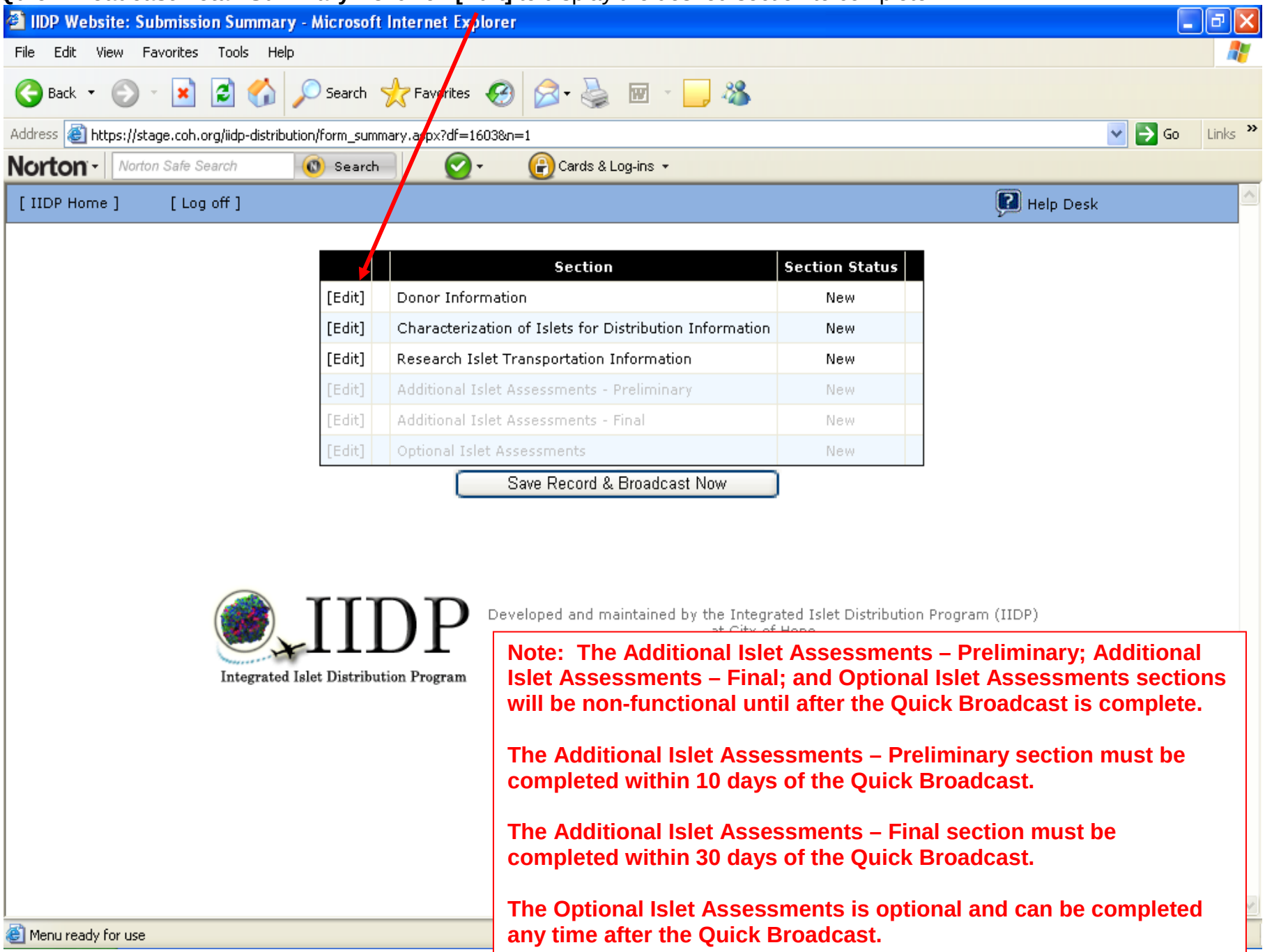
View All Entries screen - Find the desired Distribution Record and click on **[Edit]** to view and/or edit the Distribution Record.



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	M010	M010	CIT		01/18/2010	Basic Science Research	University of Miami	Staff Member
2	[Edit]	AKJ_TEST_877	877_test_akj	IIDP		01/16/2010	Basic Science Research	University of Miami	Amy Jacobs
3	[Edit]	WYX456	h567	CIT		01/14/2010	Basic Science Research	University of Miami	Barbara Olack
4	[Edit]	AKJ_TEST_676	676_test_akj			01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs
5	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
6	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
7	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
8	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
9	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
10	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
11	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
12	[Edit]	JEN123	12345	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
13	[Edit]	JEN321	32111	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang

The system will display the **Distribution Record Detail Summary** screen - refer to page 63.

Quick Broadcast Detail Summary - Click on **[Edit]** to display the desired section to complete.



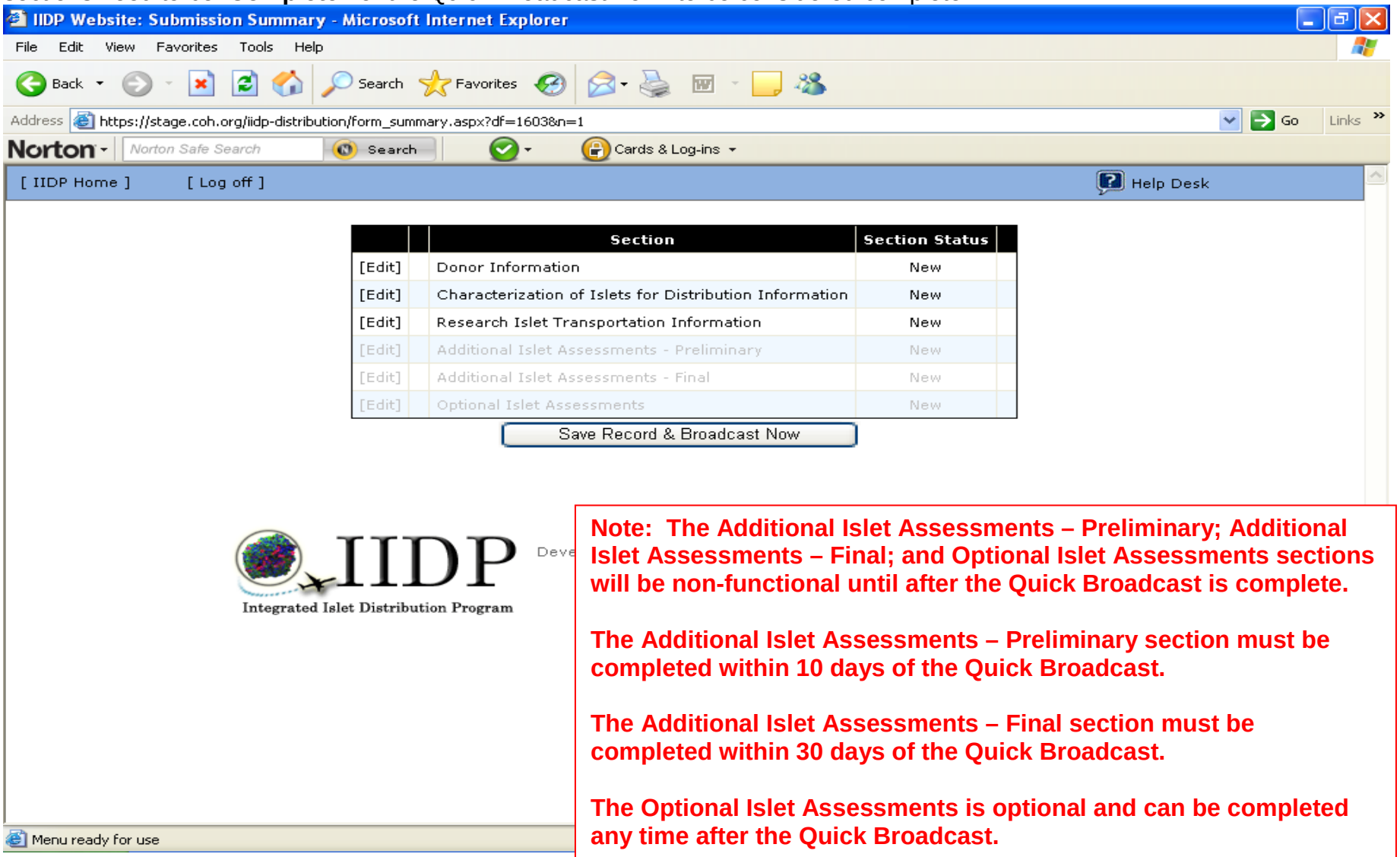
Note: The Additional Islet Assessments – Preliminary; Additional Islet Assessments – Final; and Optional Islet Assessments sections will be non-functional until after the Quick Broadcast is complete.

The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.

The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.

The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.

Quick Broadcast Detail Summary - The system will display the **Status** of each section as '**New', 'Complete', or 'Incomplete'.** The Donor Information, Characterization of Islets for Distribution Information, and Research Islet Transportation Information sections need to be **'Complete'** for the Quick Broadcast Form to be considered complete.



Note: The Additional Islet Assessments – Preliminary; Additional Islet Assessments – Final; and Optional Islet Assessments sections will be non-functional until after the Quick Broadcast is complete.

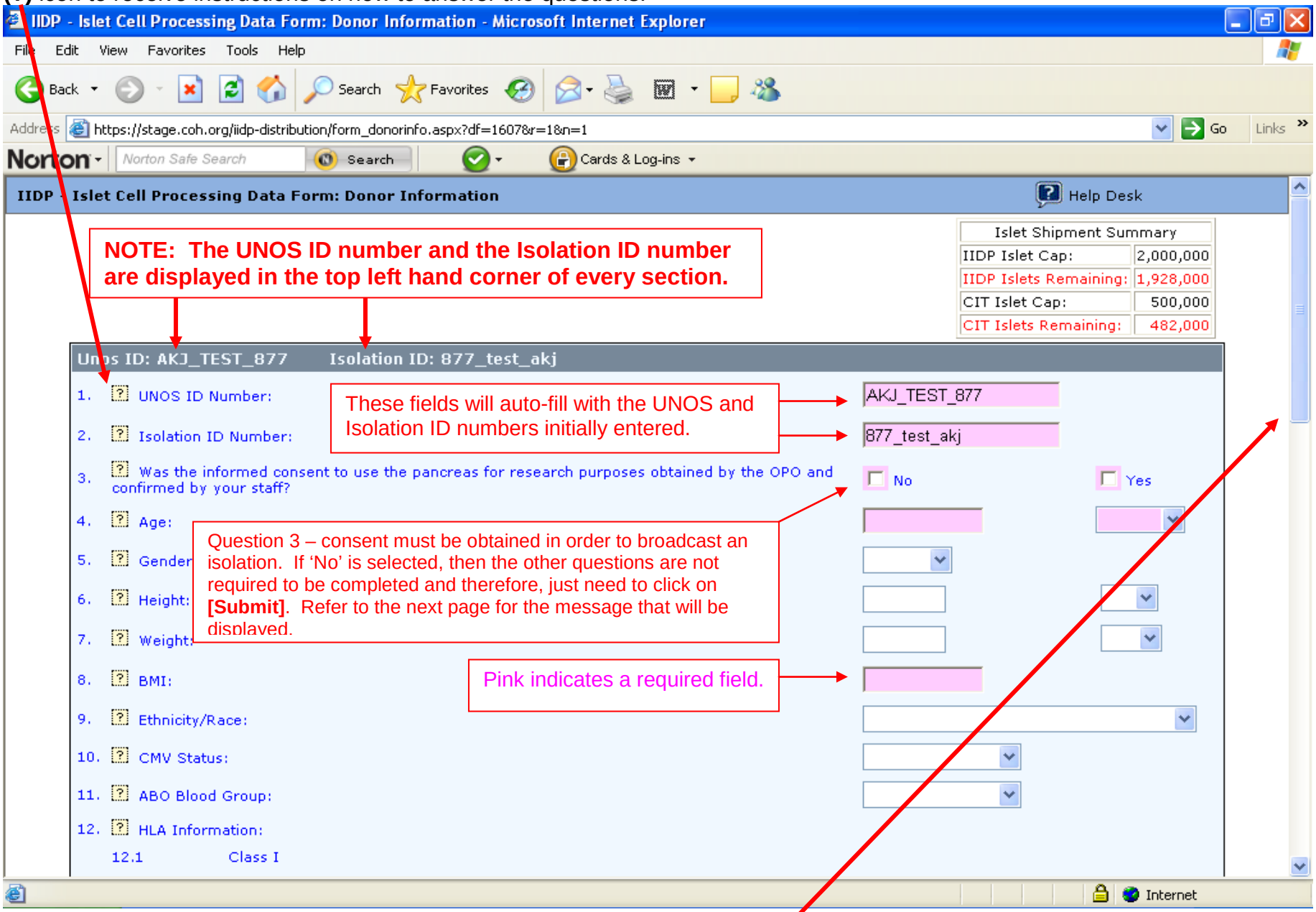
The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.

The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.

The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.

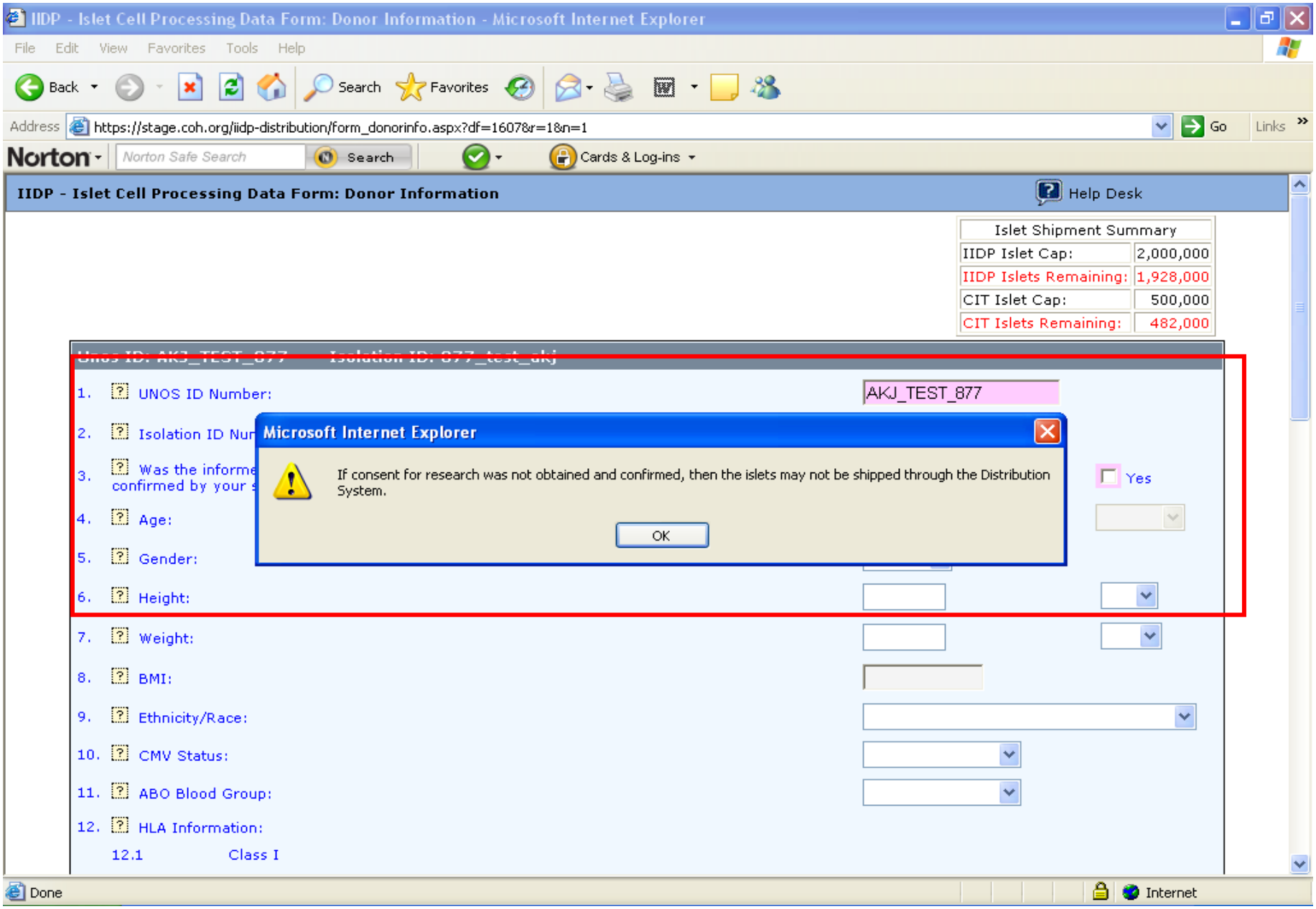
NOTE: The user may randomly select the order in which to complete each section (e.g., Donor Information section, then the Research Islet Transportation Information section, and then the Characterization of Islets for Distribution Information section). However for the purpose of this User's Guide, the sections will be discussed in the order as listed above.

Donor Information section - Complete the questions in the Donor Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.

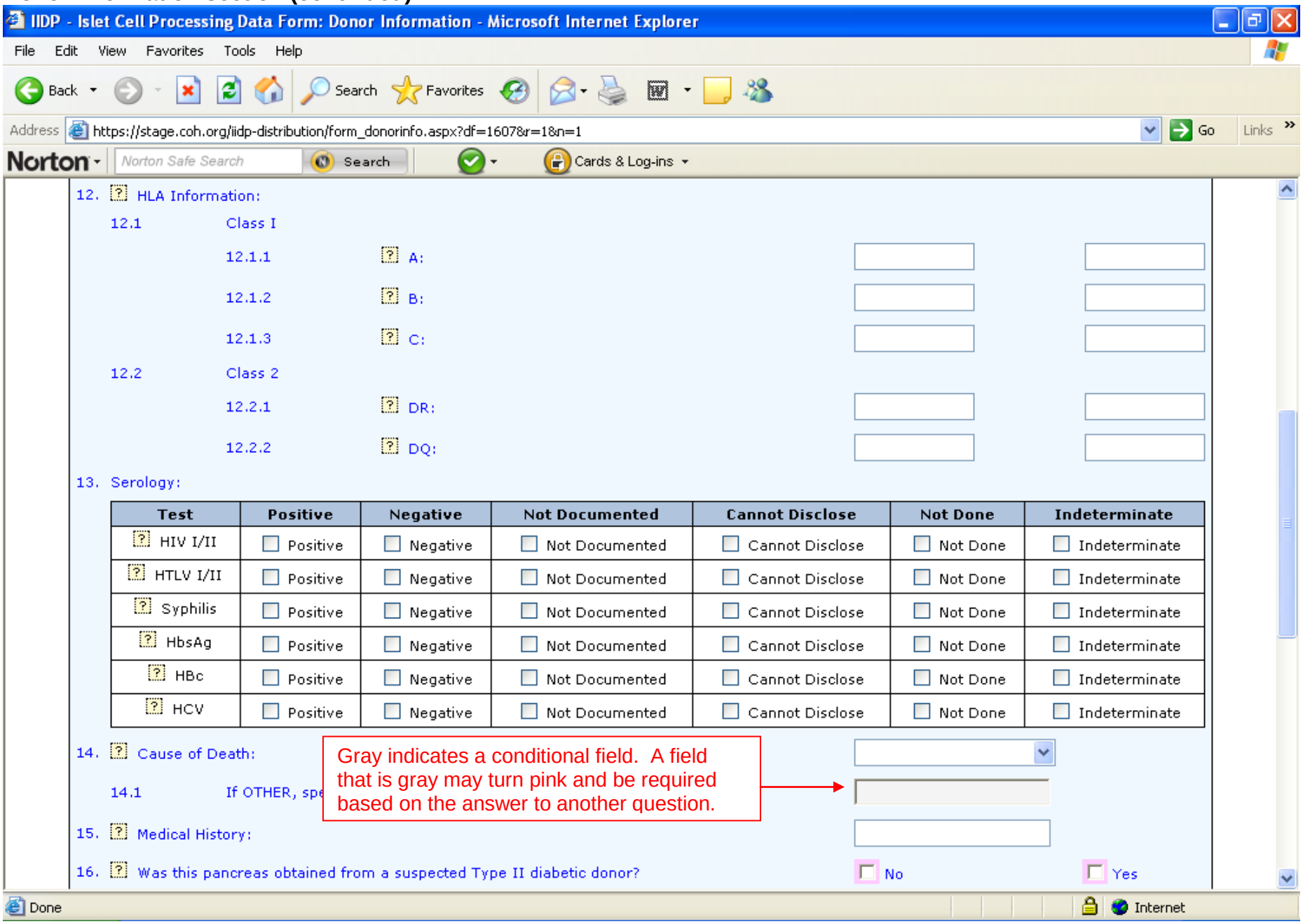


Each section in the form is considered a 'single page'. You can use the **scroll bar** to scroll down to the bottom of the section. The **Donor Information section** is continued on the next page.

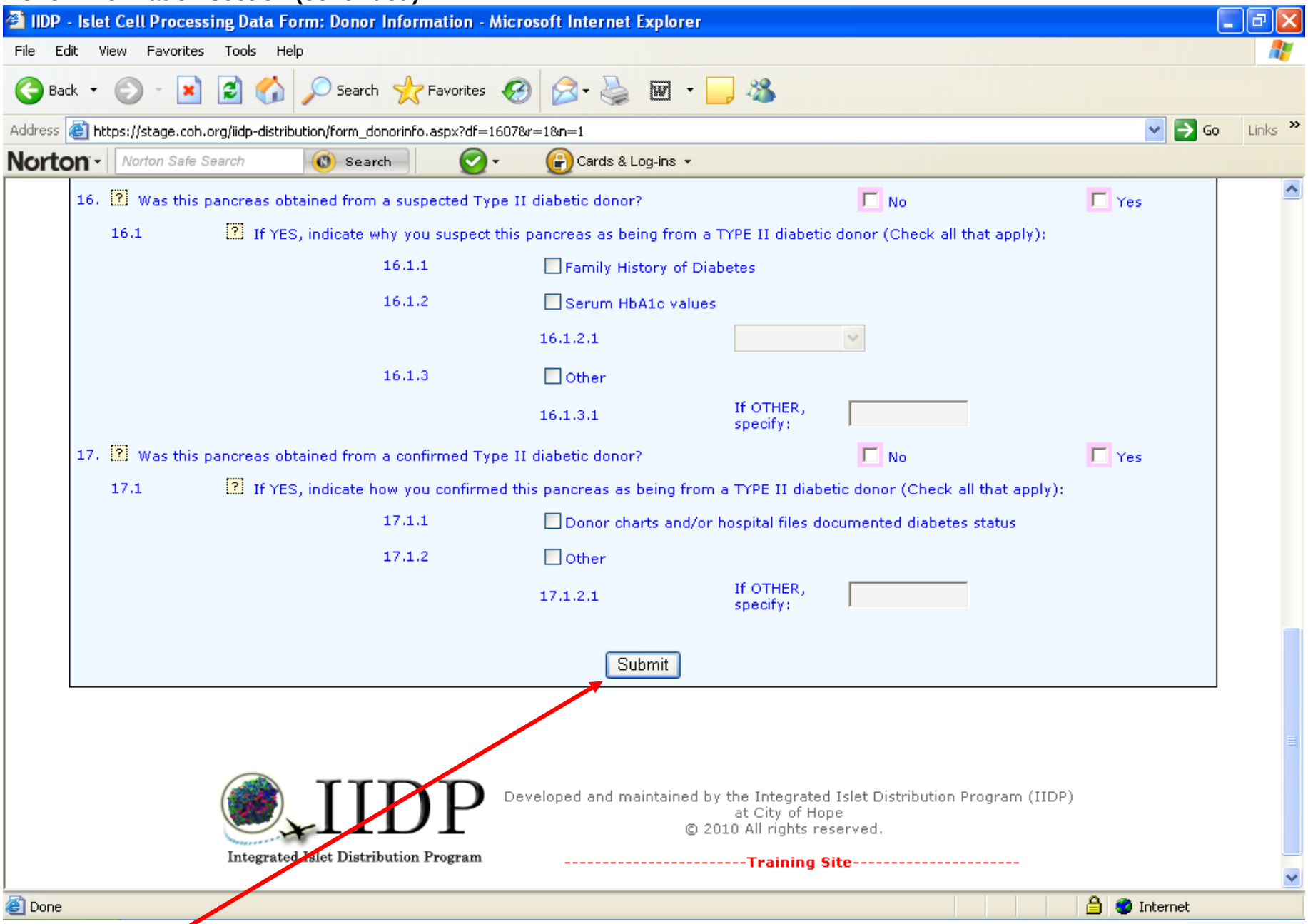
Consent Not Obtained - This message will be displayed if 'No' is checked for question 3. Refer to **4.1 Consent Has Not Been Obtained.**



Donor Information section (continued)

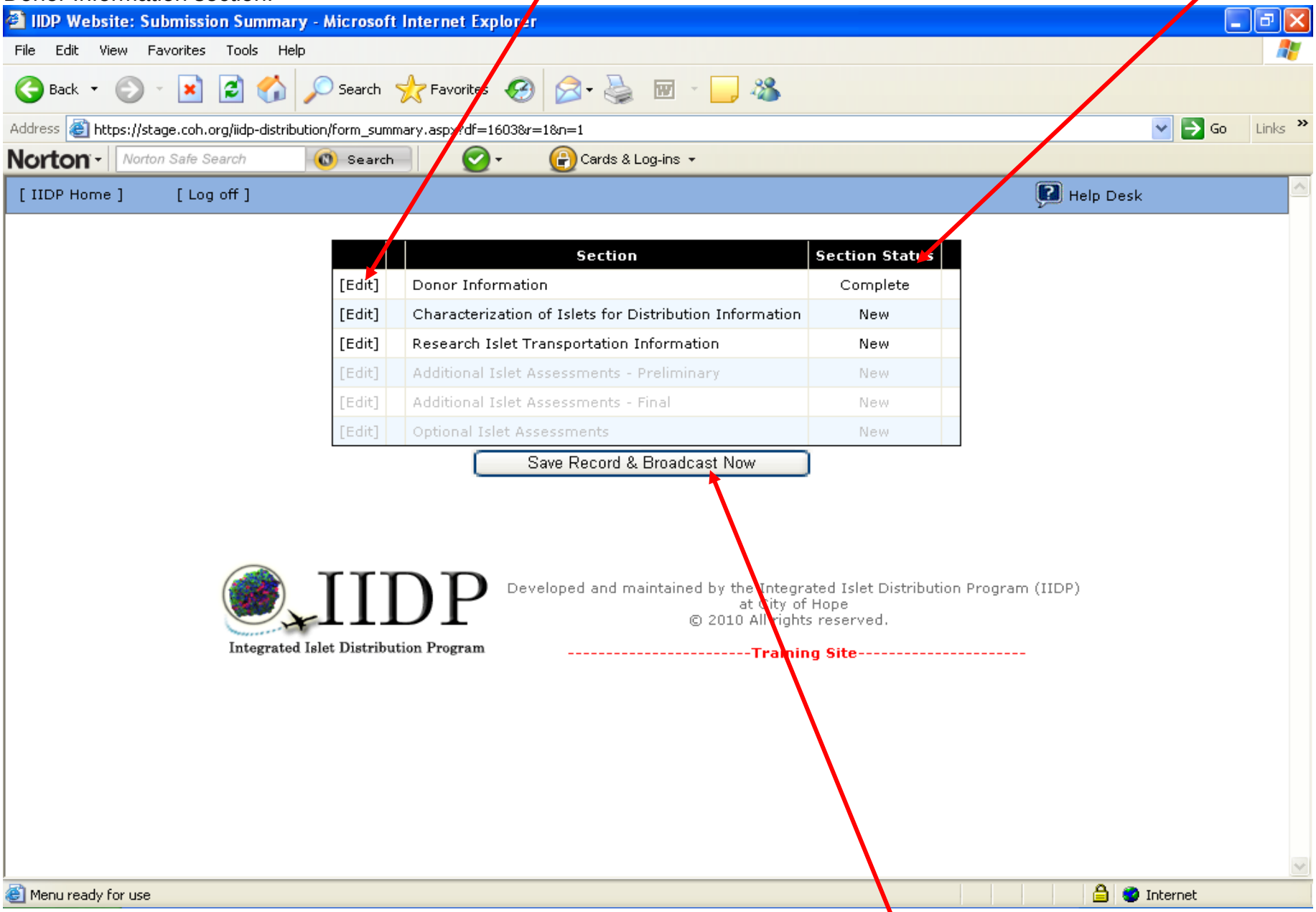


Donor Information section (continued)



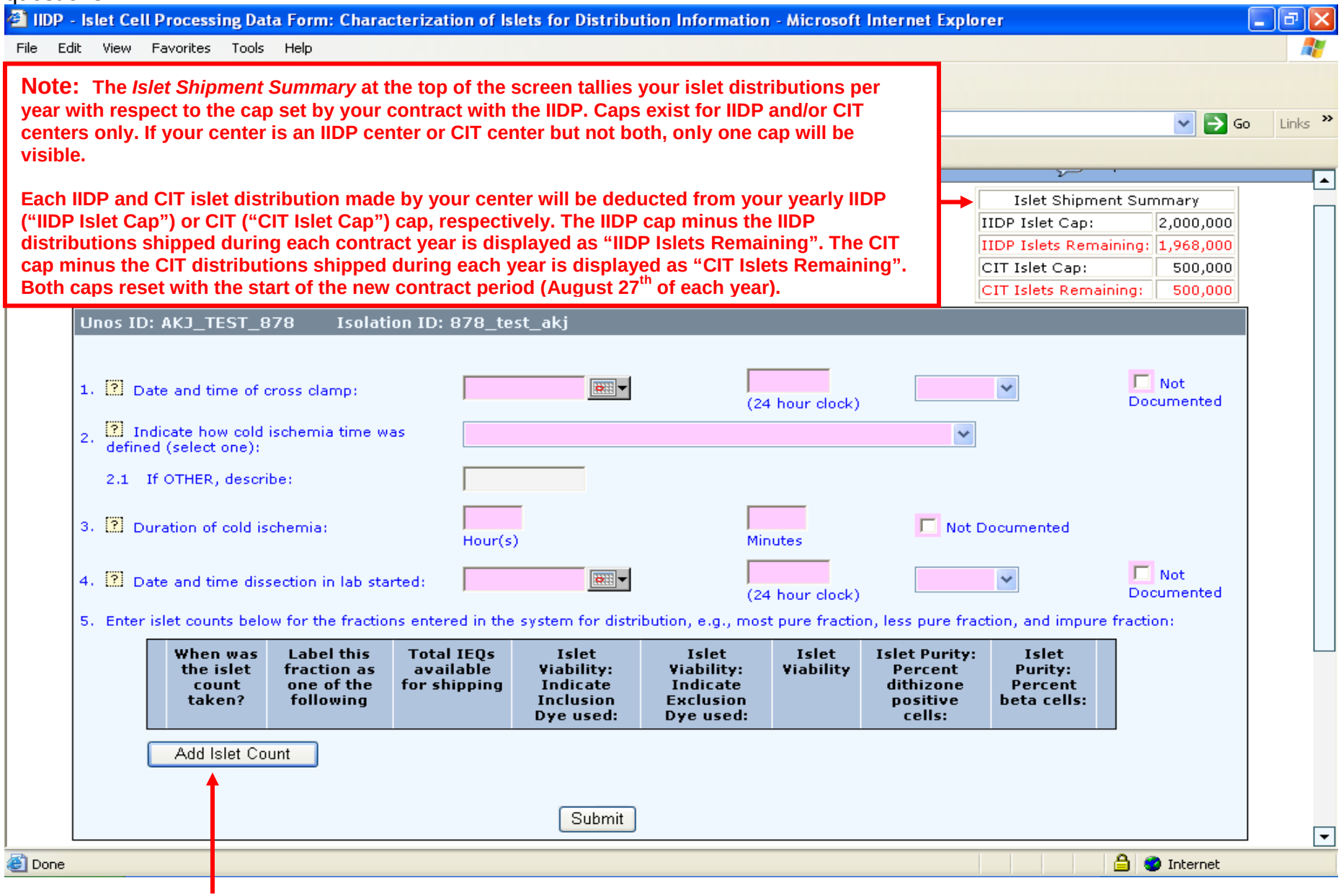
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of the Donor Information section.



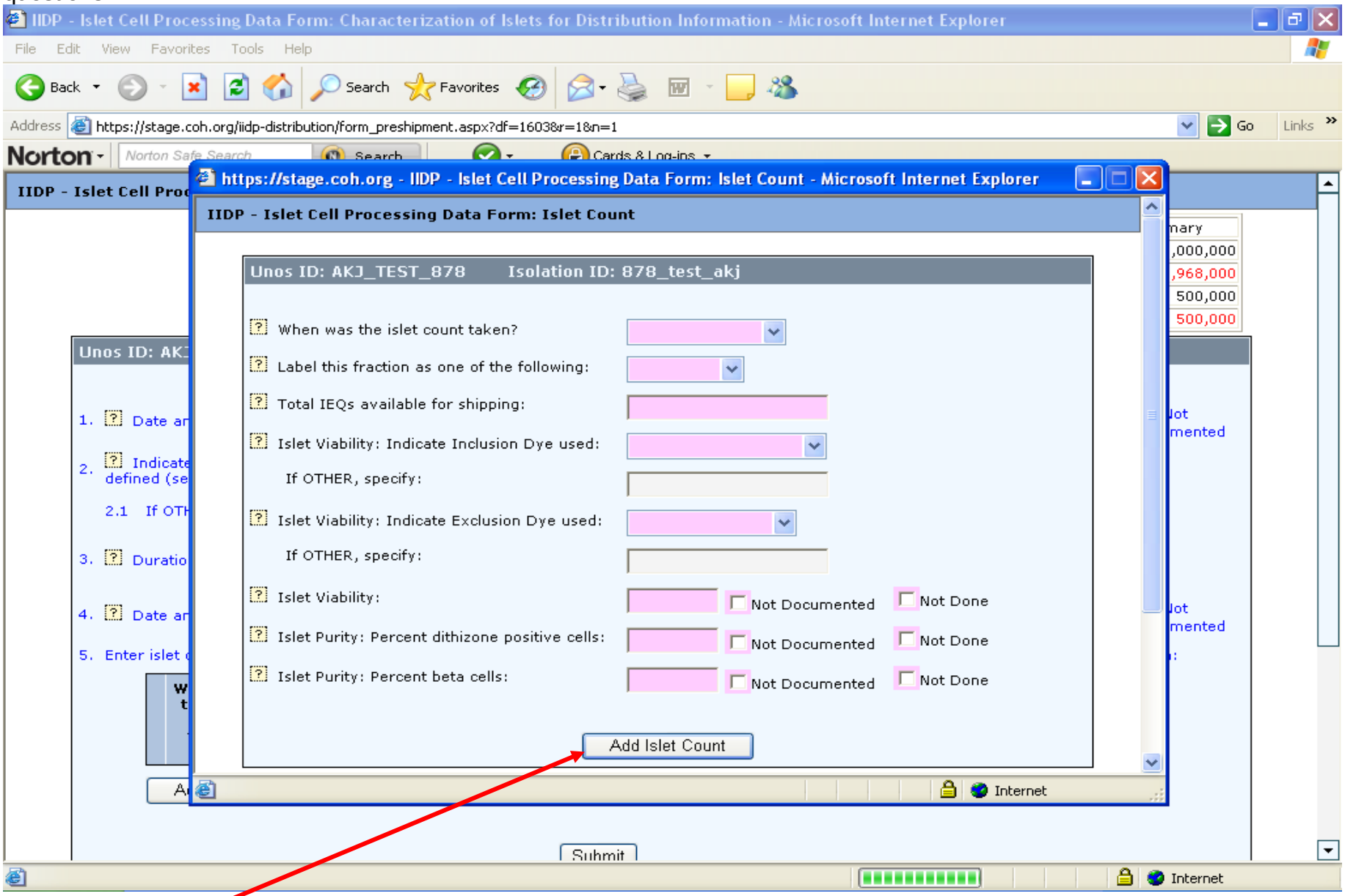
The user may close out of a Quick Broadcast Form at any time - click on **[Save Record & Broadcast Now]** to submit the Islet Cell Processing Data Form to the system. The system will display the **[Broadcast Message]** screen – refer to page 31.

Characterization of Islets for Distribution Information section - Complete the questions in the Characterization of Islets for Distribution Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



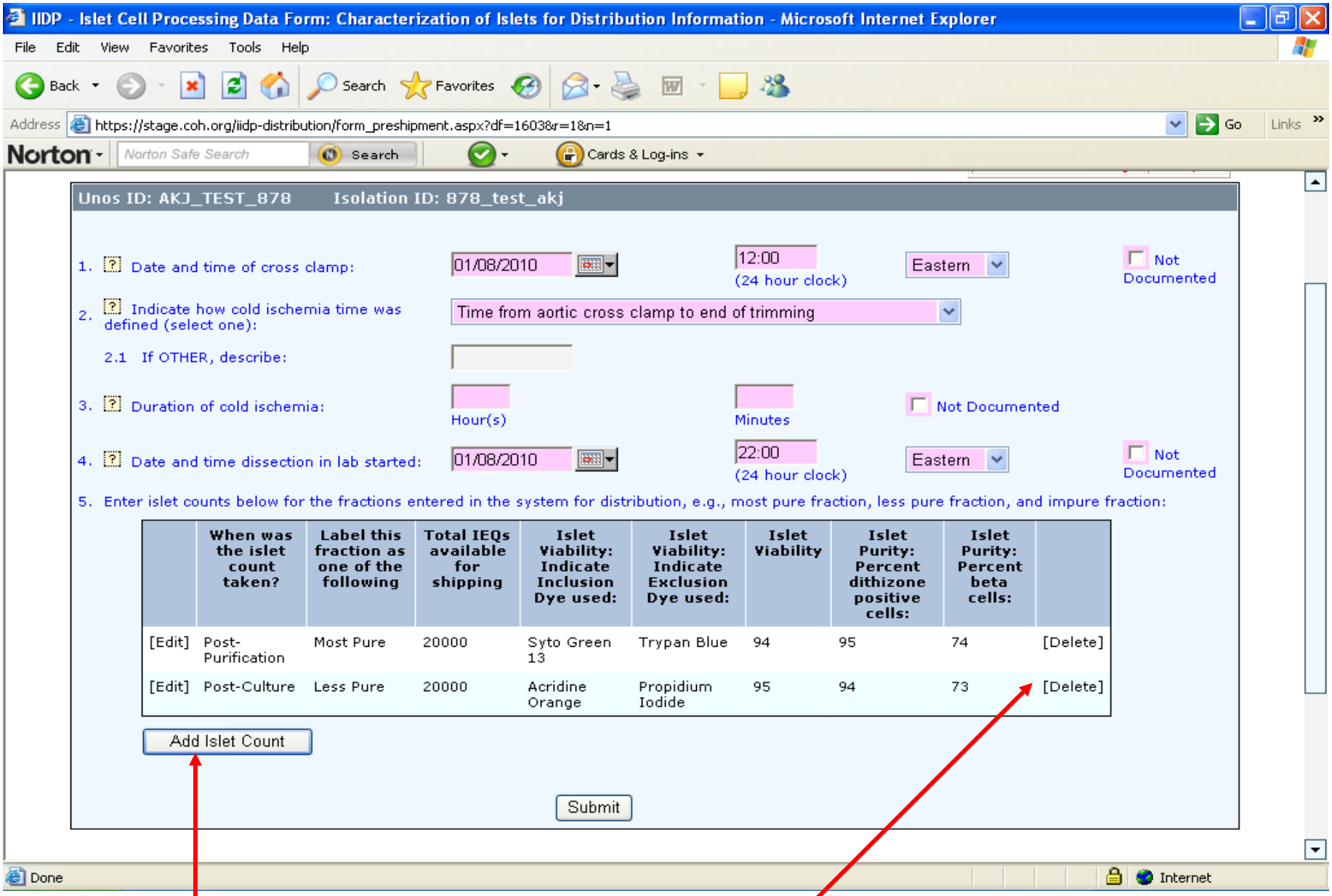
Click on **[Add Islet Count]** to enter data about an islet count. The system will display a separate screen to enter the islet count data – refer to the next page.

Characterization of Islets for Distribution Information section (continued): [Add Islet Count] screen – Complete the questions in the Islet Count screen. Place the cursor on the question mark **(?)** icon to receive instruction on how to answer the questions.



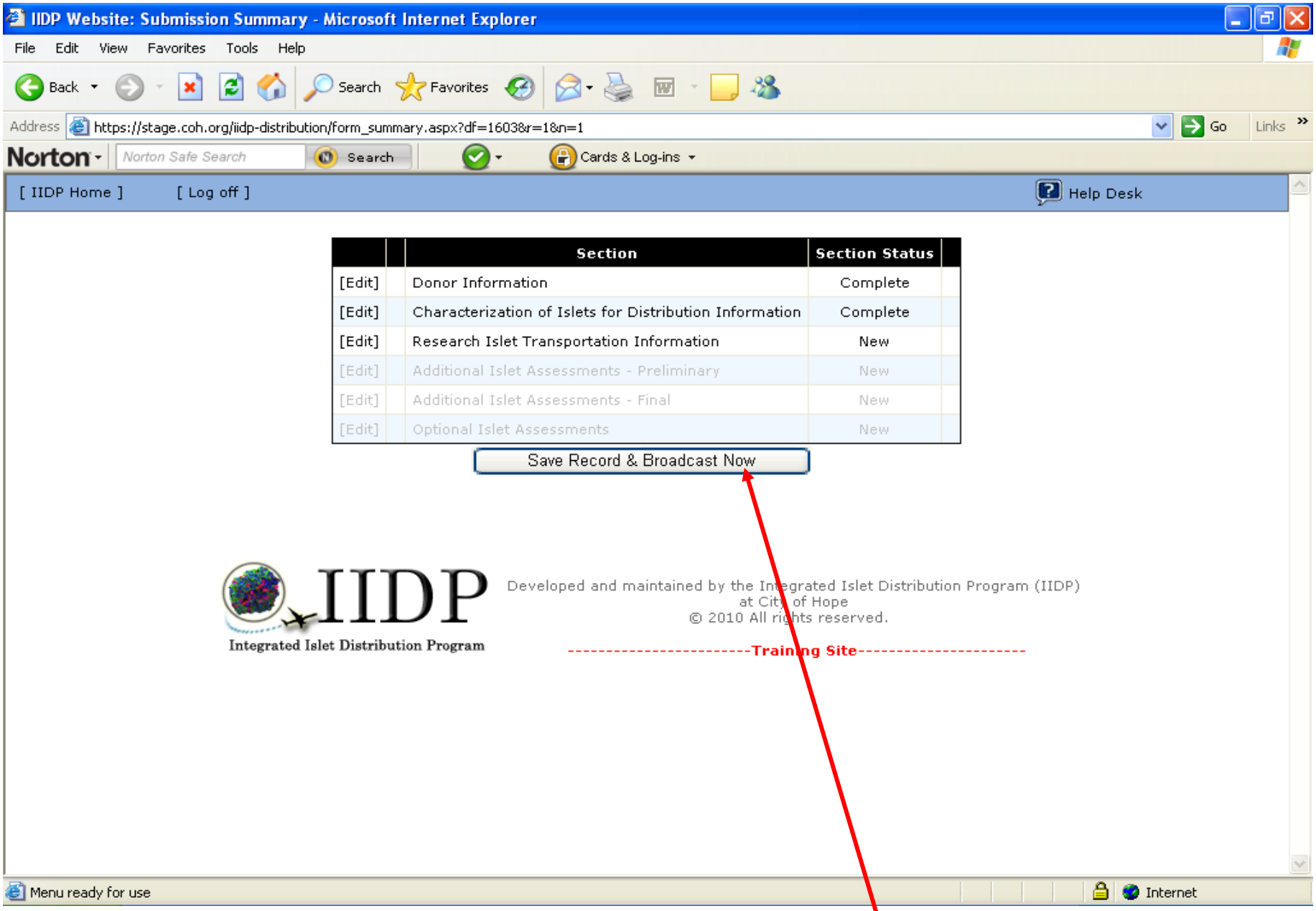
Click on **[Add Islet Count]** to add the Islet Count to the form. The system will add the islet count data to the form – refer to the next page.

Characterization of Islets for Distribution Information section (continued) – Islet Count added to the Characterization of Islets for Distribution Information section.



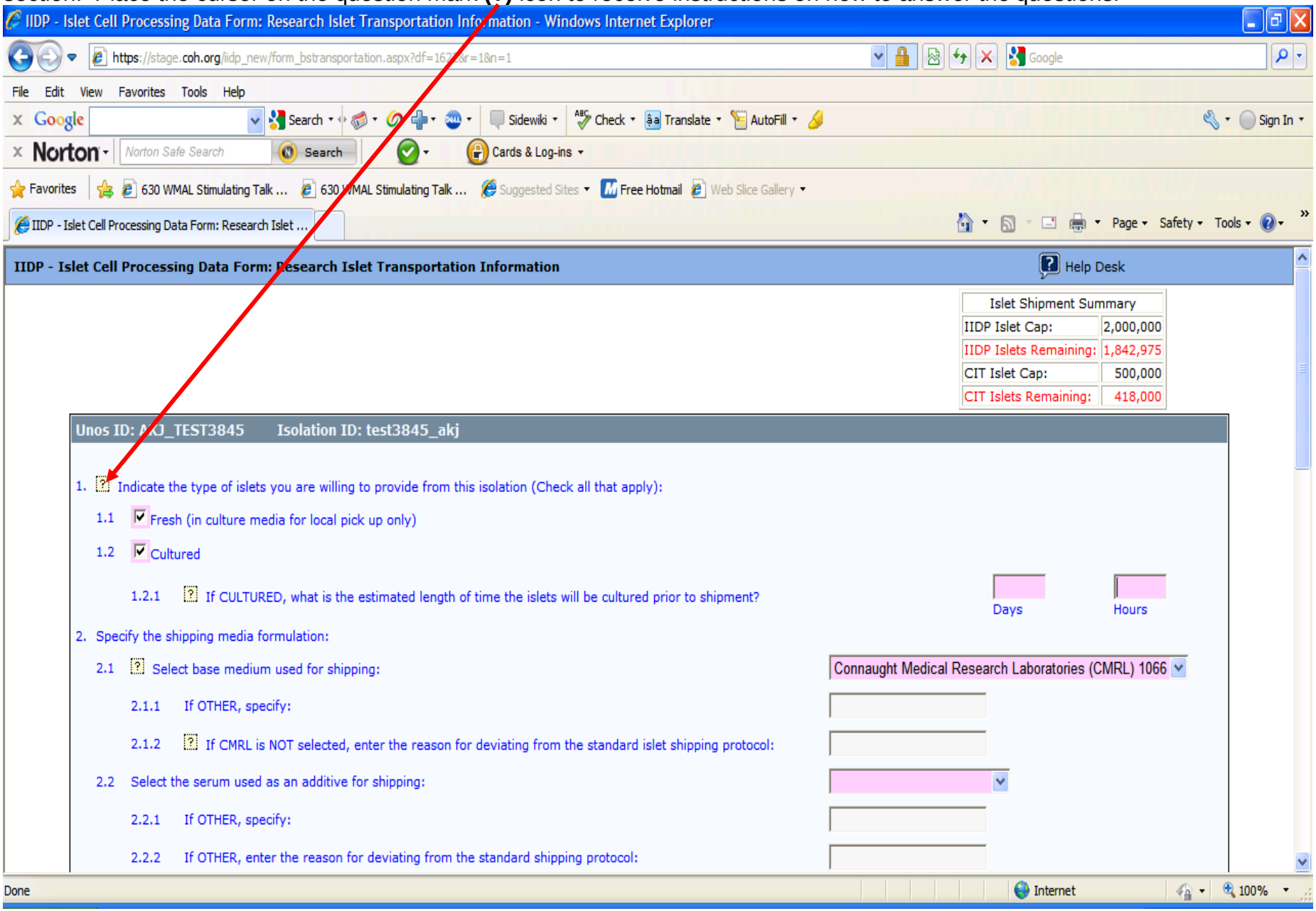
Click on **[Add Islet Count]** to enter additional islet count data. Click on **[Delete]** to delete the islet count data previously entered. Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.

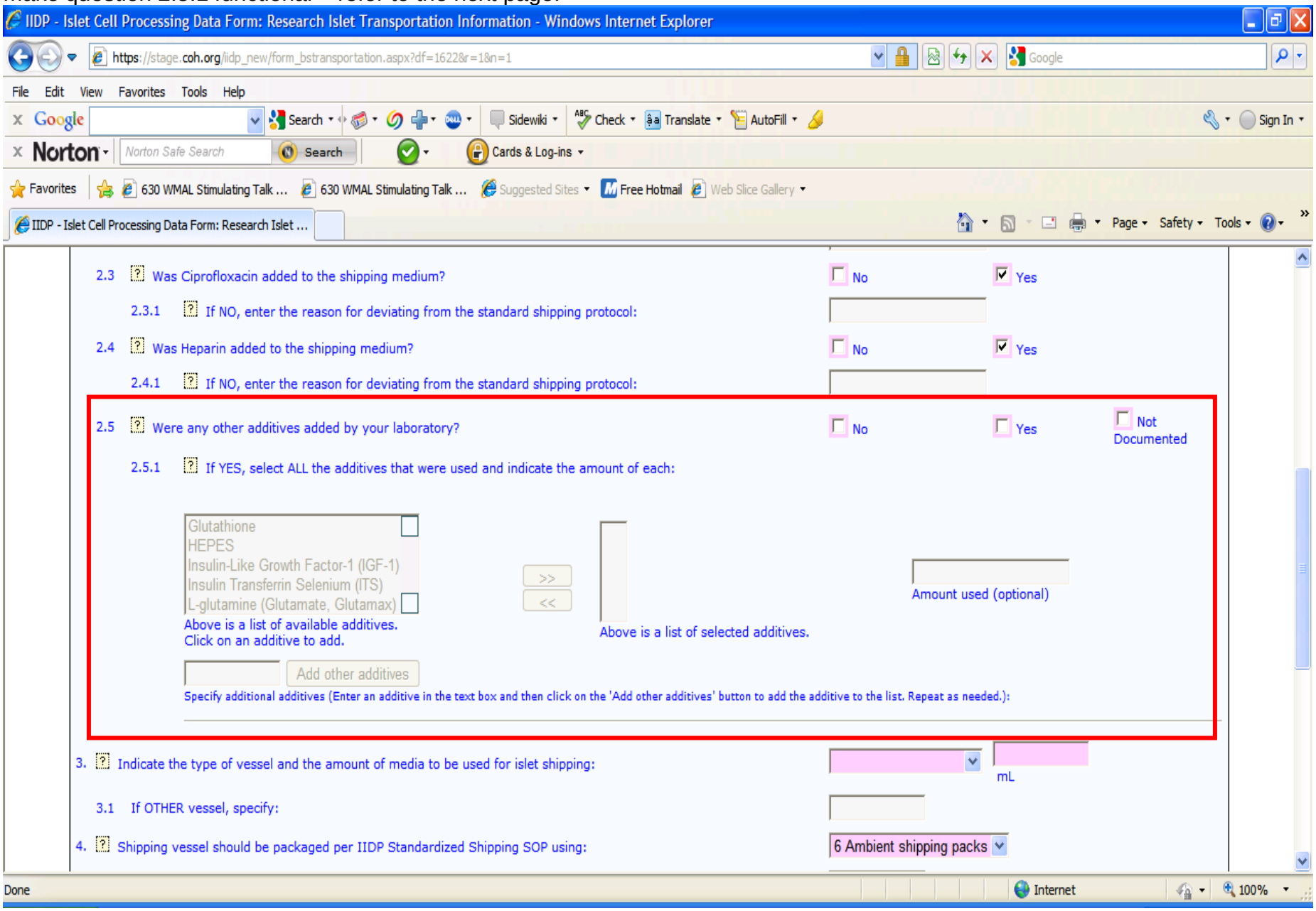


The user may close out of an Quick Broadcast Form at any time - click on **[Save Record & Broadcast Now]** to submit the Quick Broadcast Form to the system. The system will display the **Broadcast Message** screen – refer to page 31.

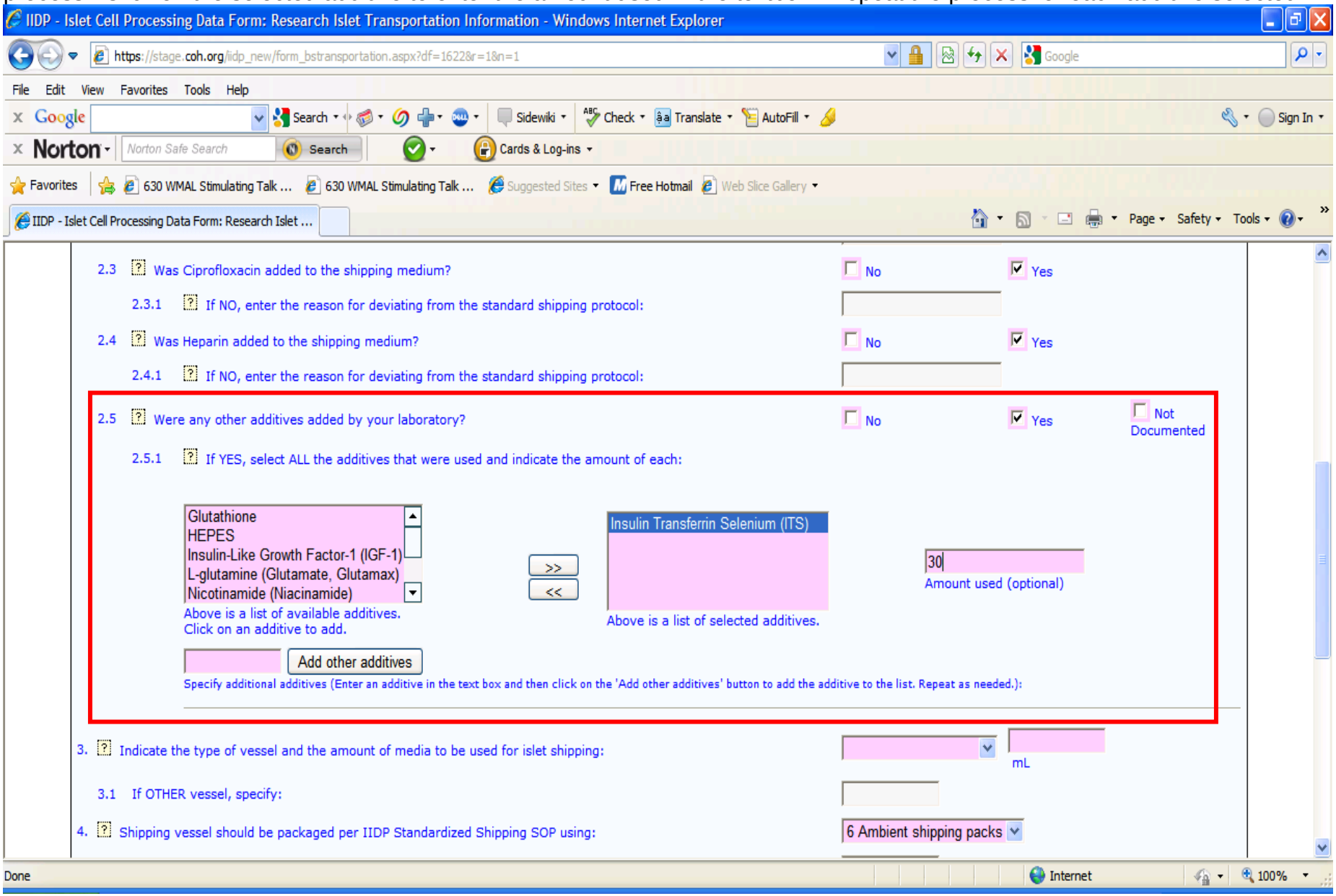
Research Islet Transportation Information section - Complete the questions in the Research Islet Transportation Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



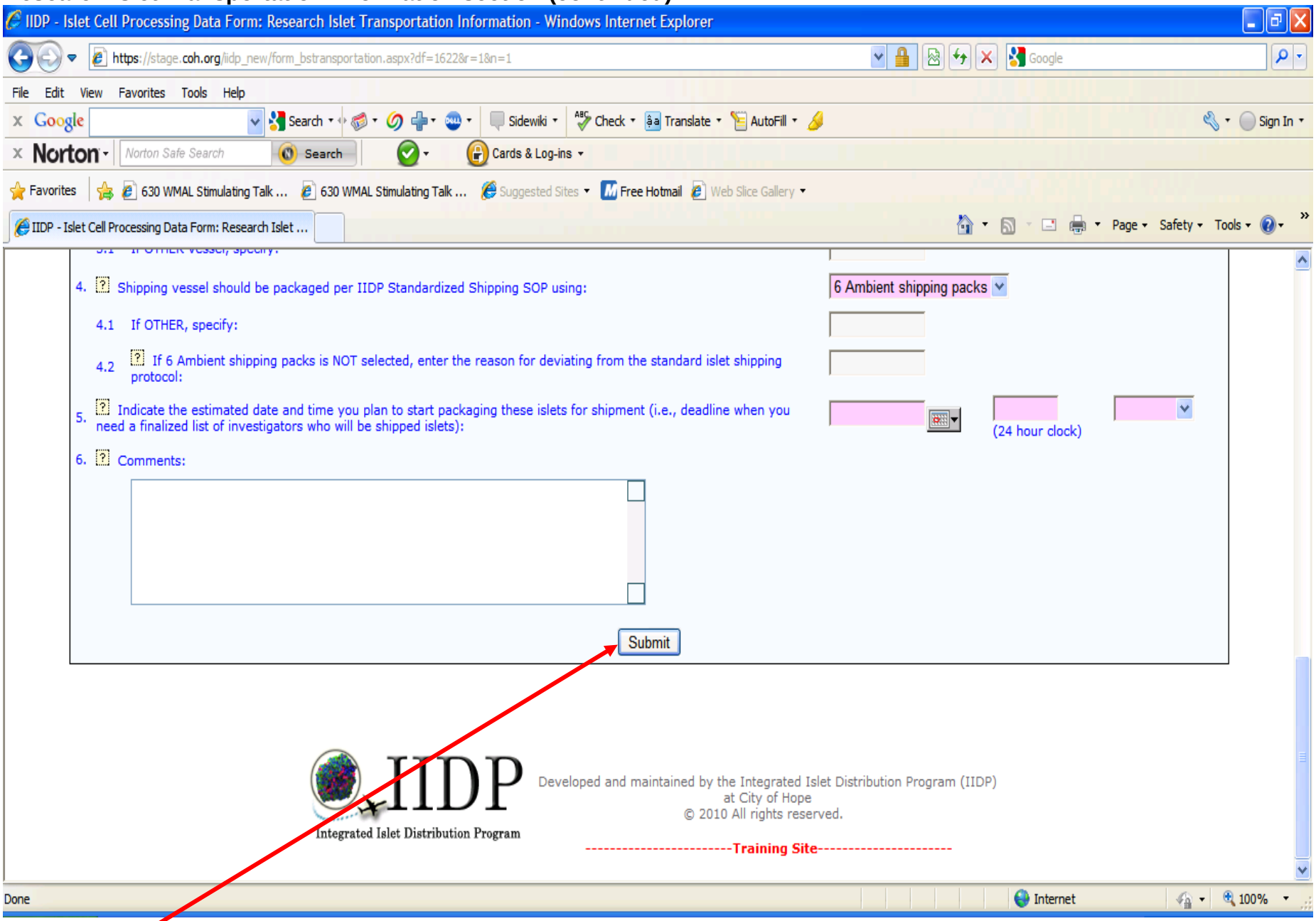
Research Islet Transportation Information section (continued) – If 'Yes' is selected for question 2.5, then the system will make question 2.5.1 functional – refer to the next page.



Research Islet Transportation Information section (continued) – If 'Yes' is selected for question 2.5, the system will make question 2.5.1 functional. Select the additive(s) from the drop down list and/or enter another additive by the 'Add other additives' process. Click on the selected additive to enter the amount used in the textbox. Repeat the process for each additive selected.



Research Islet Transportation Information section (continued)

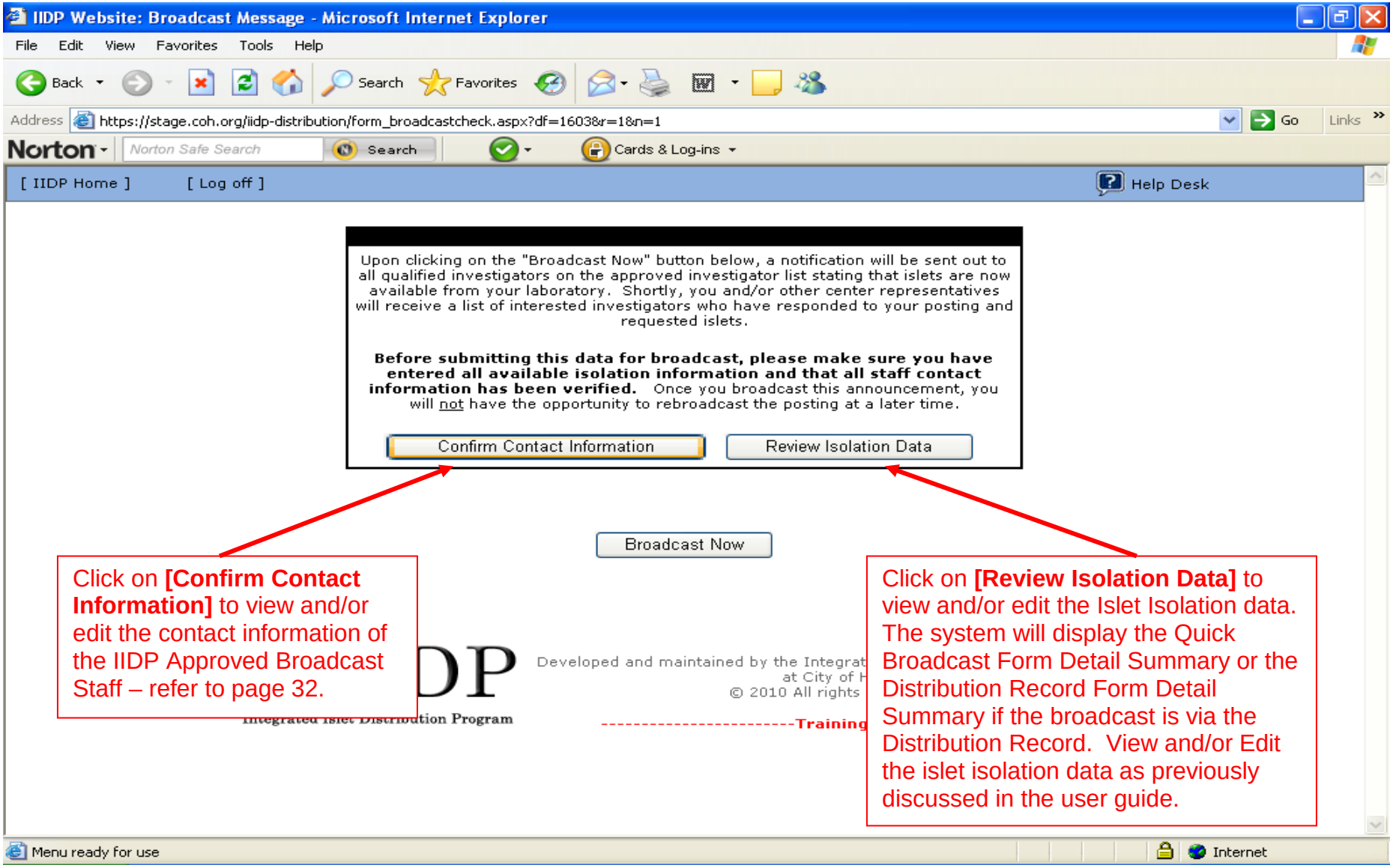


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

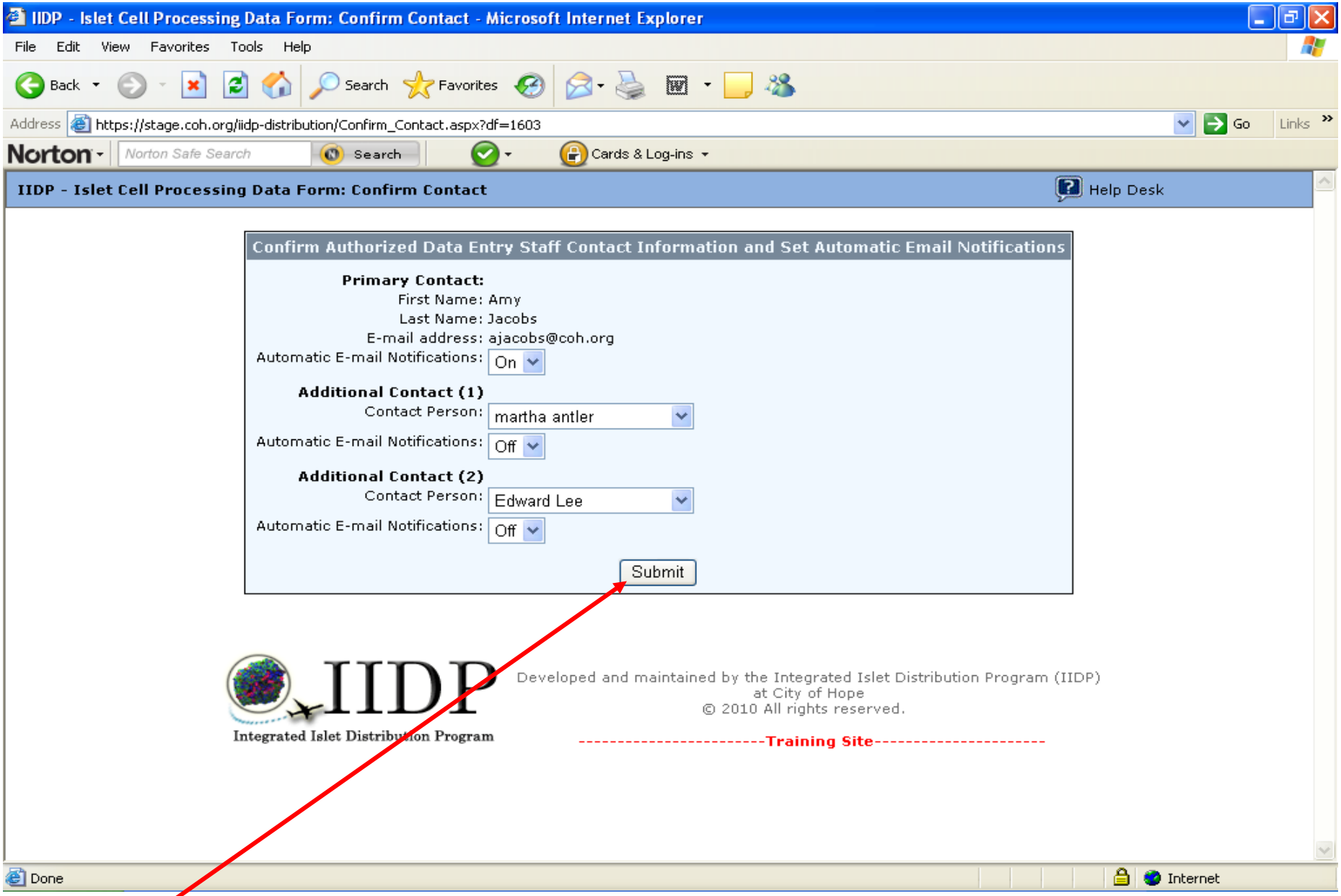
Quick Broadcast Form Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.

The user may close out of a Quick Broadcast Form at any time - Click on **[Save Record & Broadcast Now]** to submit the Quick Broadcast Form to the system. The system will display the **Broadcast Message** screen - refer to the next page.

Islet Availability Broadcast Message – The system will display the Broadcast Message screen when a new Islet Cell Processing Data Form has been submitted and islets are available. [**Confirm Contact Information]** and **[Review Isolation Data]** should be reviewed and/or edited as needed prior to clicking on **[Broadcast Now]** to broadcast the message about the availability of islets. Refer to the message on the Broadcast Message screen – essentially that it is important to review the information before clicking on **[Broadcast Now]** because once the message is broadcast, you cannot re-broadcast the message if changes are later made to the contact or islet isolation data.

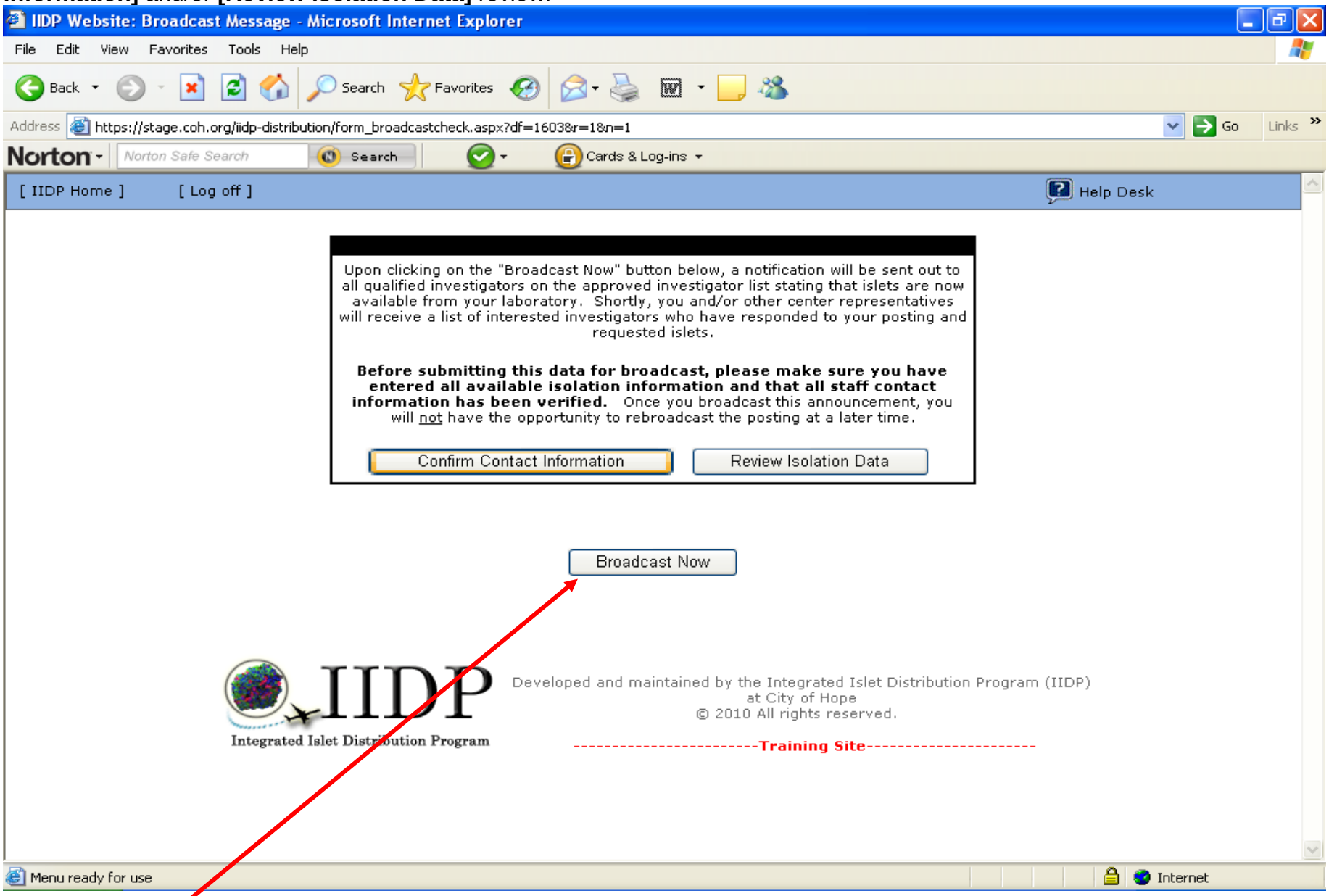


IIDP Approved Broadcast Staff Contact Information – Edit the contact information as needed. The IIDP Approved Broadcast Staff entering the Islet Isolation data and preparing to send the Broadcast Message is automatically pre-populated as the Primary Contact.



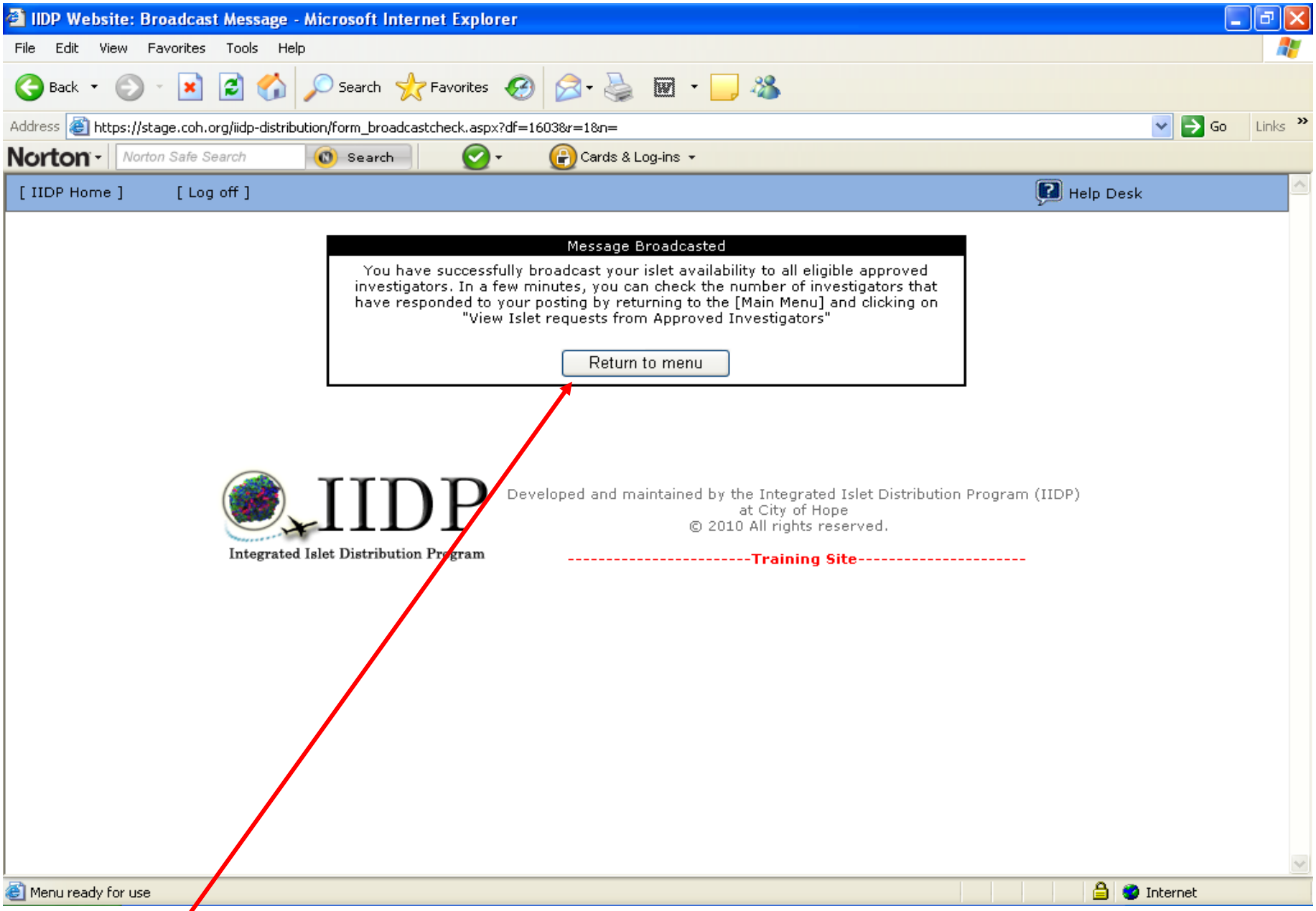
Click on **[Submit]** to return to the **[Broadcast Message]** screen.

Islet Availability Broadcast Message – The system returns the user to the Broadcast Message screen after [**Confirm Contact Information**] and/or **[Review Isolation Data]** review.



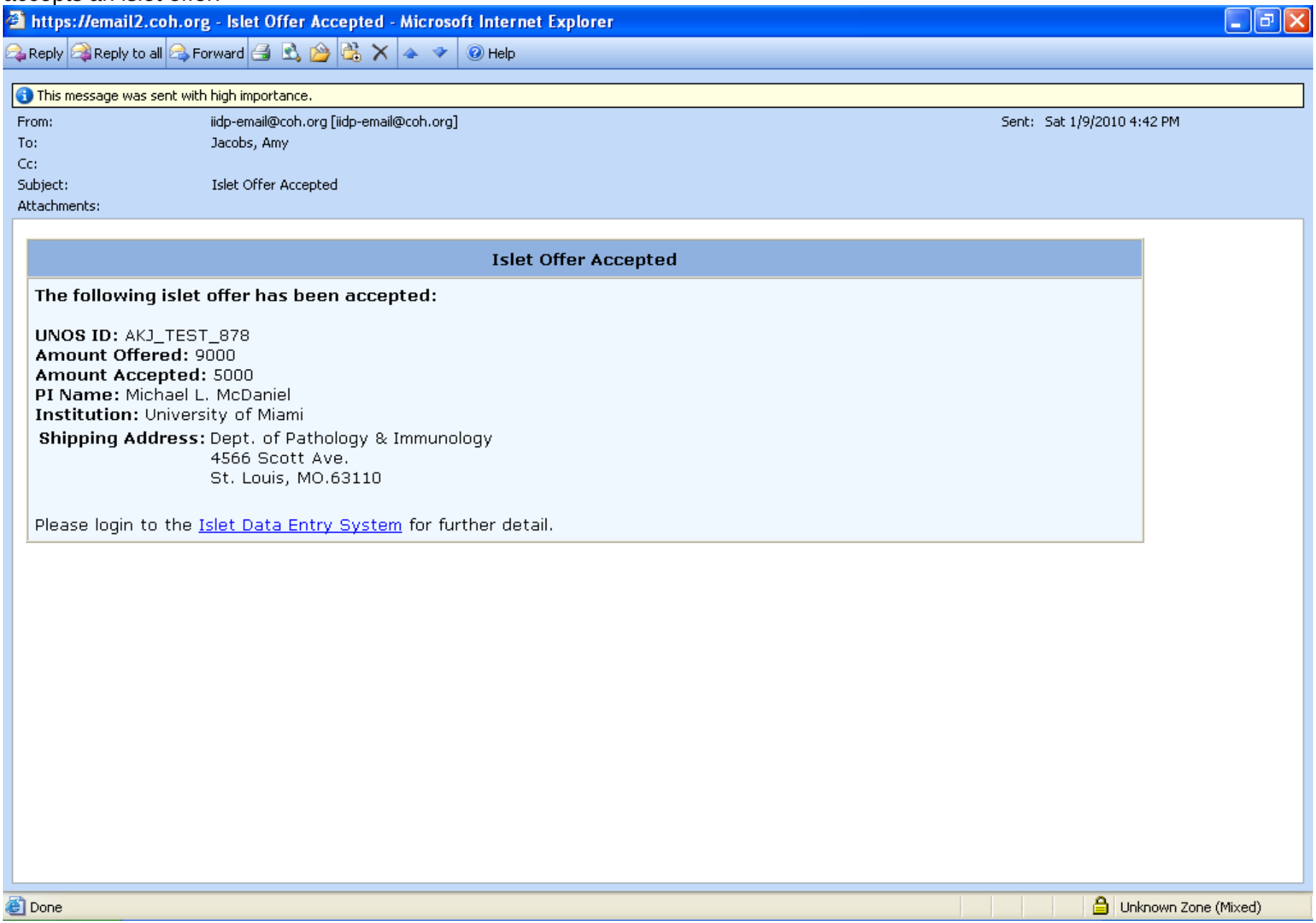
Click on **[Broadcast Now]** to send the Islet Availability Broadcast Message to the designated IIDP Approved Investigators. The system will then display a confirmation message – refer to the next page.

Islet Availability Broadcast Message – The system will display a confirmation message that the Broadcast Message has been sent.



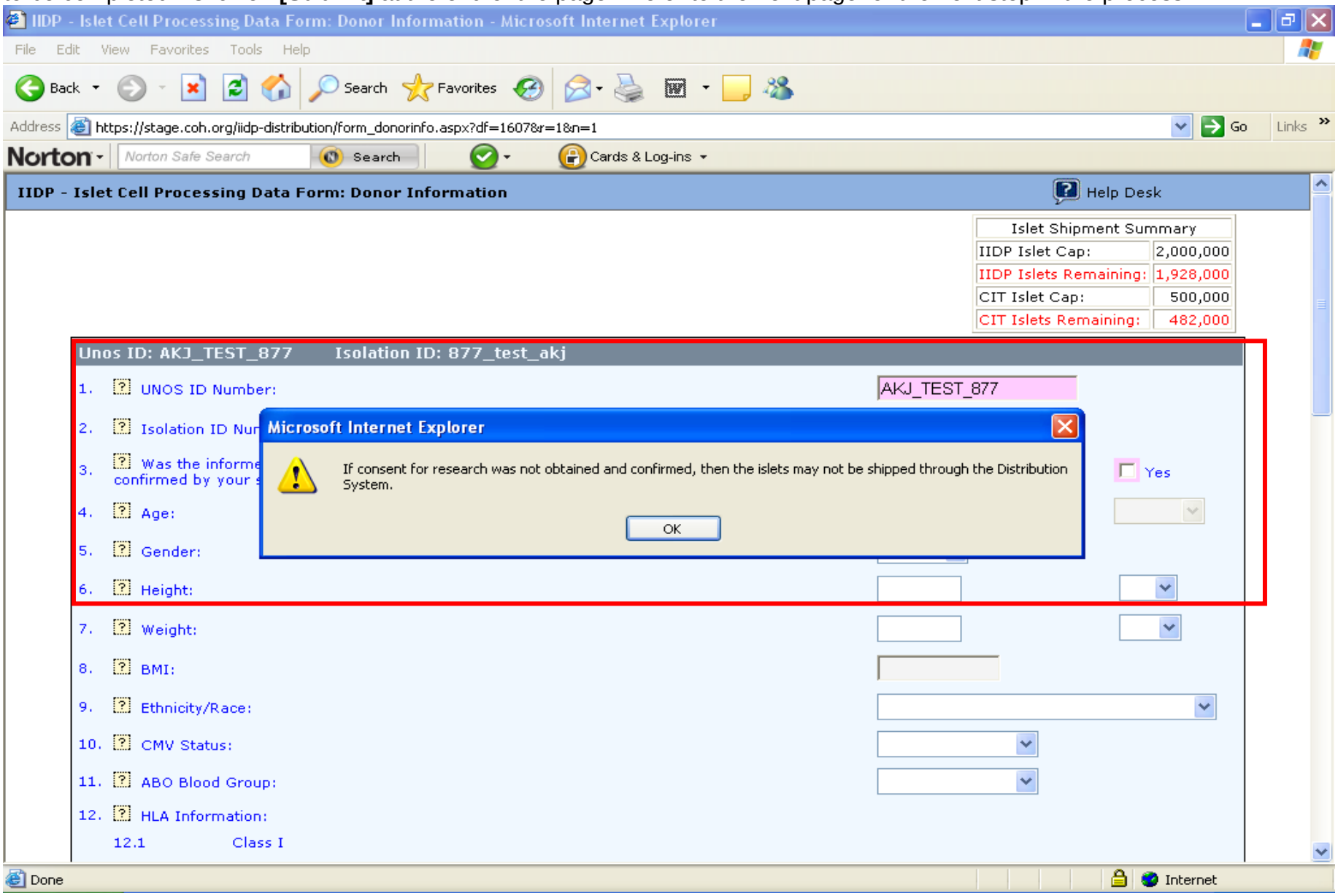
Click on **[Return to menu]** and the system returns the user to the Main Page.

Islet Offer Accepted Email Message – this is an example of an email message that the IIDP Broadcast Staff receives when a PI accepts an islet offer.

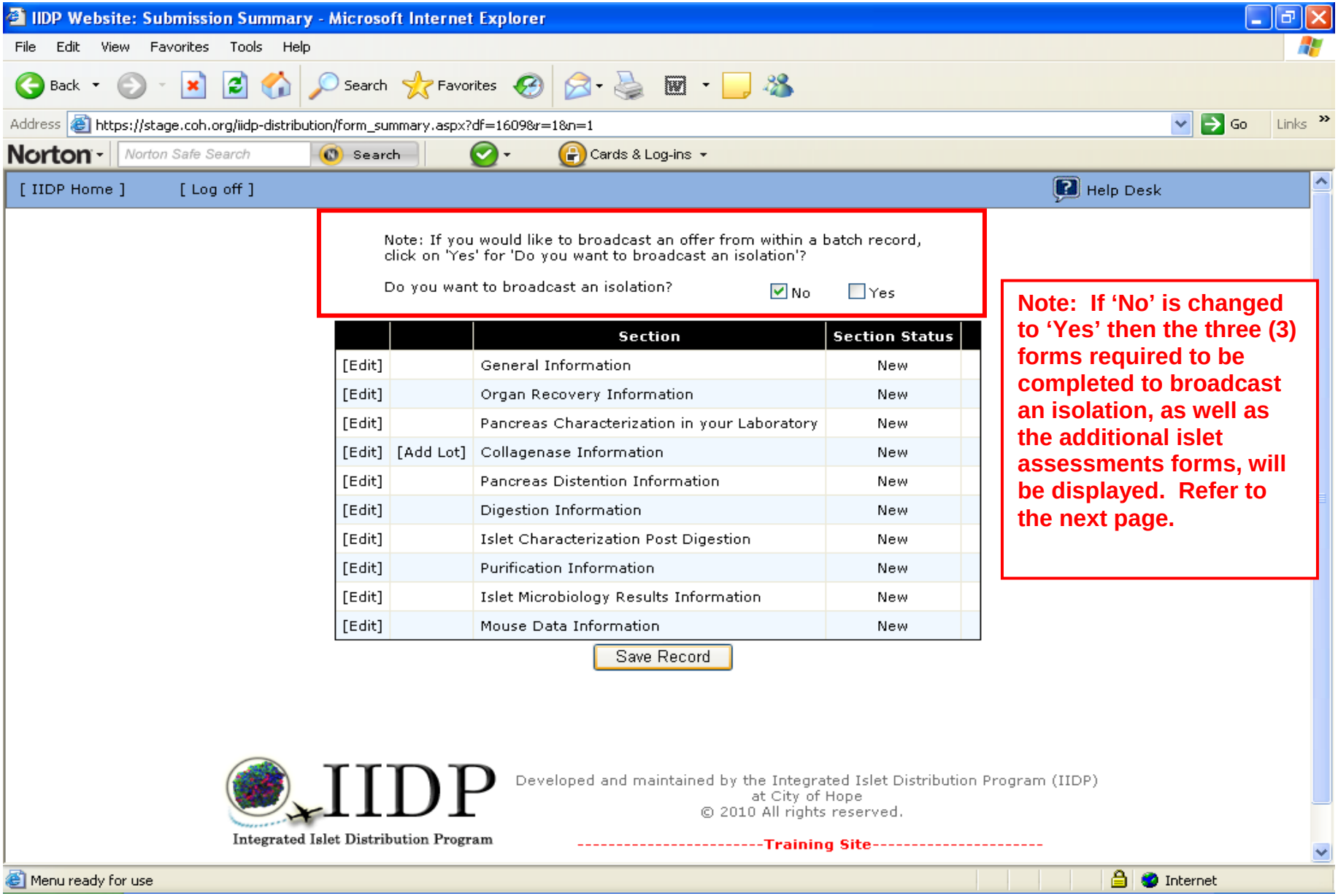


4.1 Consent Has Not Been Obtained

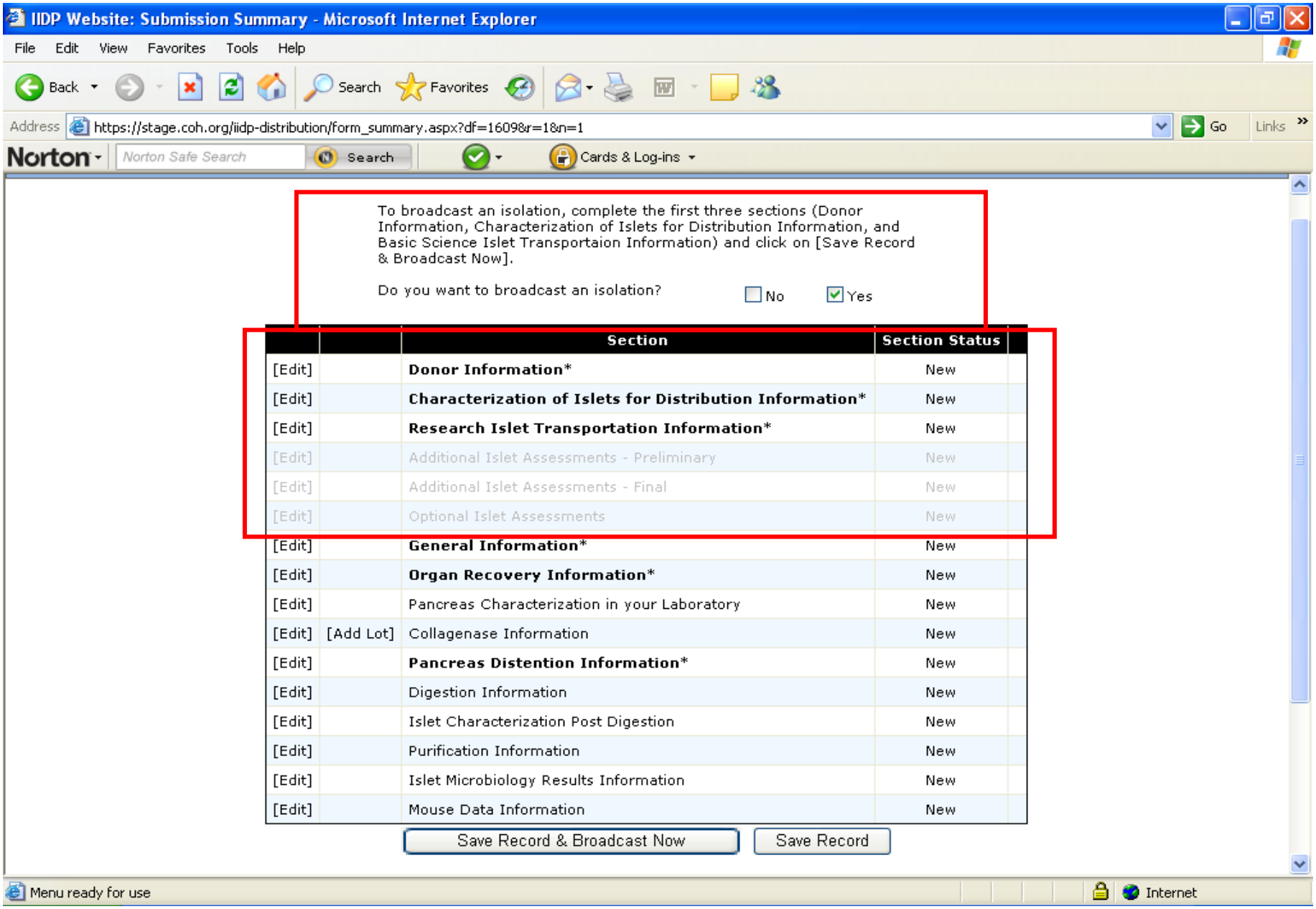
Consent Not Obtained – This message will be displayed if 'No' is checked for question 3. The rest of the questions will not need to be completed. Click on **[Submit]** at the end of the page. Refer to the next page for the next step in the process.



The **Distribution Record Form Detail Summary** screen will be displayed with the default of 'No' to the question "Do you want to broadcast an isolation?". The Distribution Record can now be completed – **refer to 5.0 Complete the Distribution Record.** If the user wants to broadcast an isolation, the user must click on 'Yes' to the question "Do you want to broadcast an isolation?" AND must have obtained consent in order to broadcast an isolation.

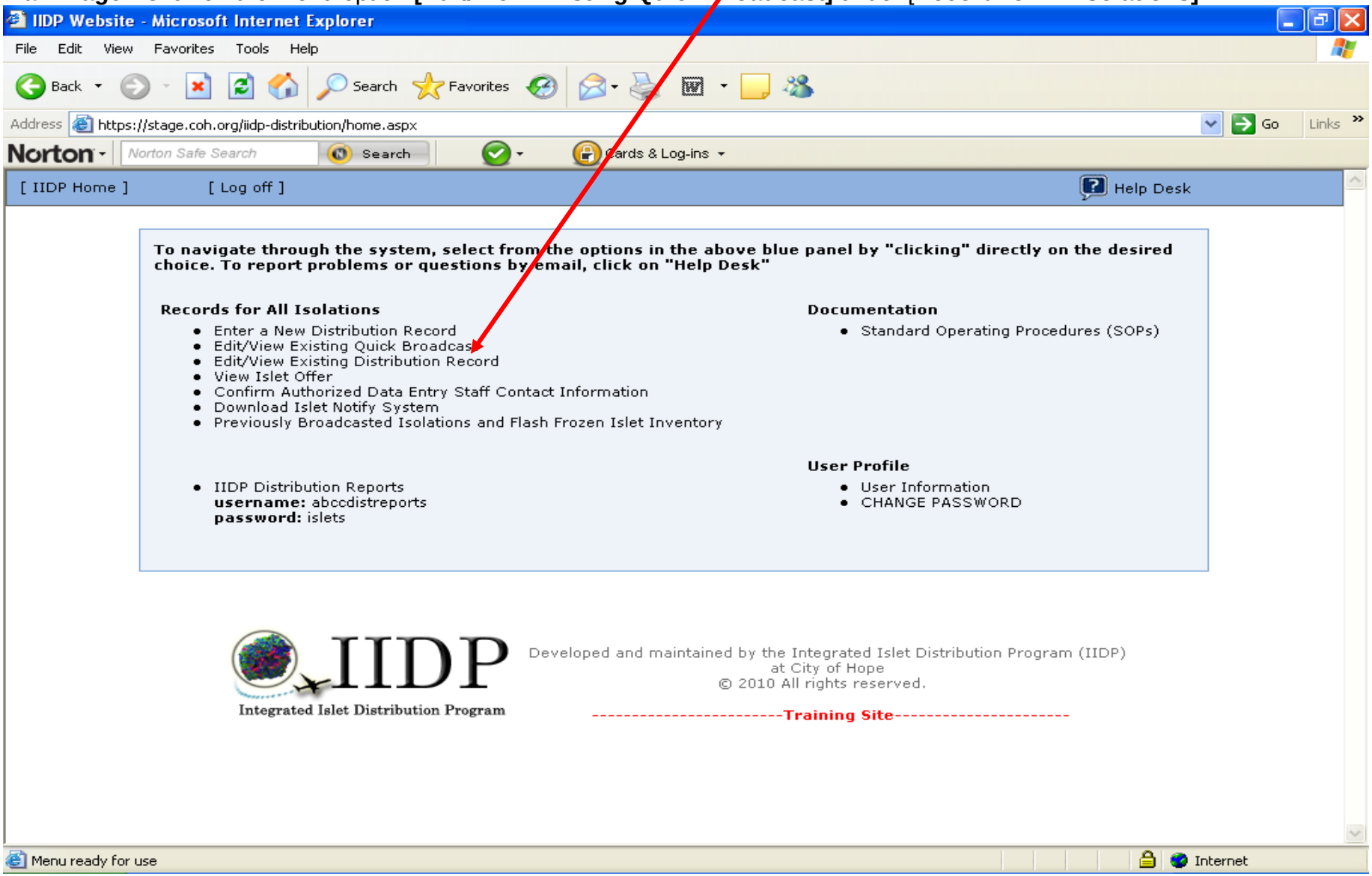


This **Distribution Form Detail Summary** screen will be displayed if 'Yes' is selected for "Do you want to broadcast an isolation?" within the Distribution Record. **Refer to 6.0 Broadcast an Isolation from within the Distribution Record.**



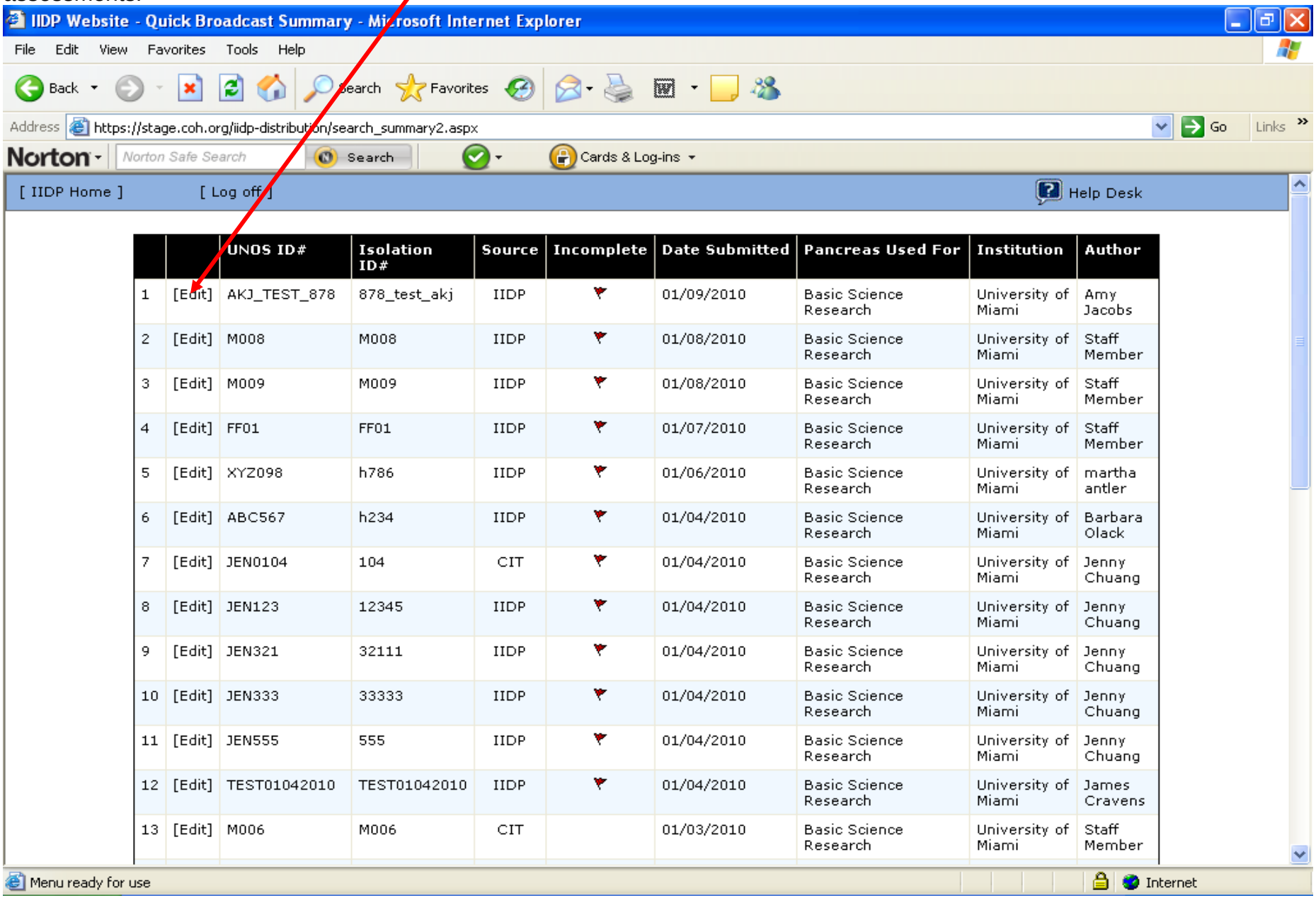
4.2 Complete Additional and Optional Islet Assessments

Main Page - Click on the menu option **[Edit/View Existing Quick Broadcast]** under [**Record for All Isolations].**



The system will display the list of existing quick broadcasts for your institution – refer to the next page.

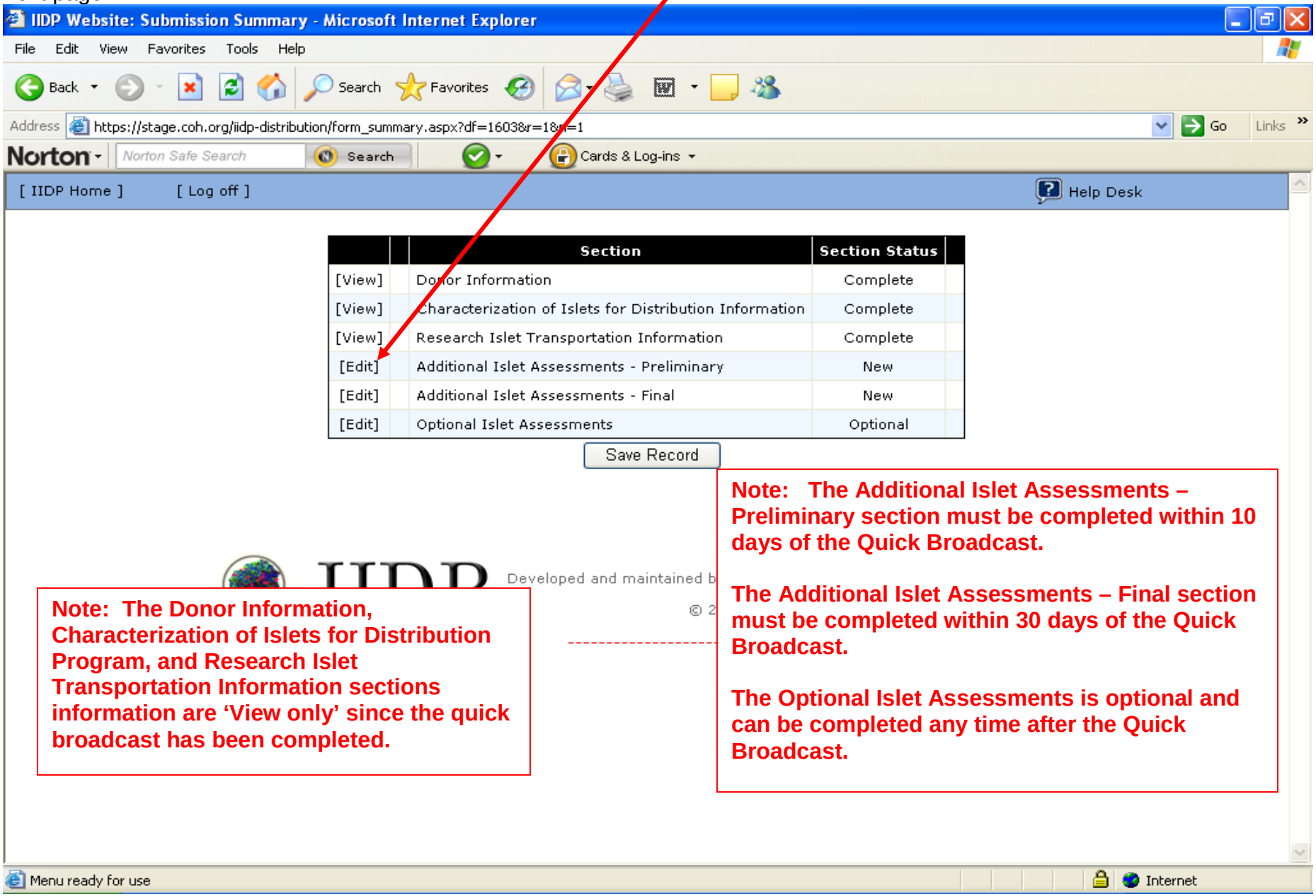
Existing Quick Broadcasts – Click on **[Edit]** of the desired quick broadcast to view and/or complete the additional islet assessments.



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
2	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
3	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
4	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
5	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
6	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
7	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
8	[Edit]	JEN123	12345	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
9	[Edit]	JEN321	32111	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
10	[Edit]	JEN333	33333	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
11	[Edit]	JEN555	555	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
12	[Edit]	TEST01042010	TEST01042010	IIDP		01/04/2010	Basic Science Research	University of Miami	James Cravens
13	[Edit]	M006	M006	CIT		01/03/2010	Basic Science Research	University of Miami	Staff Member

The system will display the Quick Broadcast Detail Summary – refer to the next page.

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete an Additional Islet Assessments section. For this example, click on **[Edit]** of Additional Islet Assessments – Preliminary – refer to the next page.



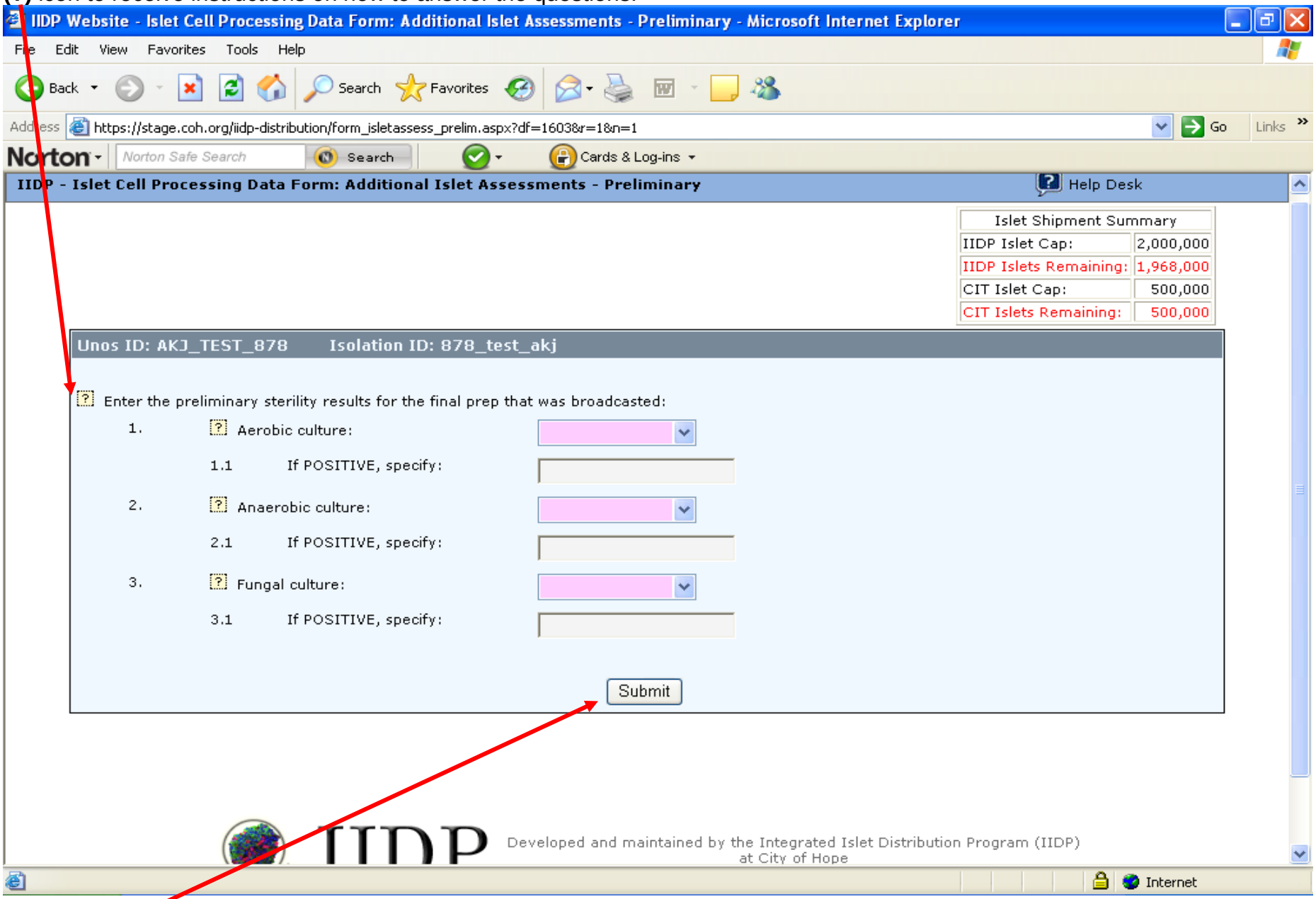
Note: The Donor Information, Characterization of Islets for Distribution Program, and Research Islet Transportation Information sections information are 'View only' since the quick broadcast has been completed.

Note: The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.

The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.

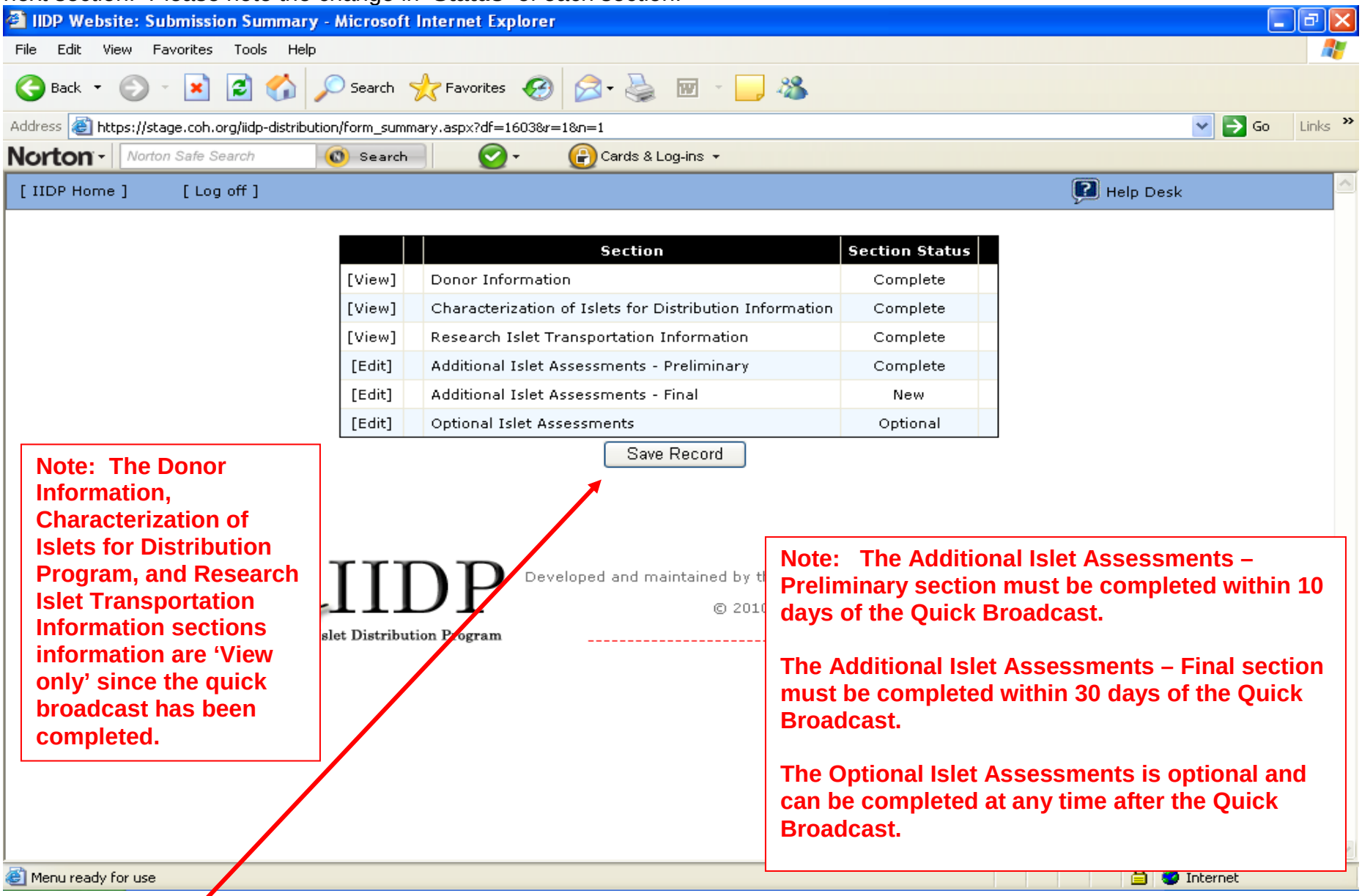
The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.

Additional Islet Assessments – Preliminary – Complete the questions in this section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



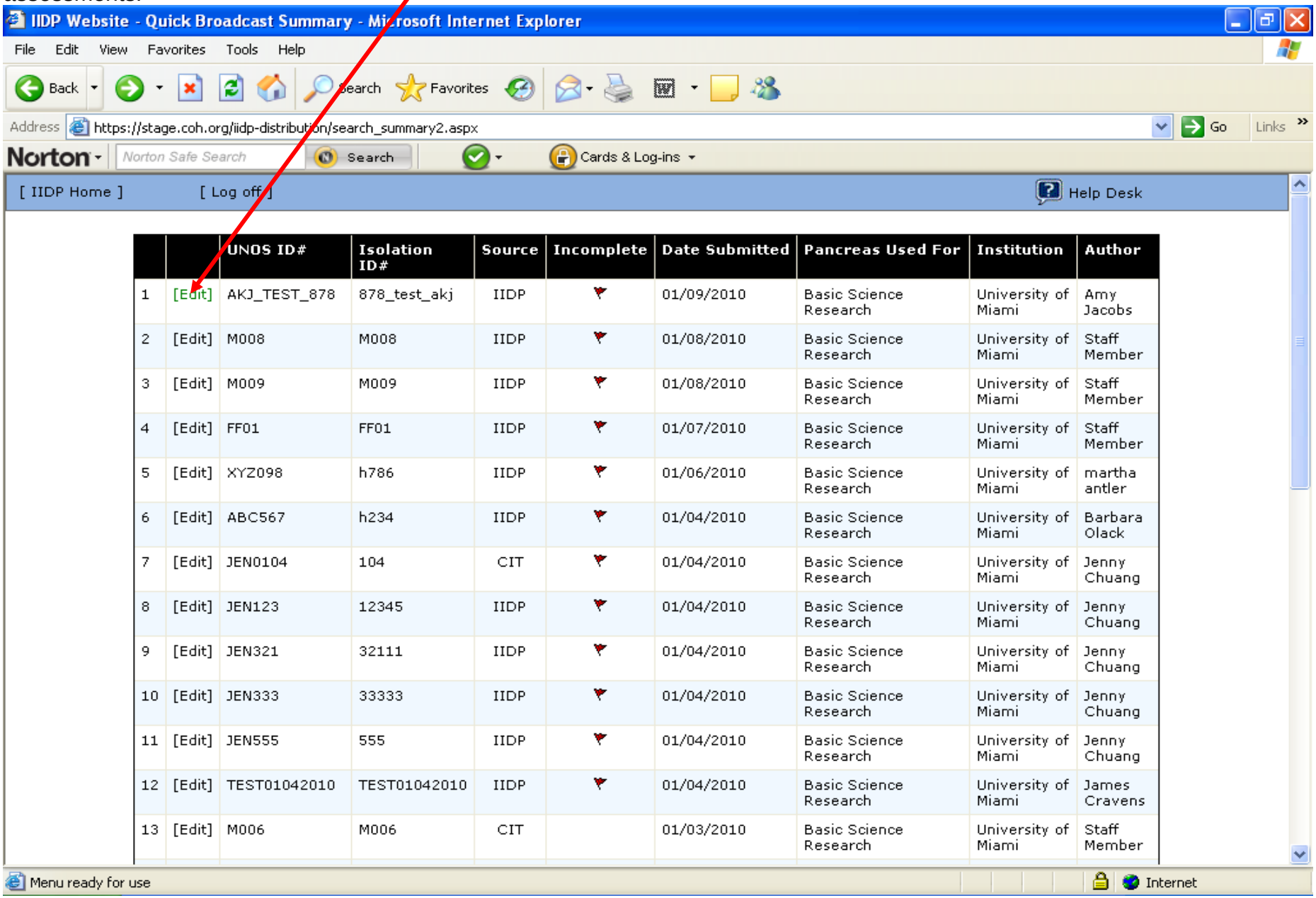
Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

Additional Islet Assessments – Preliminary - Confirmation Message – This message will be displayed to confirm that the information has been submitted and saved in the system.

Click on **[Done]** and the system will return the user to the Main Page.

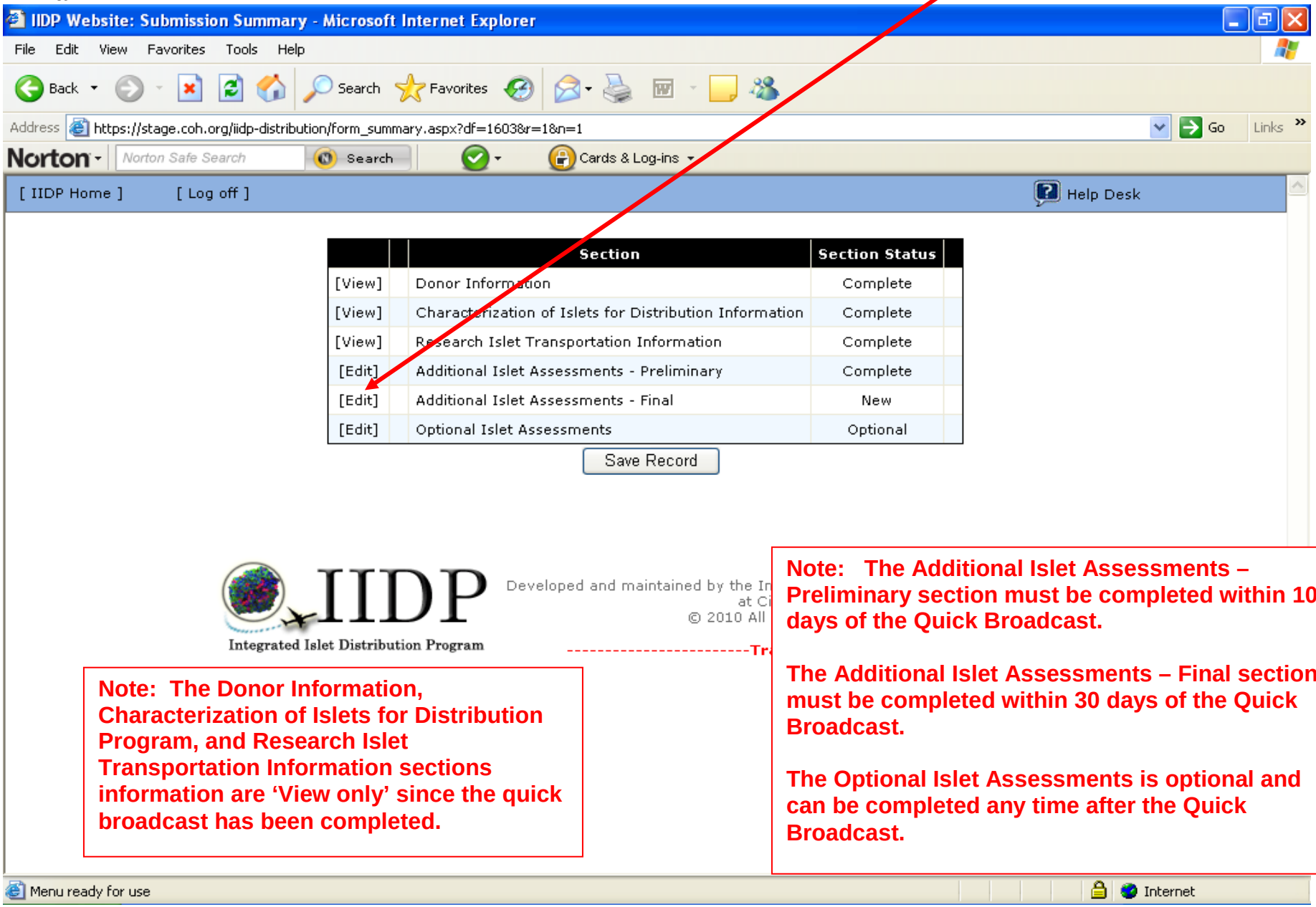
Main Page - Click on the menu option **[Edit/View Existing Quick Broadcast]** under **[Record for All Isolations].**

Existing Quick Broadcasts – Click on **[Edit]** of the desired quick broadcast to view and/or complete the additional islet assessments.



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
2	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
3	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
4	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
5	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
6	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
7	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
8	[Edit]	JEN123	12345	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
9	[Edit]	JEN321	32111	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
10	[Edit]	JEN333	33333	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
11	[Edit]	JEN555	555	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
12	[Edit]	TEST01042010	TEST01042010	IIDP		01/04/2010	Basic Science Research	University of Miami	James Cravens
13	[Edit]	M006	M006	CIT		01/03/2010	Basic Science Research	University of Miami	Staff Member

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section. For this example, click on **[Edit]** of Additional Islet Assessments – Final.



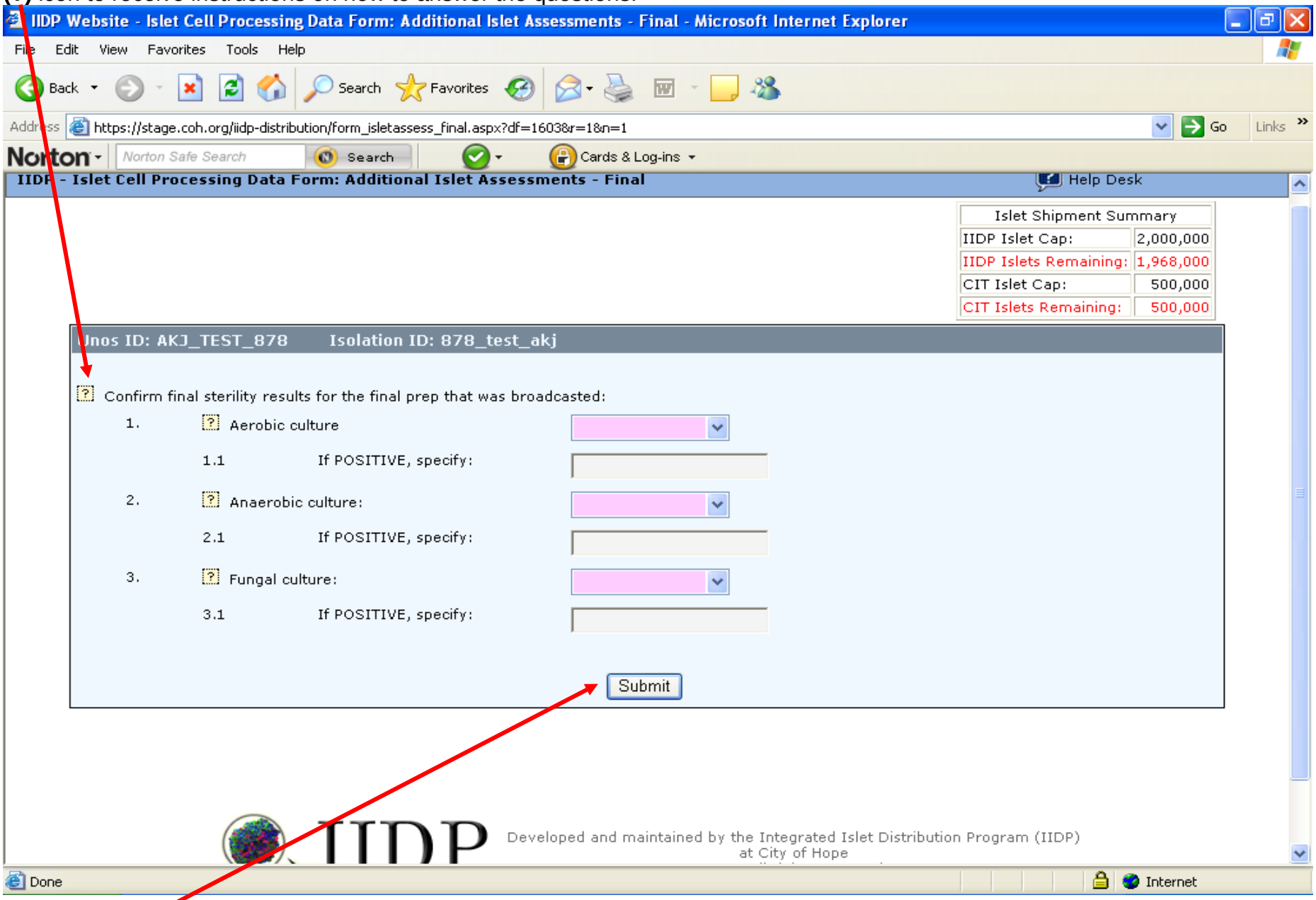
Note: The Donor Information, Characterization of Islets for Distribution Program, and Research Islet Transportation Information sections information are 'View only' since the quick broadcast has been completed.

Note: The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.

The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.

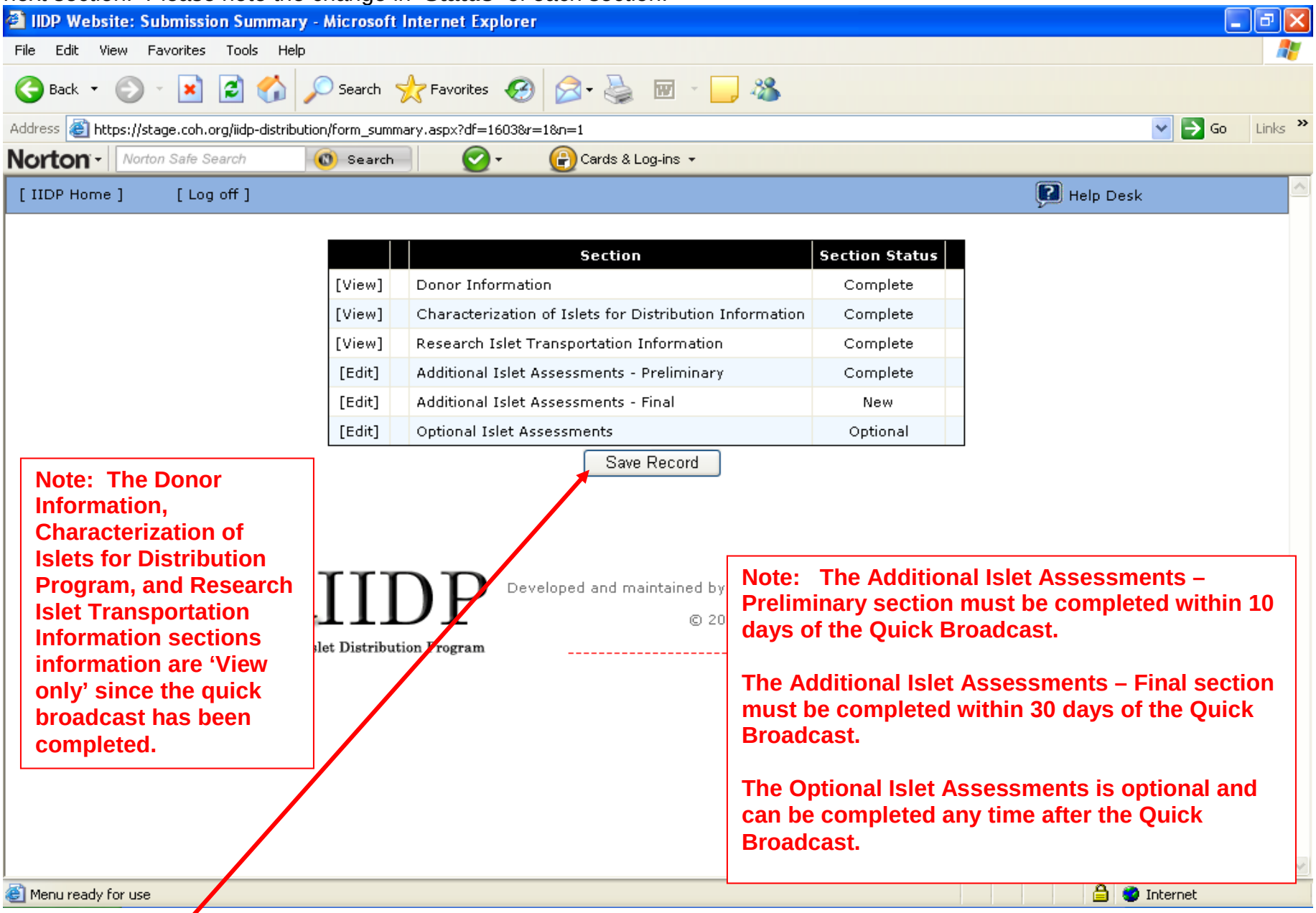
The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.

Additional Islet Assessments – Final – Complete the questions in this section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



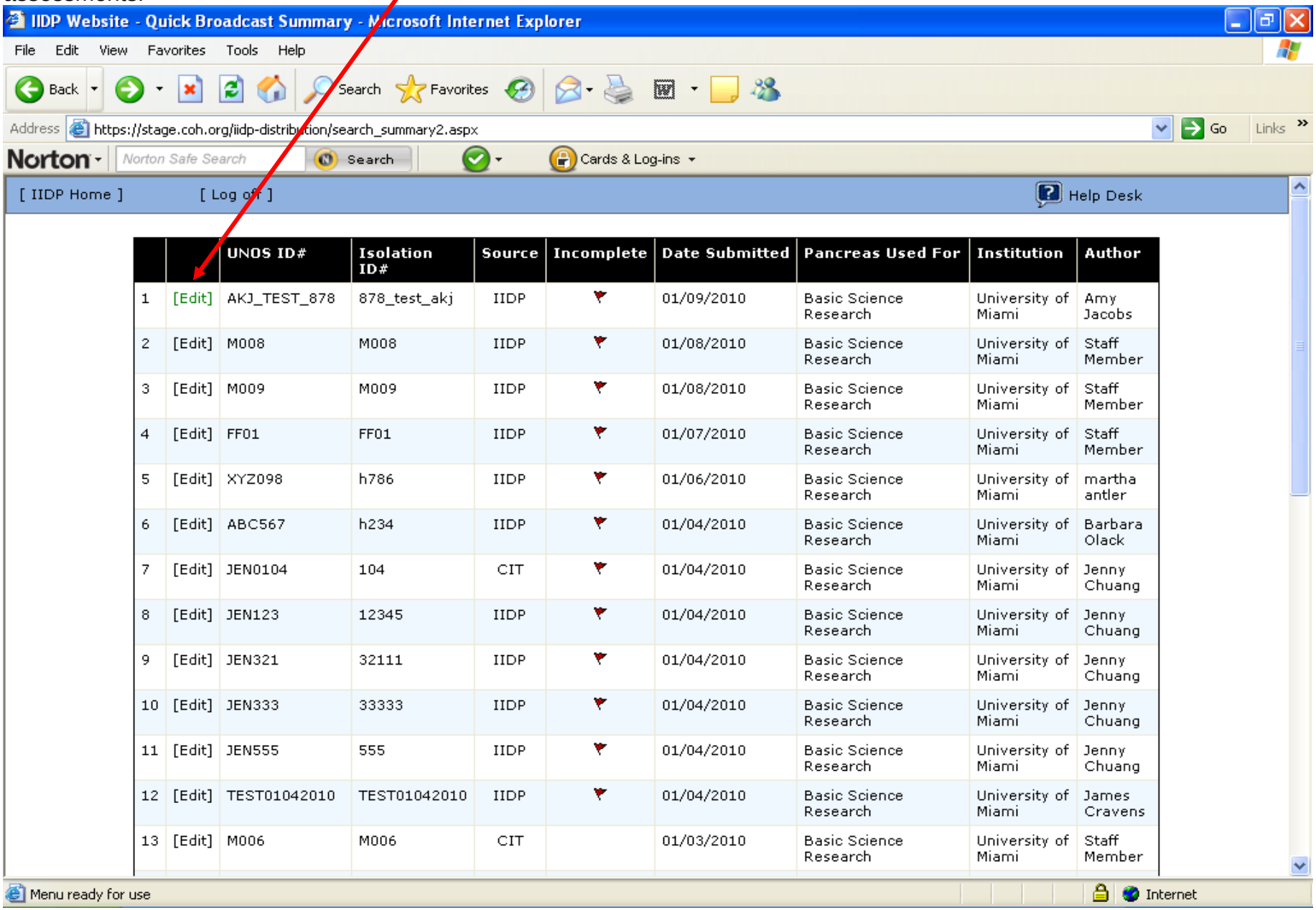
Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

Additional Islet Assessments – Final - Confirmation Message – This message will be displayed to confirm that the information has been submitted and saved in the system.

Click on **[Done]** and the system will return the user to the Main Page.

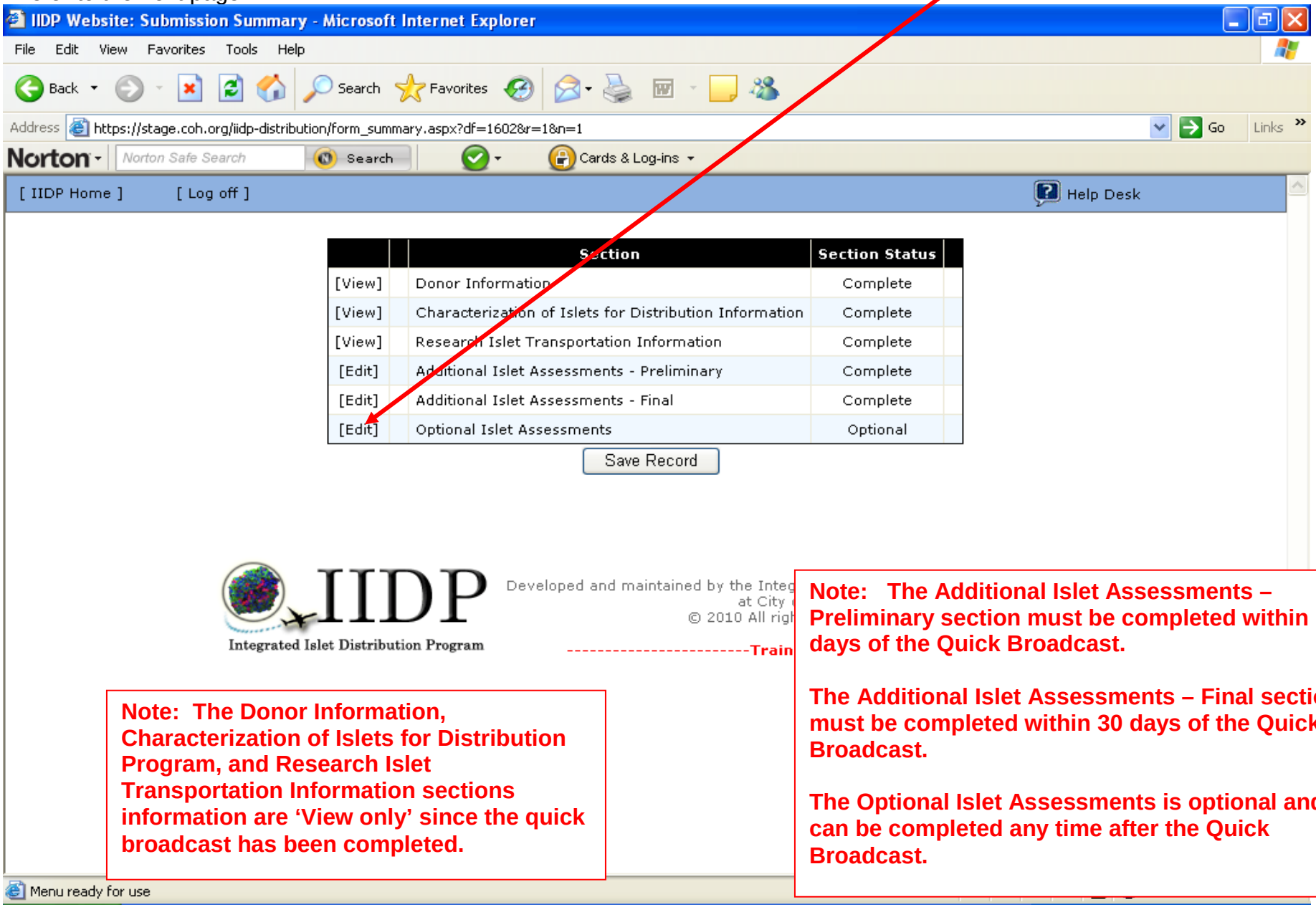
Main Page - Click on the menu option **[Edit/View Existing Quick Broadcast]** under **[Record for All Isolations].**

Existing Quick Broadcasts – Click on **[Edit]** of the desired quick broadcast to view and/or complete the additional islet assessments.



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
2	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
3	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
4	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
5	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
6	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
7	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
8	[Edit]	JEN123	12345	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
9	[Edit]	JEN321	32111	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
10	[Edit]	JEN333	33333	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
11	[Edit]	JEN555	555	IIDP		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang
12	[Edit]	TEST01042010	TEST01042010	IIDP		01/04/2010	Basic Science Research	University of Miami	James Cravens
13	[Edit]	M006	M006	CIT		01/03/2010	Basic Science Research	University of Miami	Staff Member

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section. For this example, click on **[Edit]** of Optional Islet Assessments – refer to the next page.



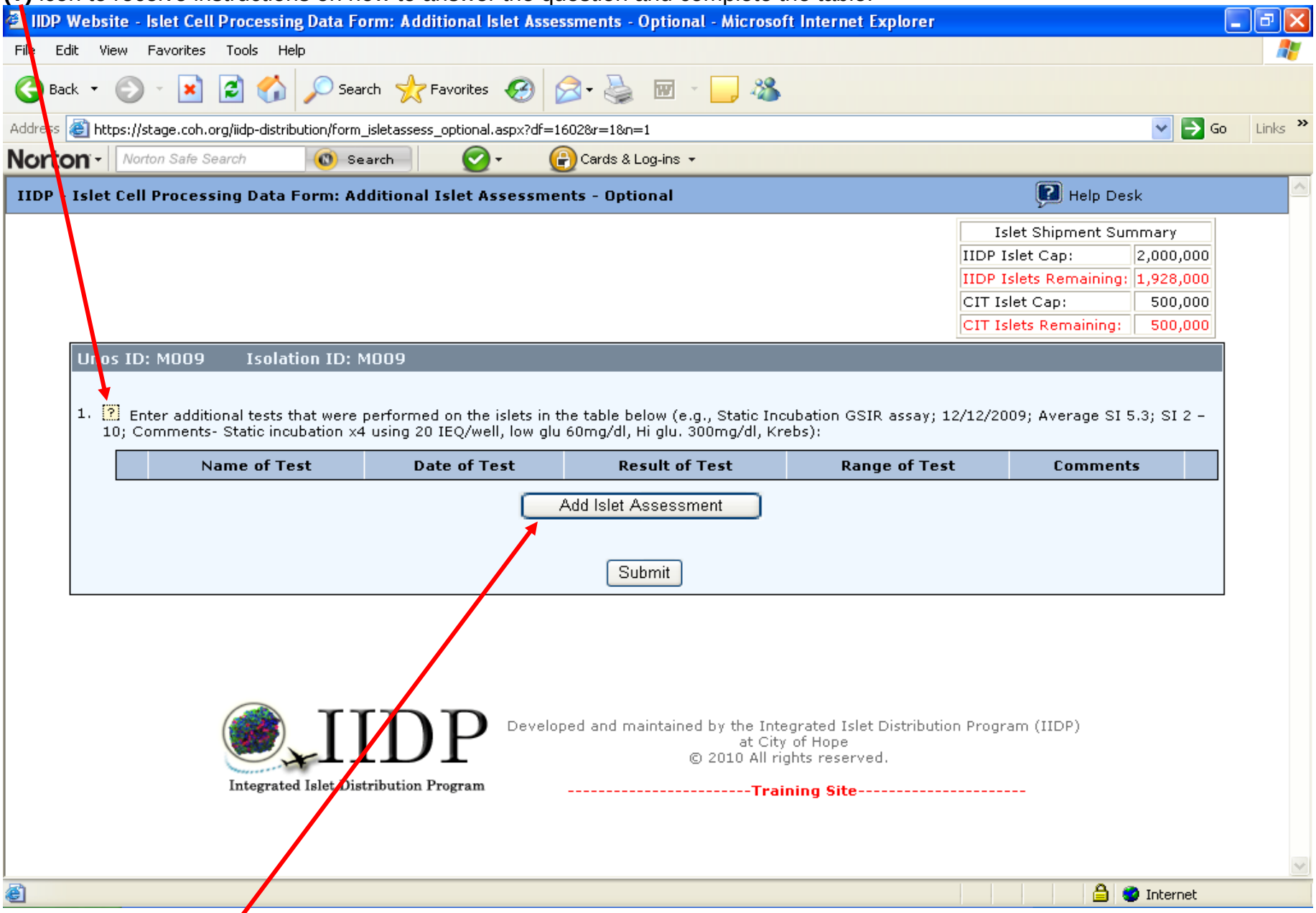
Note: The Donor Information, Characterization of Islets for Distribution Program, and Research Islet Transportation Information sections information are 'View only' since the quick broadcast has been completed.

Note: The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.

The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.

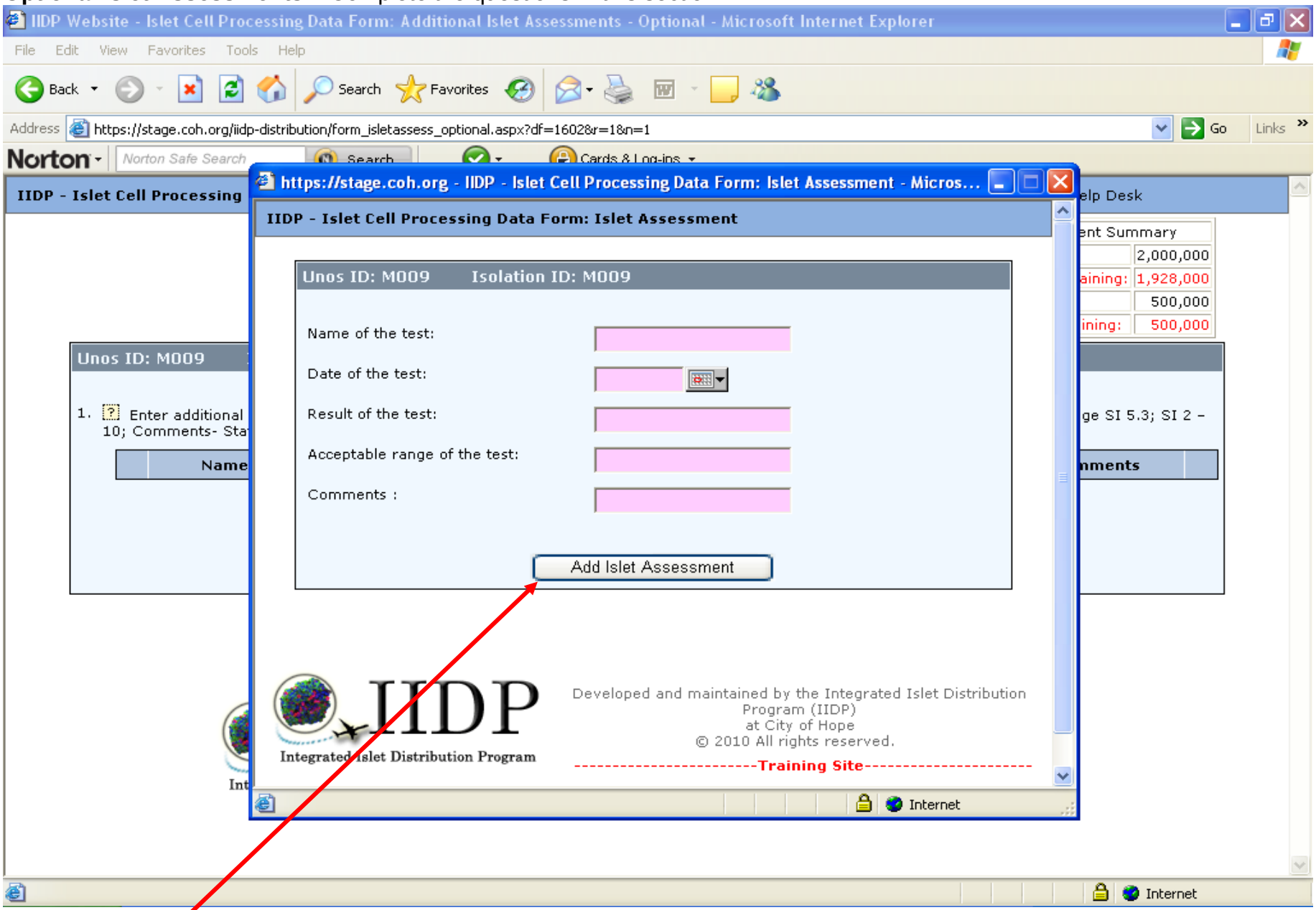
The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.

Optional Islet Assessments – Complete the questions in this section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the question and complete the table.



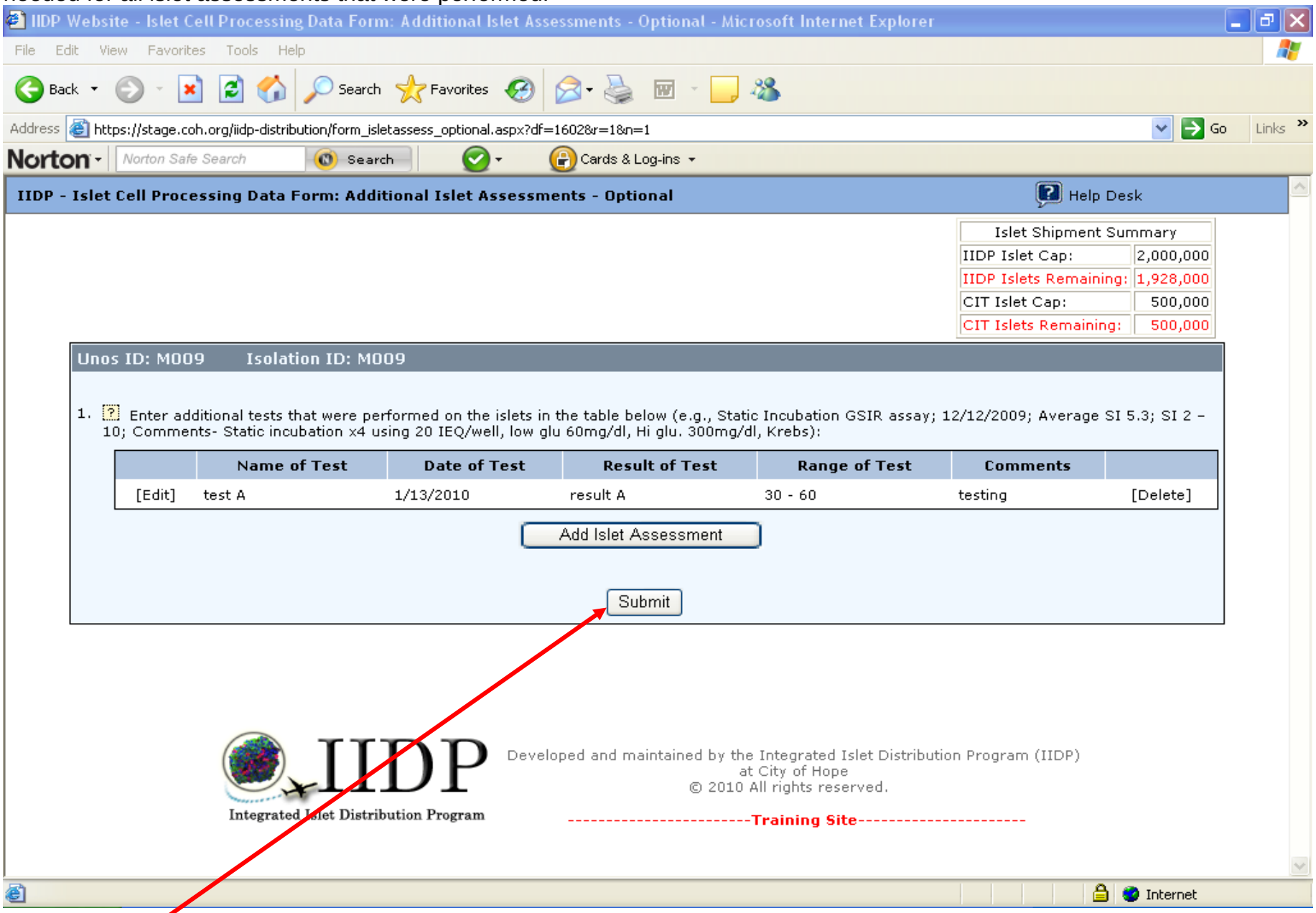
Click on **[Add Islet Assessment]** to enter an islet assessment test information – refer to the next page.

Optional Islet Assessments – Complete the questions in this section.



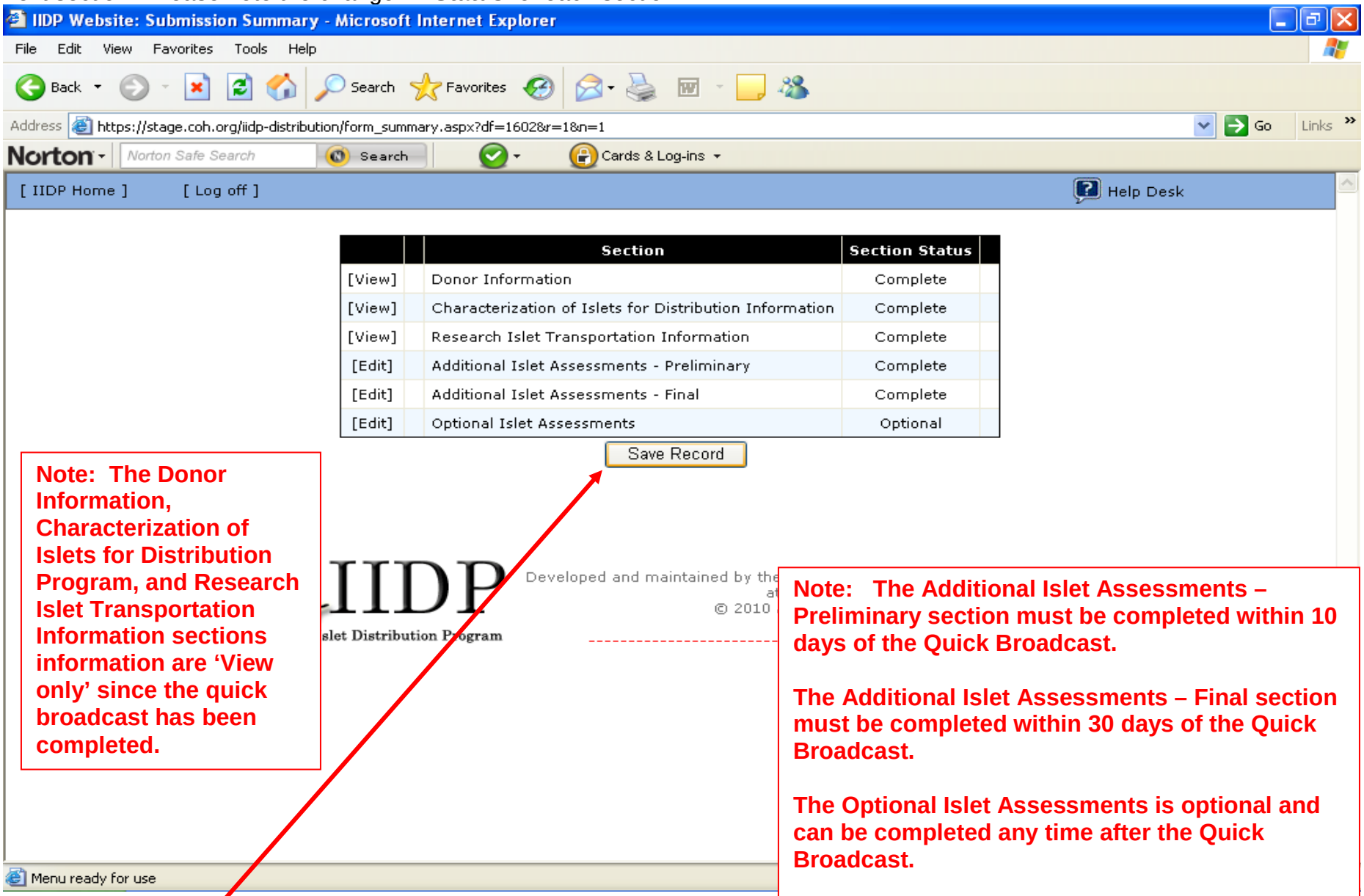
Click on **[Add Islet Assessment]** to enter the islet assessment test information into the table/system – refer to the next page.

Optional Islet Assessments – Click on **[Add Islet Assessment]** to add another islet assessment and repeat the process as needed for all islet assessments that were performed.



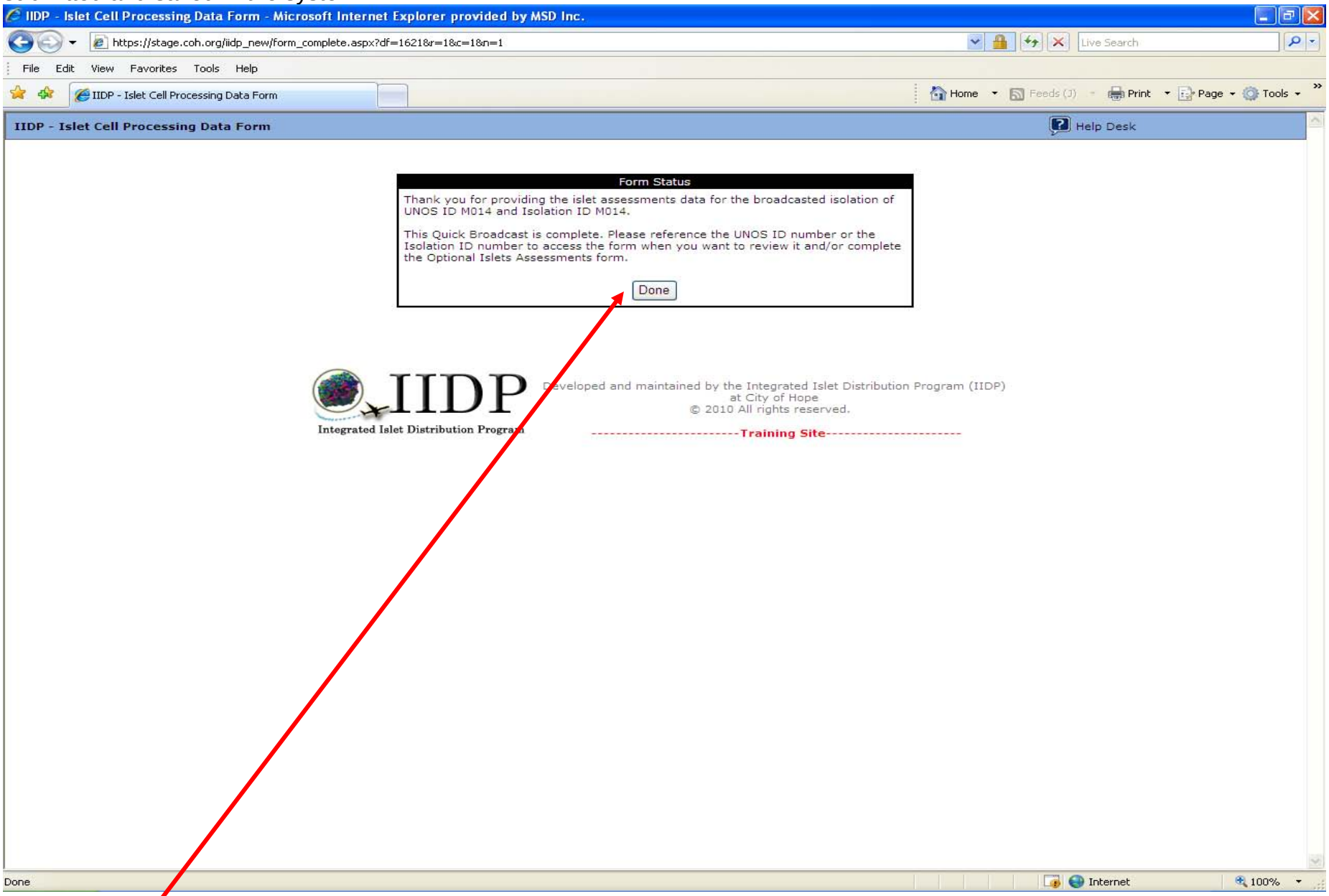
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

Optional Islet Assessments – Confirmation Message – This message will be displayed to confirm that the information has been submitted and saved in the system.

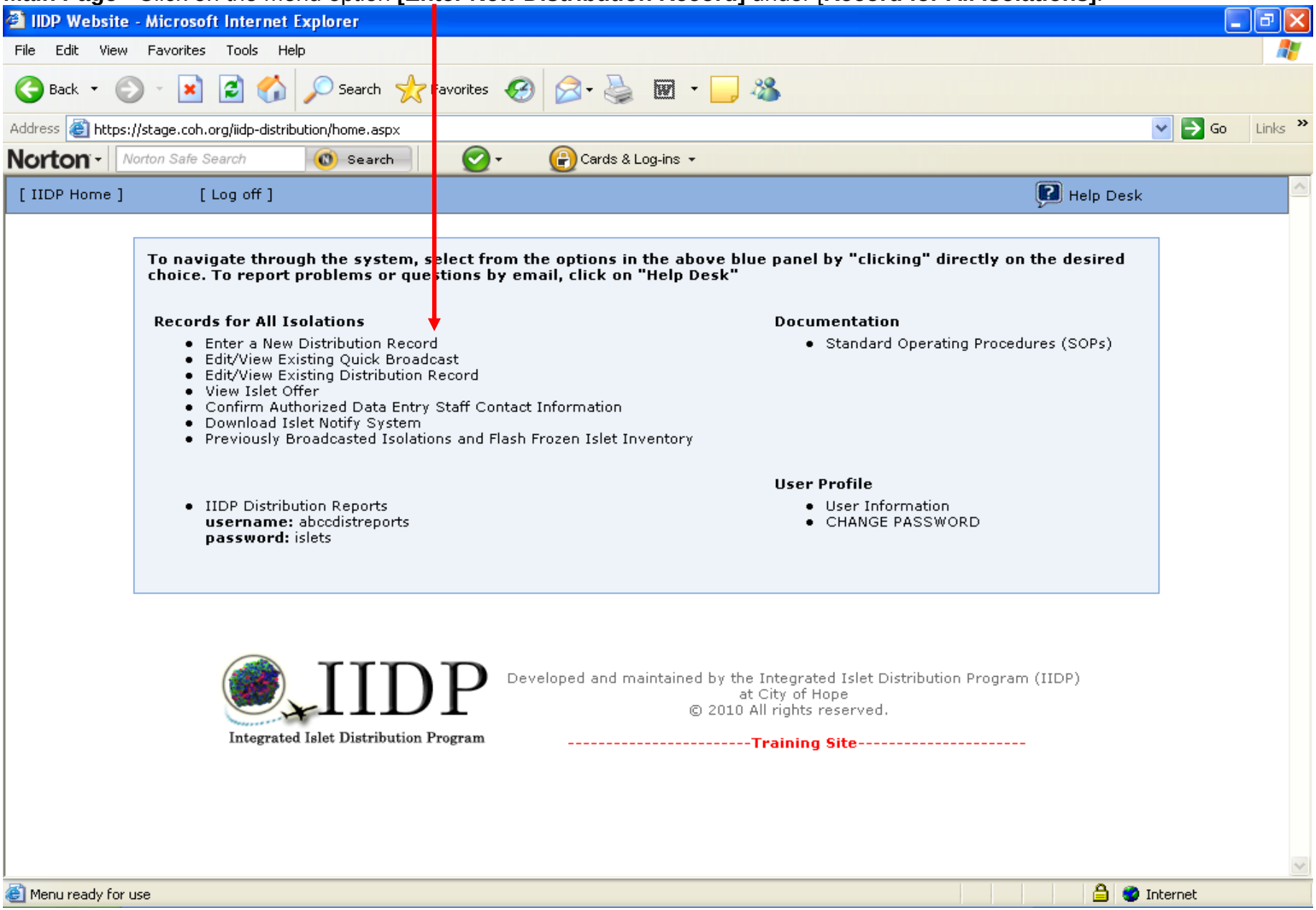


Click on **[Done]** and the system will return the user to the Main Page.

Main Page - Click on any menu option as needed OR click on **[Log off]** to log out of the system.

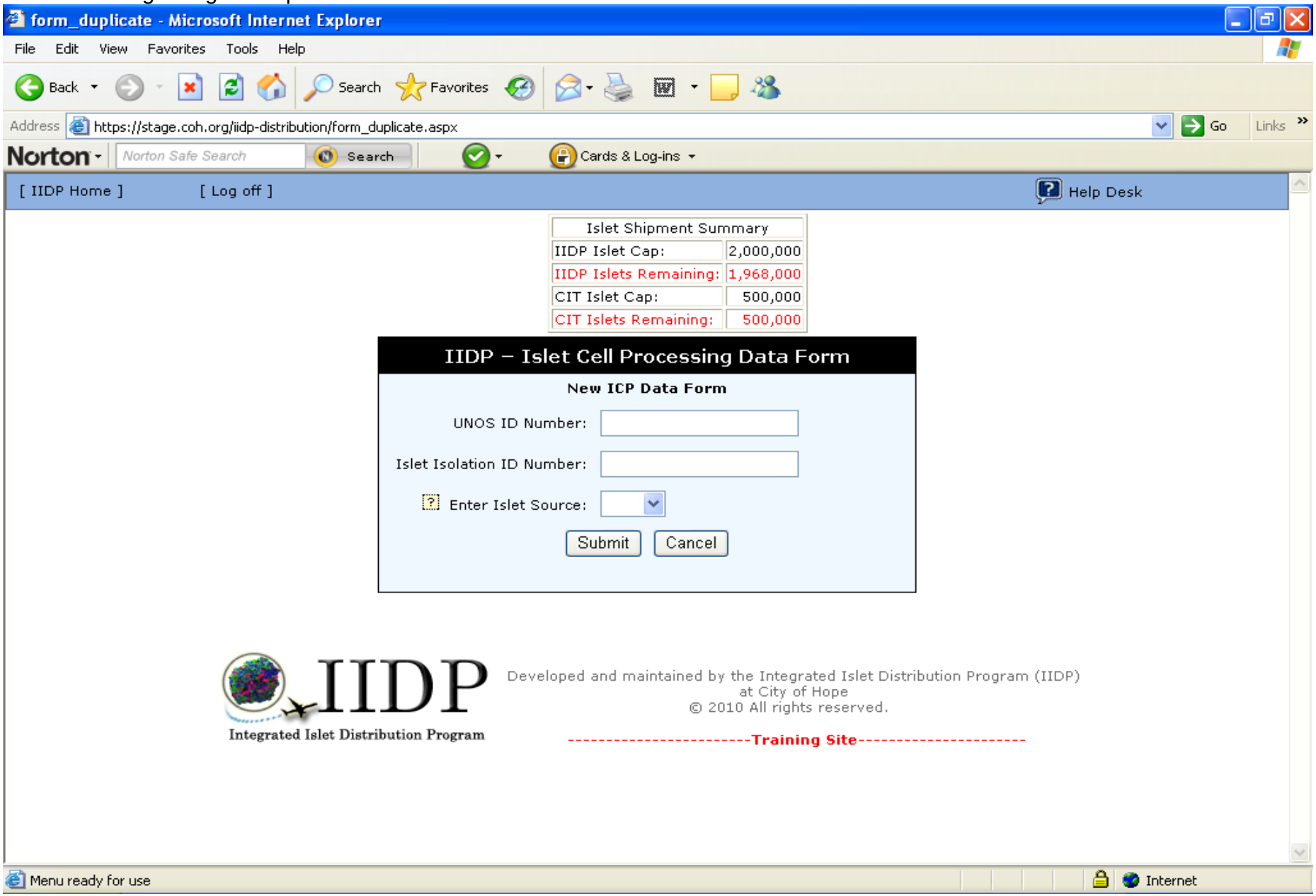
5.0 Complete a Distribution Record

Main Page - Click on the menu option **[Enter New Distribution Record]** under [**Record for All Isolations**].



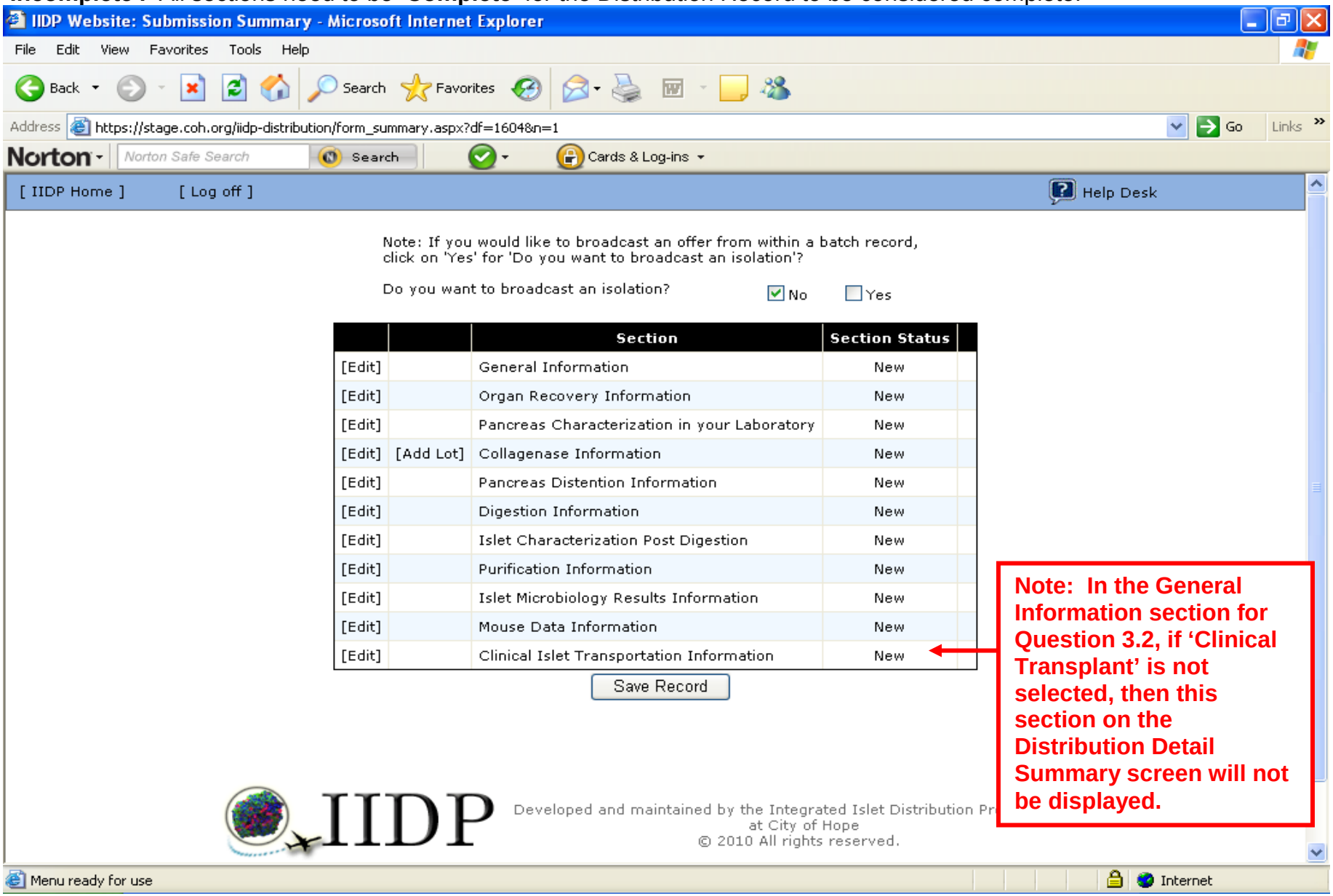
Click on **[Complete a Distribution Record]** to complete a distribution record - refer to the next page.

UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit].** Click on **[Cancel]** to return to the Main Page. Refer to pages 11 – 14 for information regarding if a duplicate UNOS ID and/or Isolation ID is entered.



The **Distribution Record Form Detail Summary** screen will be displayed with the default of 'No' to the question "Do you want to broadcast an isolation?". The Distribution Record can now be completed. Click on **[Edit]** of a designated section to display the form to complete.

Distribution Record Form Detail Summary - The system will display the **Status** of each section as '**New', 'Complete', or 'Incomplete'.** All sections need to be **'Complete'** for the Distribution Record to be considered complete.

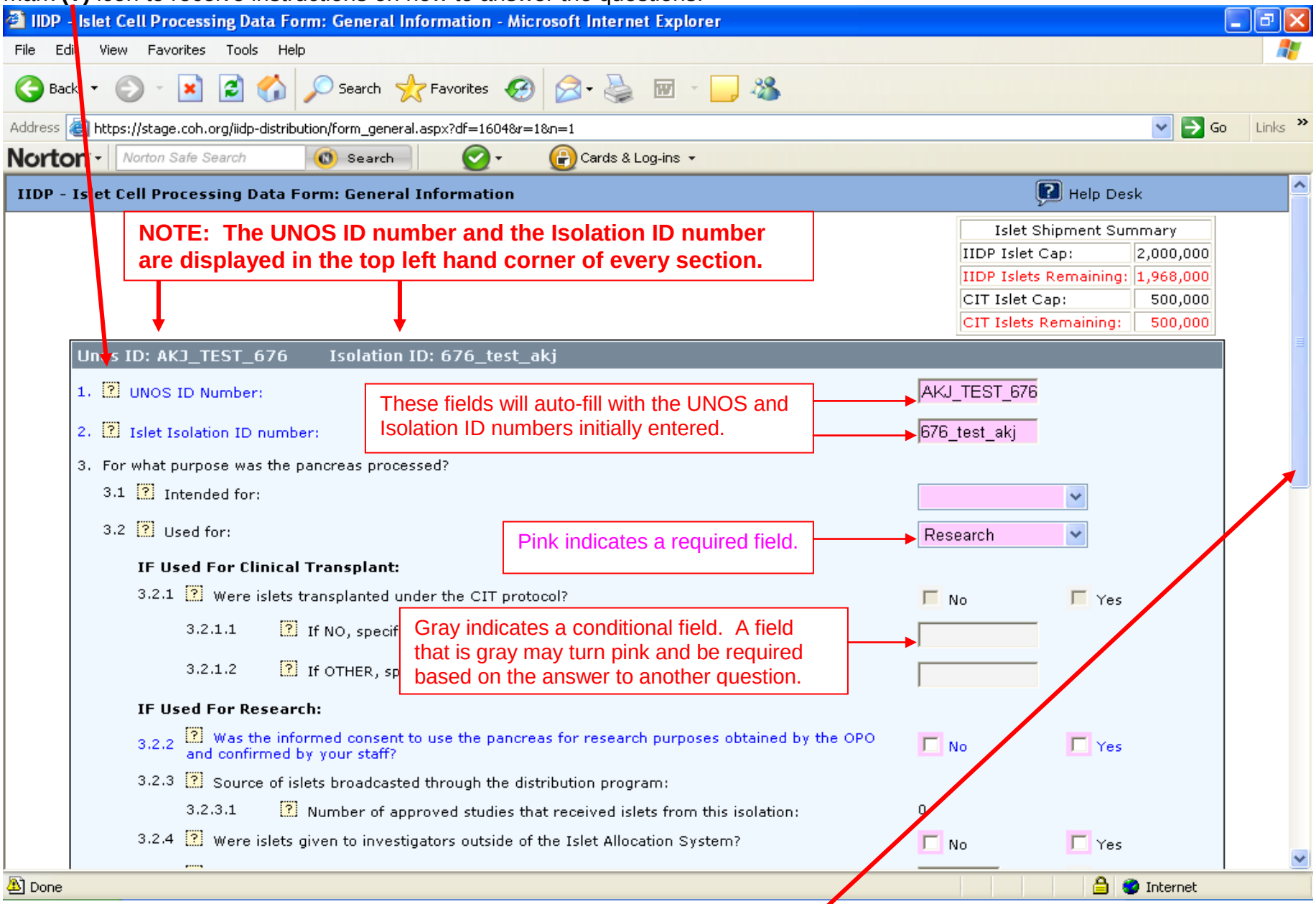


		Section	Section Status
[Edit]		General Information	New
[Edit]		Organ Recovery Information	New
[Edit]		Pancreas Characterization in your Laboratory	New
[Edit]	[Add Lot]	Collagenase Information	New
[Edit]		Pancreas Distention Information	New
[Edit]		Digestion Information	New
[Edit]		Islet Characterization Post Digestion	New
[Edit]		Purification Information	New
[Edit]		Islet Microbiology Results Information	New
[Edit]		Mouse Data Information	New
[Edit]		Clinical Islet Transportation Information	New

Note: In the General Information section for Question 3.2, if 'Clinical Transplant' is not selected, then this section on the Distribution Detail Summary screen will not be displayed.

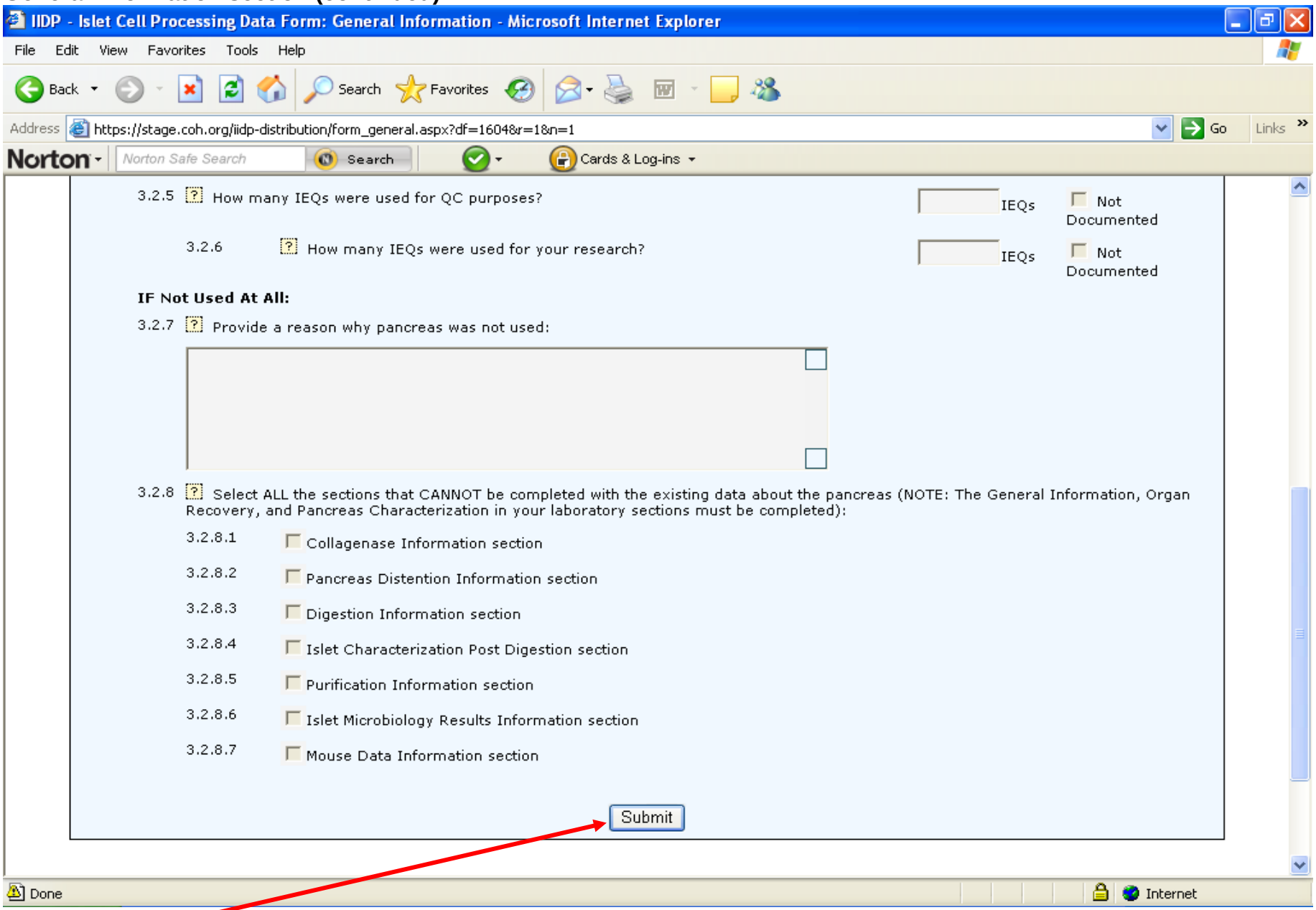
NOTE: The user may randomly select the order in which to complete each section (e.g., General Information section, then the Collagenase Information section, then the Pancreas Characterization at ICR section, etc.). However for the purpose of this User's Guide, the sections will be discussed in the order as listed above.

General Information section – Complete the questions in the General Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



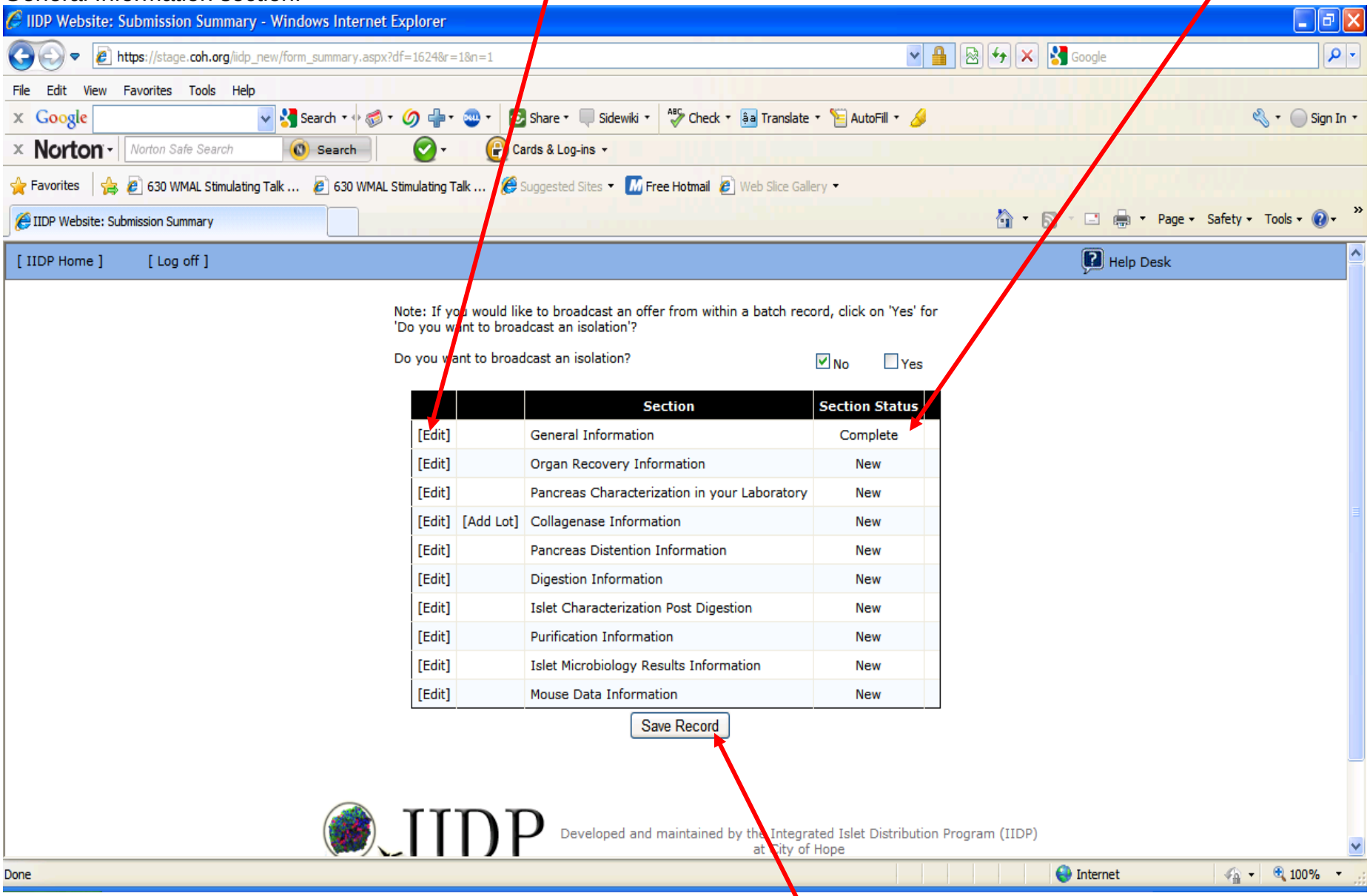
Each section in the form is considered a 'single page'. You can use the **scroll bar** to scroll down to the bottom of the section. The **General Information section** is continued on the next page.

General Information section (continued)



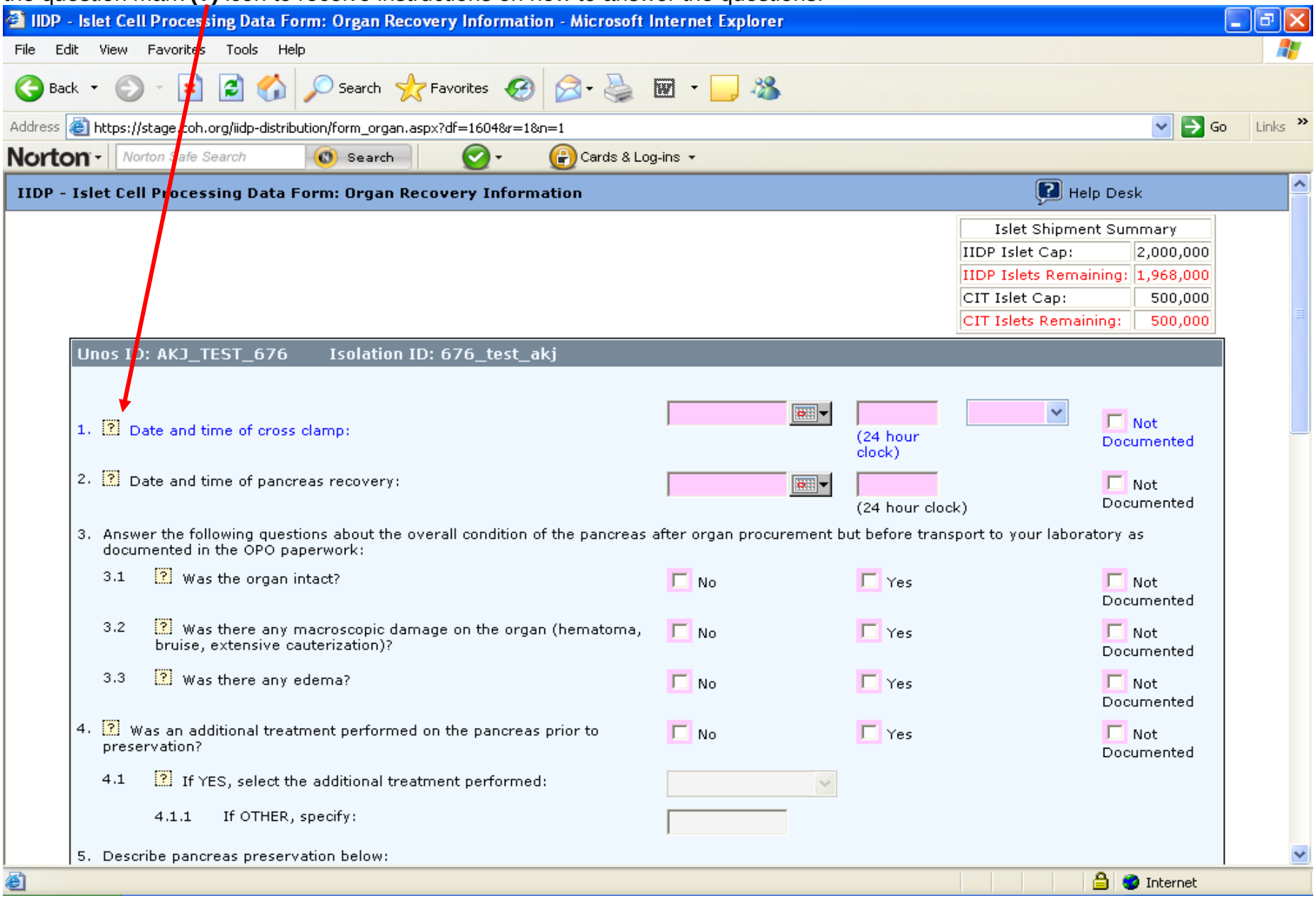
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Form Detail Summary.

Distribution Record Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of the General Information section.

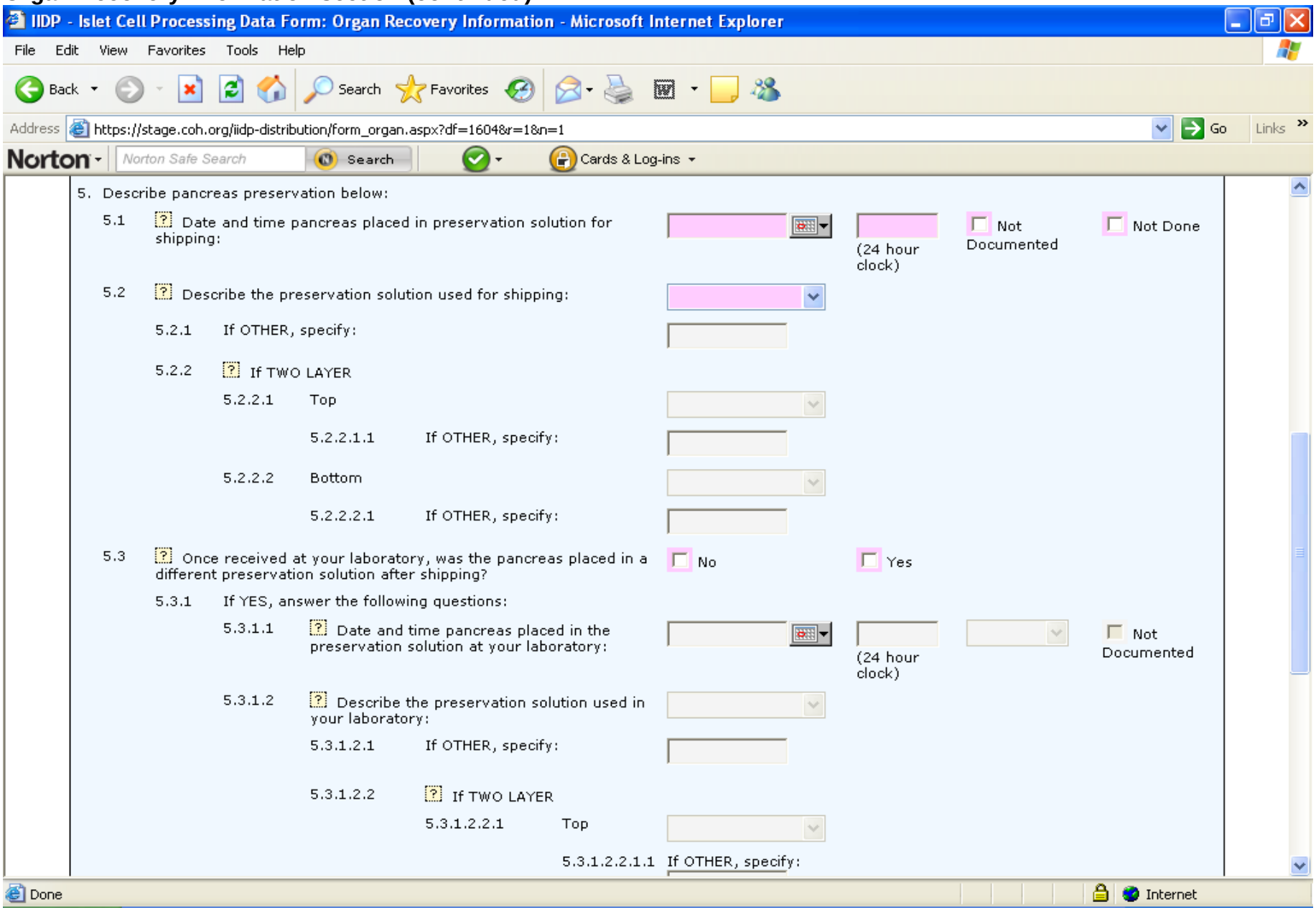


The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

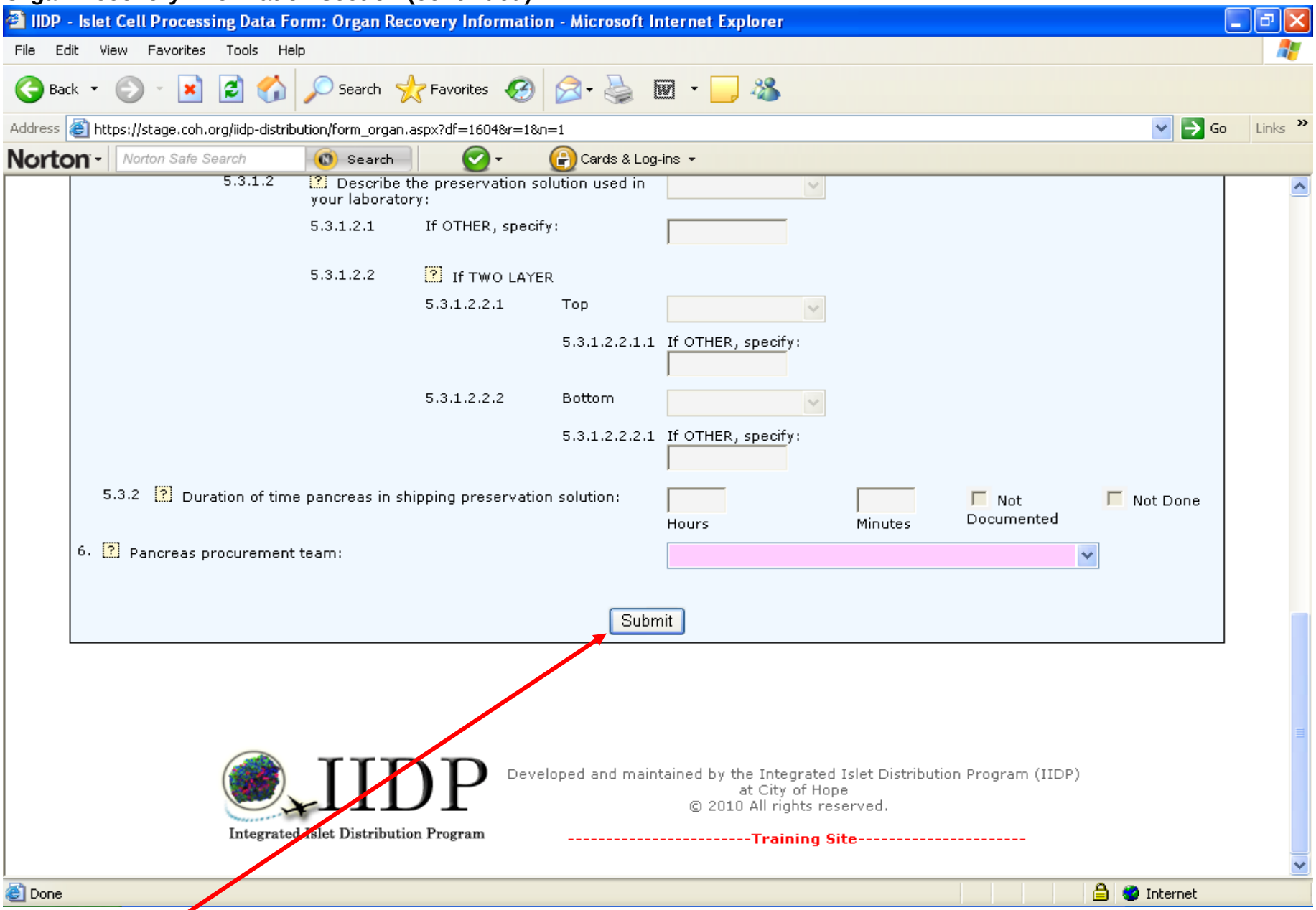
Organ Recovery Information section – Complete the questions in the Organ Recovery Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Organ Recovery Information section (continued)

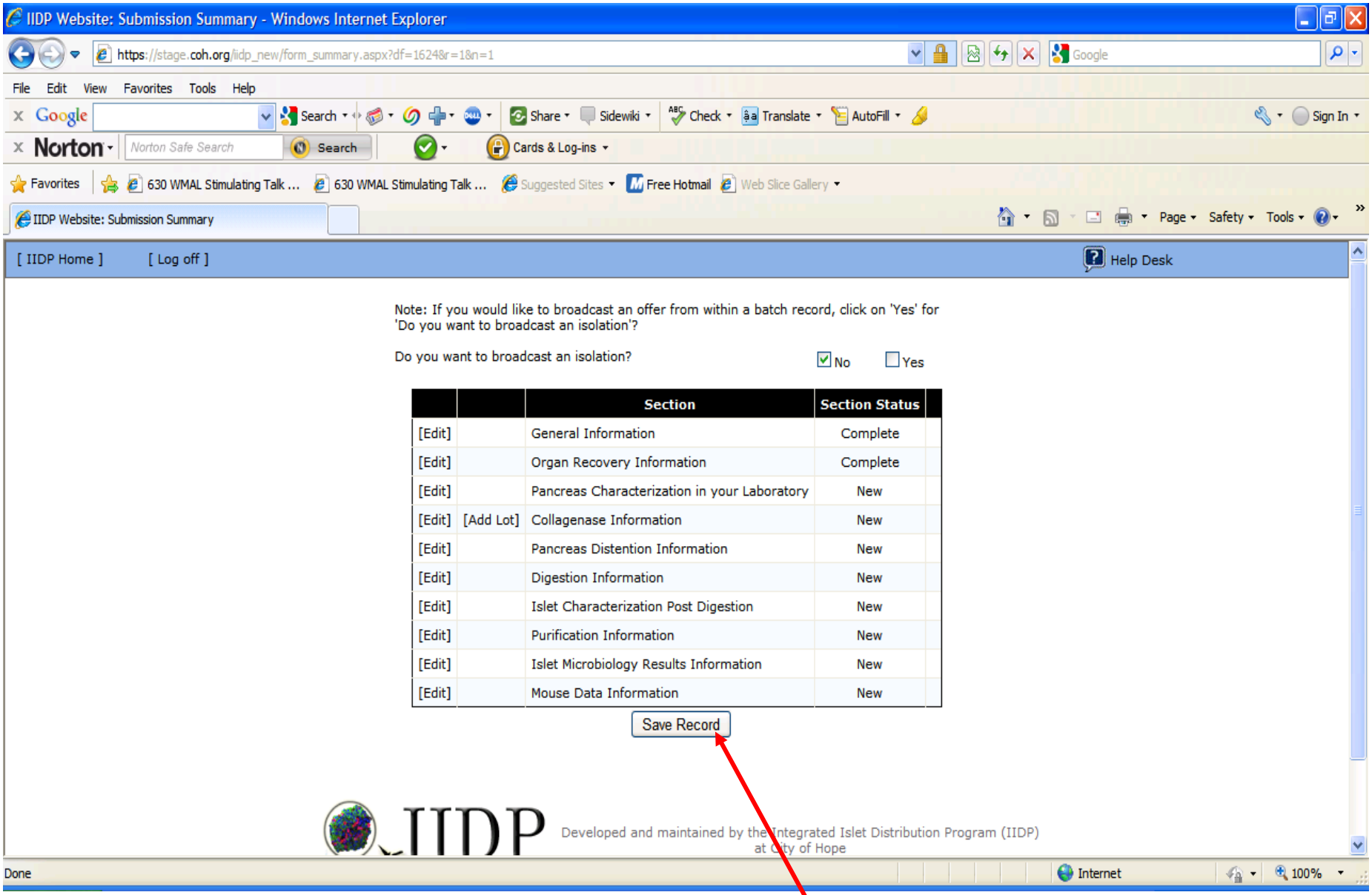


Organ Recovery Information section (continued)



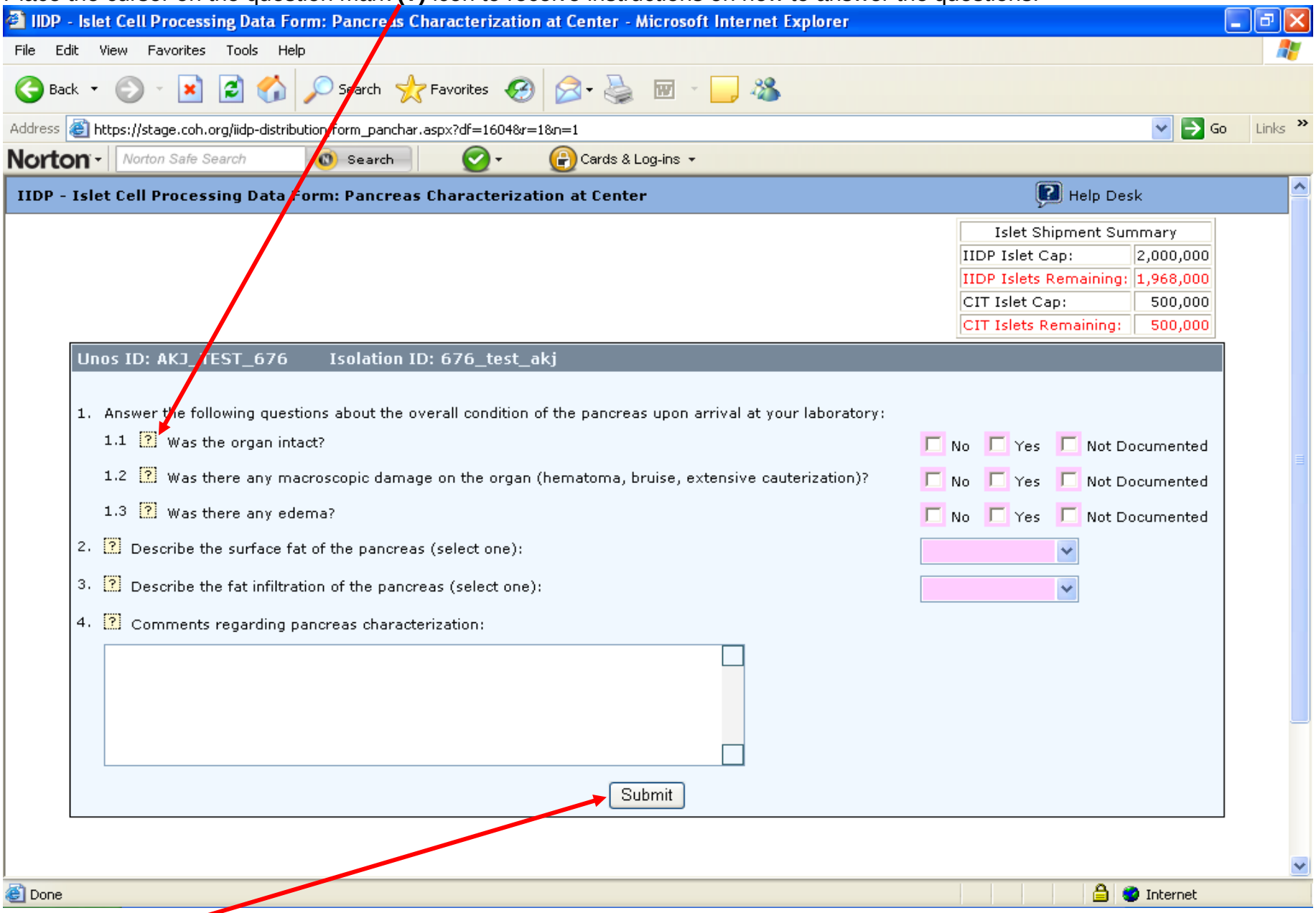
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



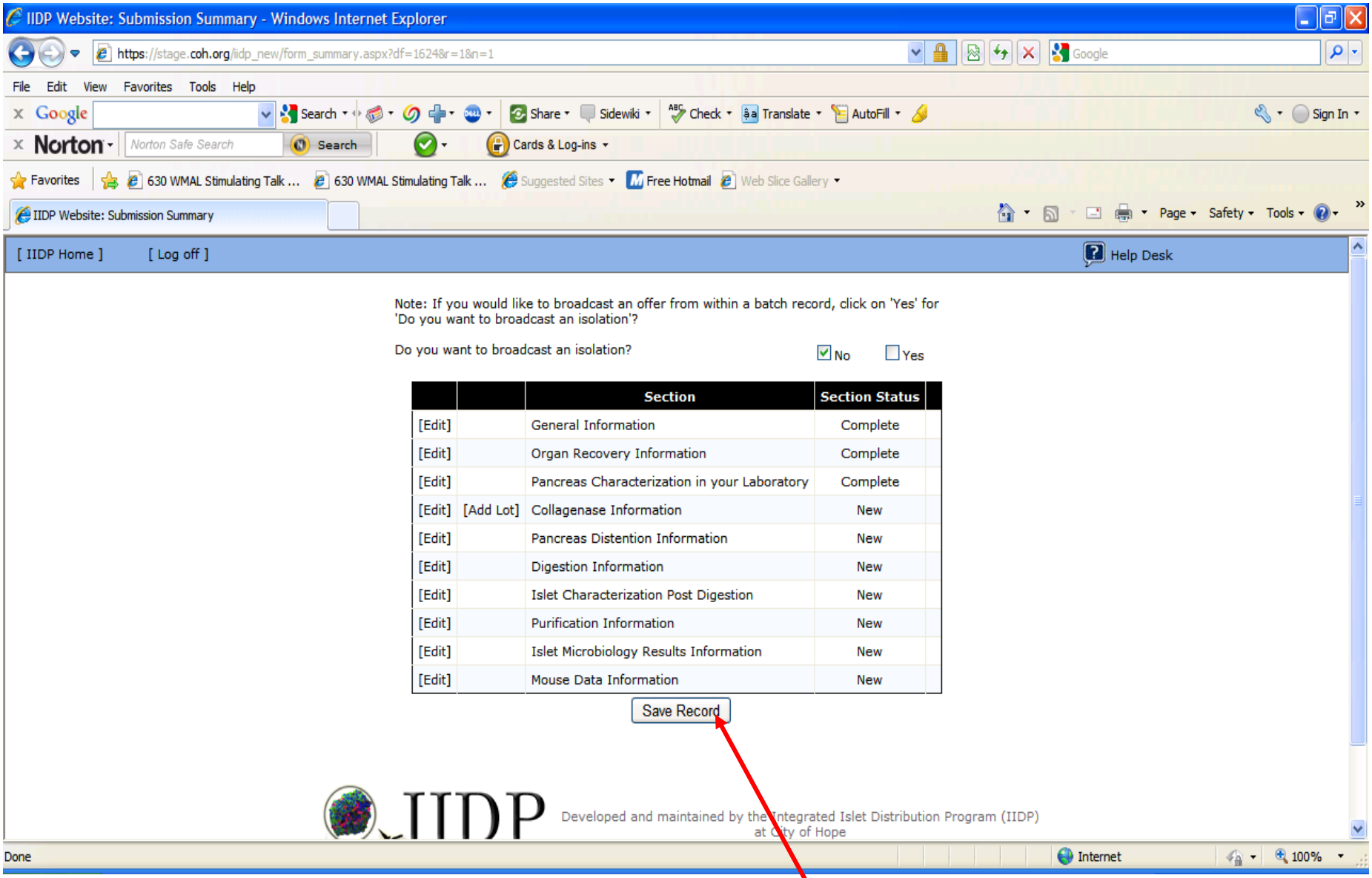
The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Pancreas Characterization at Center section – Complete the questions in the Pancreas Characterization at Center section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



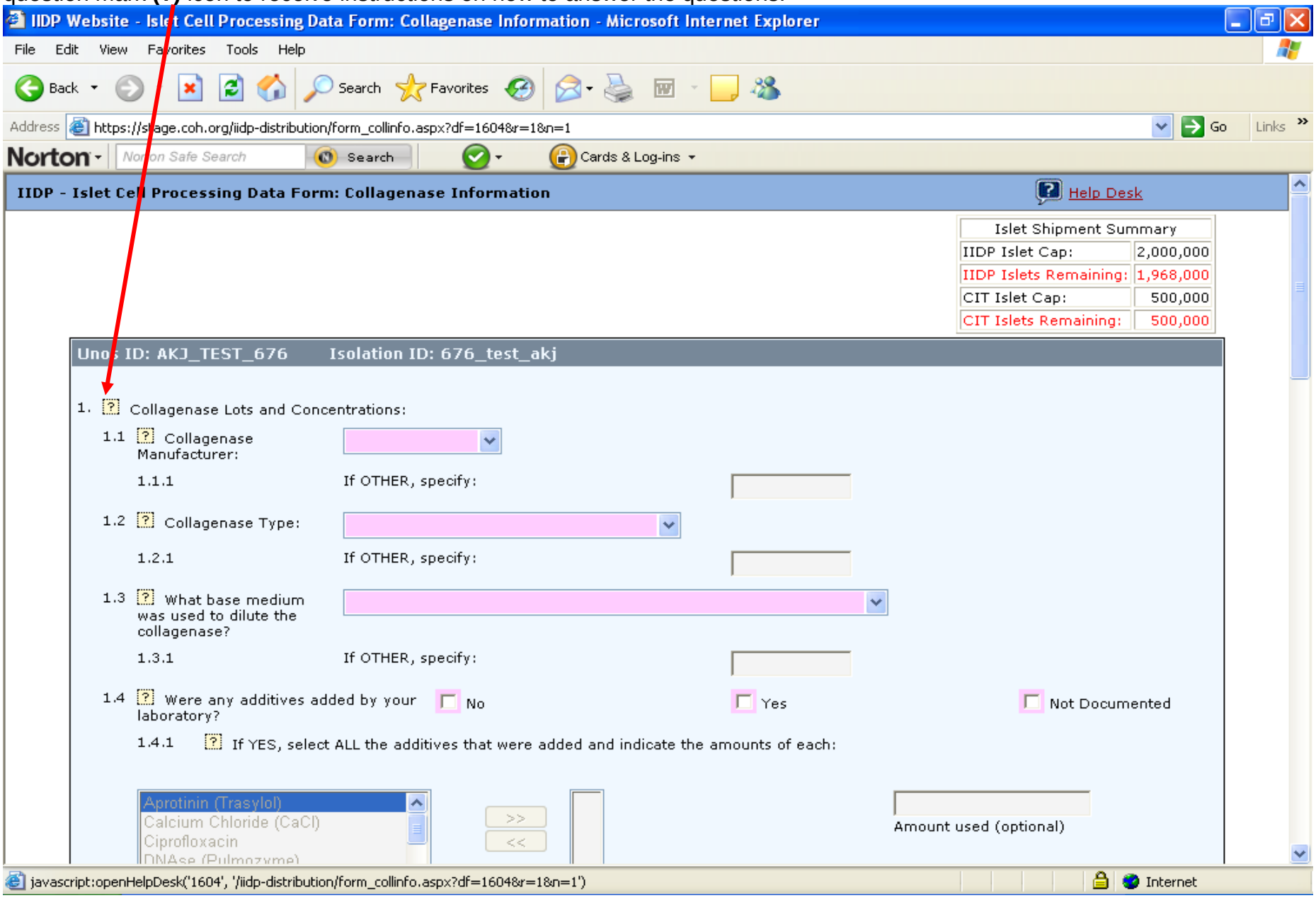
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.

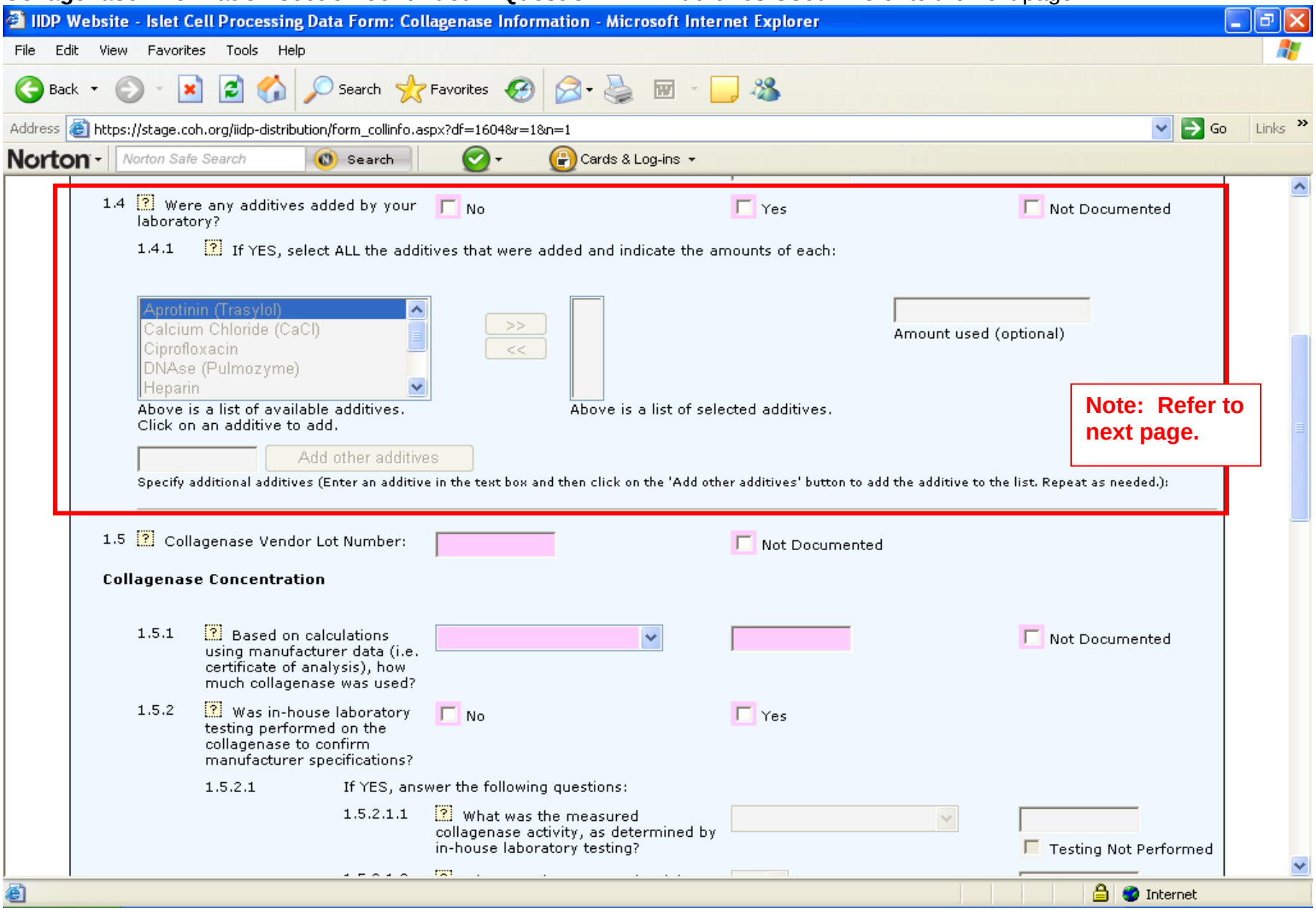


The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

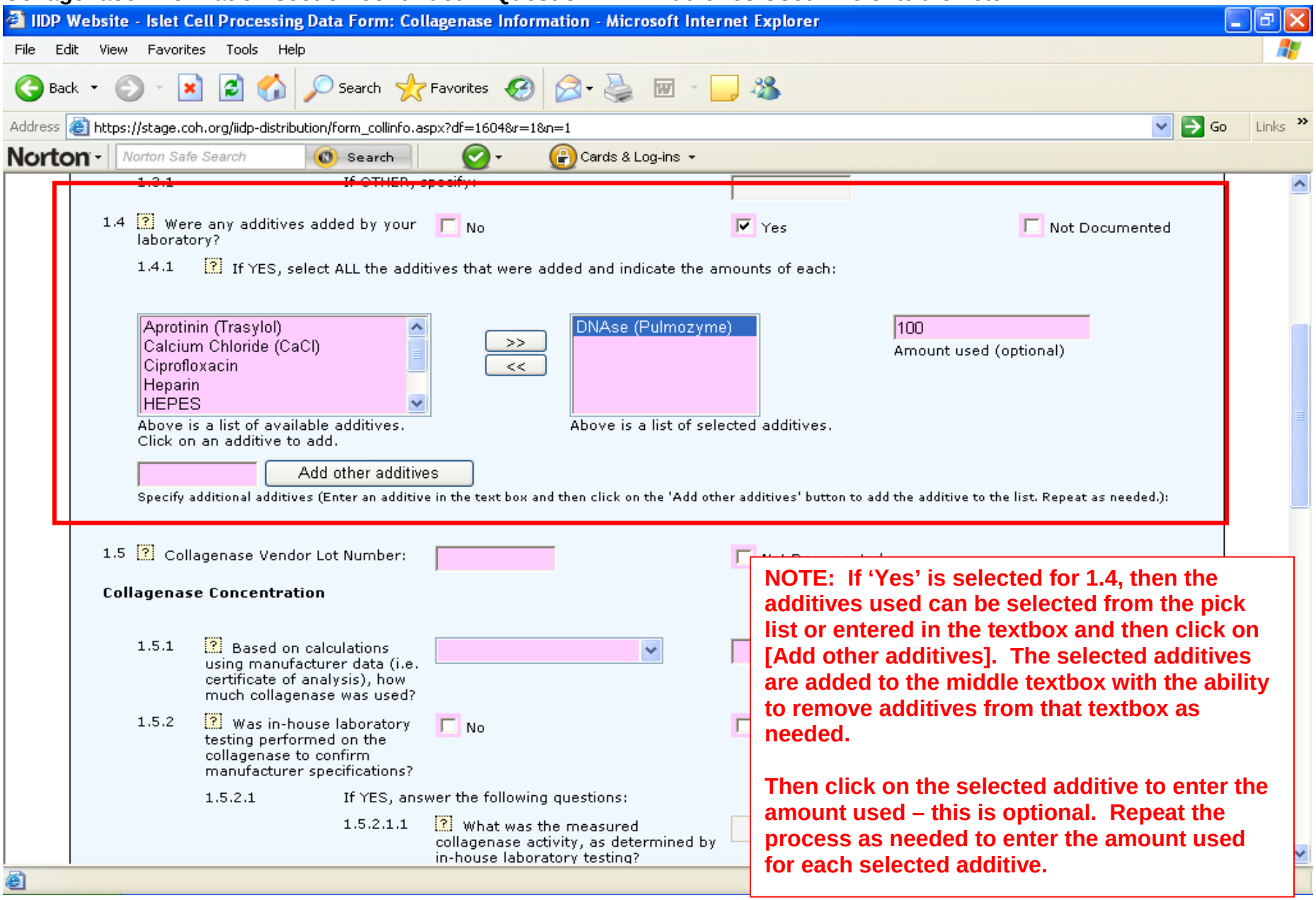
Collagenase Information section – Complete the questions in the Collagenase Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Collagenase Information section continued – Question 1.4 – Additives Used – refer to the next page.



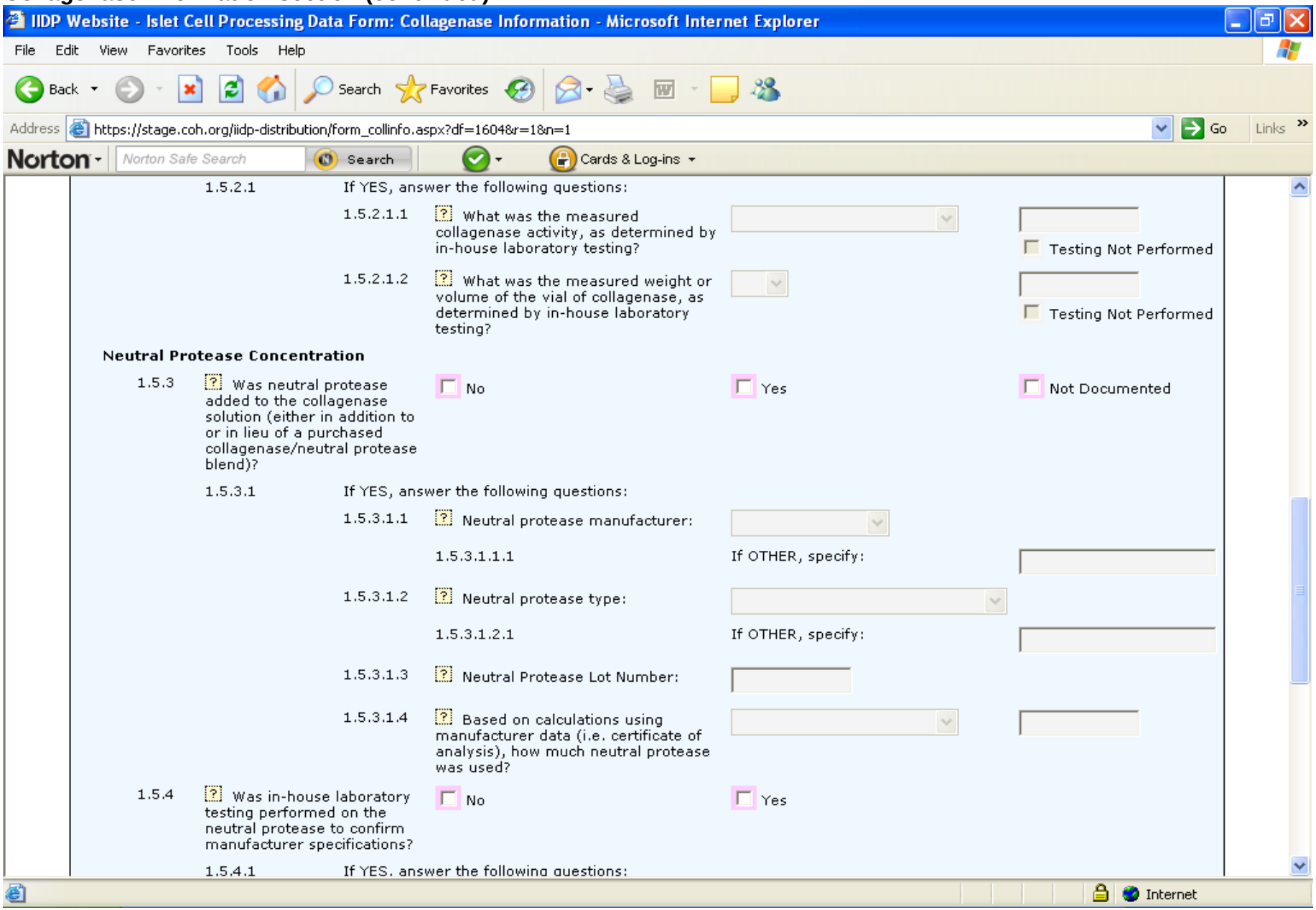
Collagenase Information section continued – Question 1.4 – Additives Used – refer to the note.



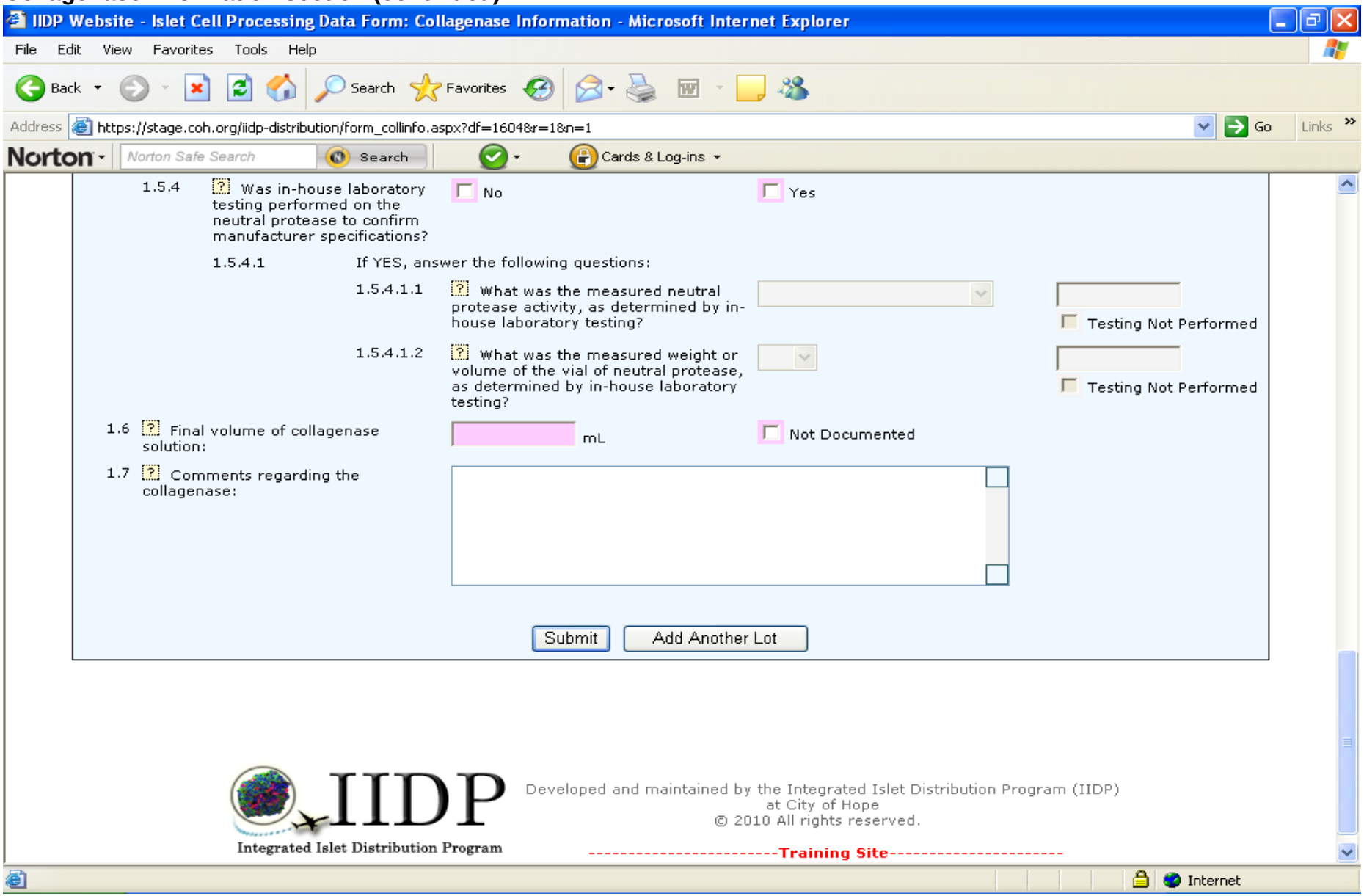
NOTE: If 'Yes' is selected for 1.4, then the additives used can be selected from the pick list or entered in the textbox and then click on [Add other additives]. The selected additives are added to the middle textbox with the ability to remove additives from that textbox as needed.

Then click on the selected additive to enter the amount used – this is optional. Repeat the process as needed to enter the amount used for each selected additive.

Collagenase Information section (continued)



Collagenase Information section (continued)

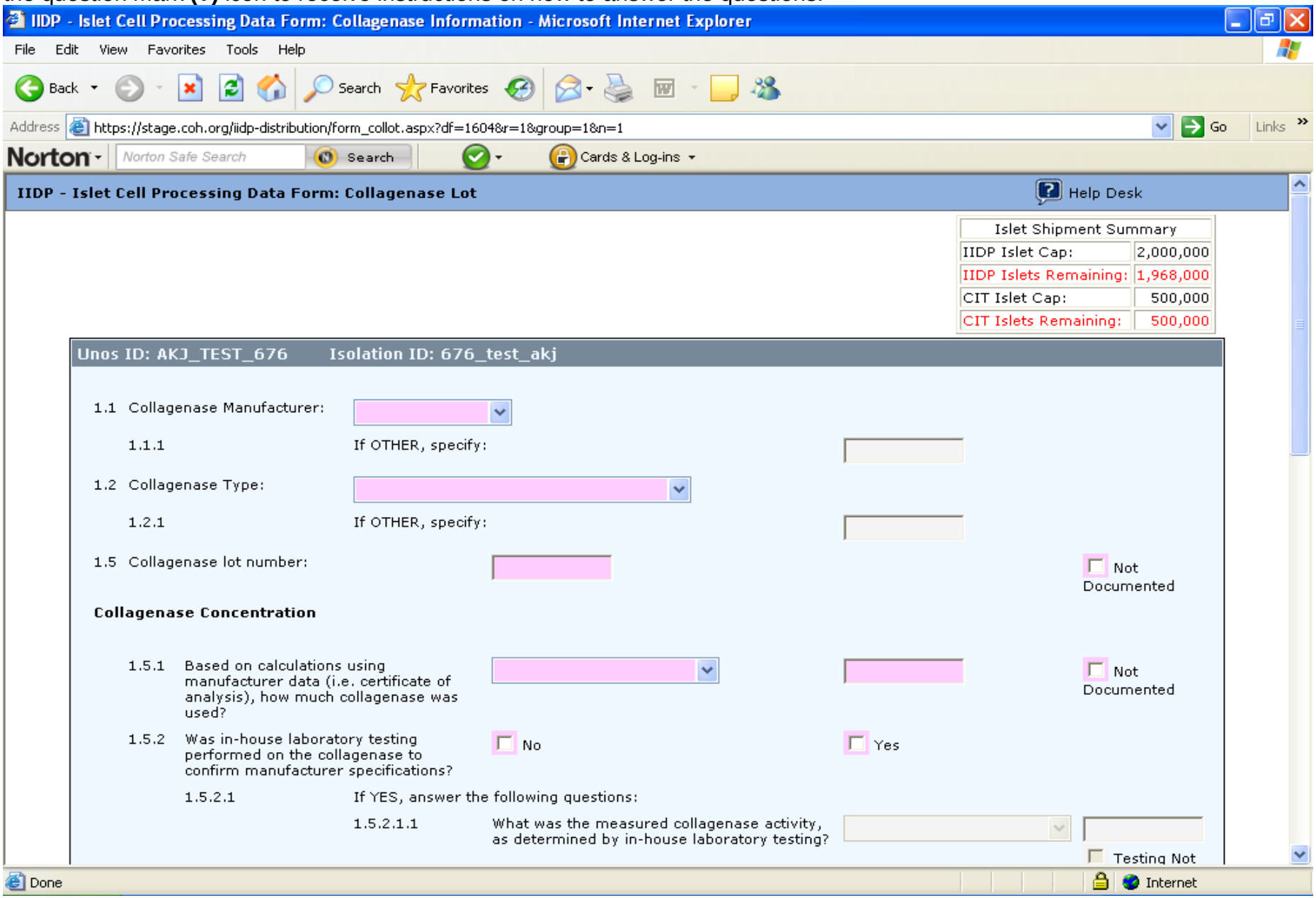


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

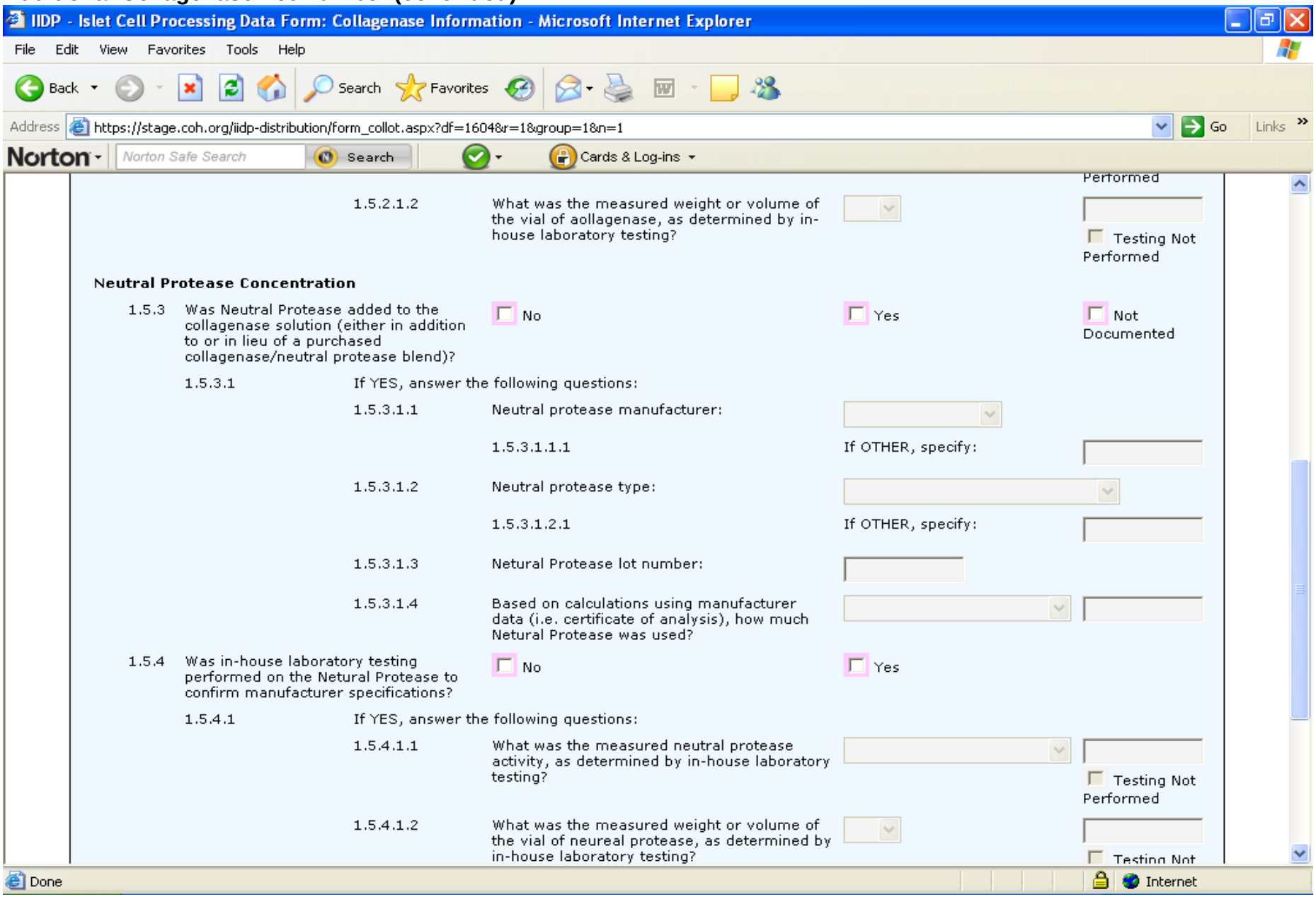
OR

Click on **[Add Another Lot]** to complete the questions for an additional Collaganese Lot number. - refer to next page.

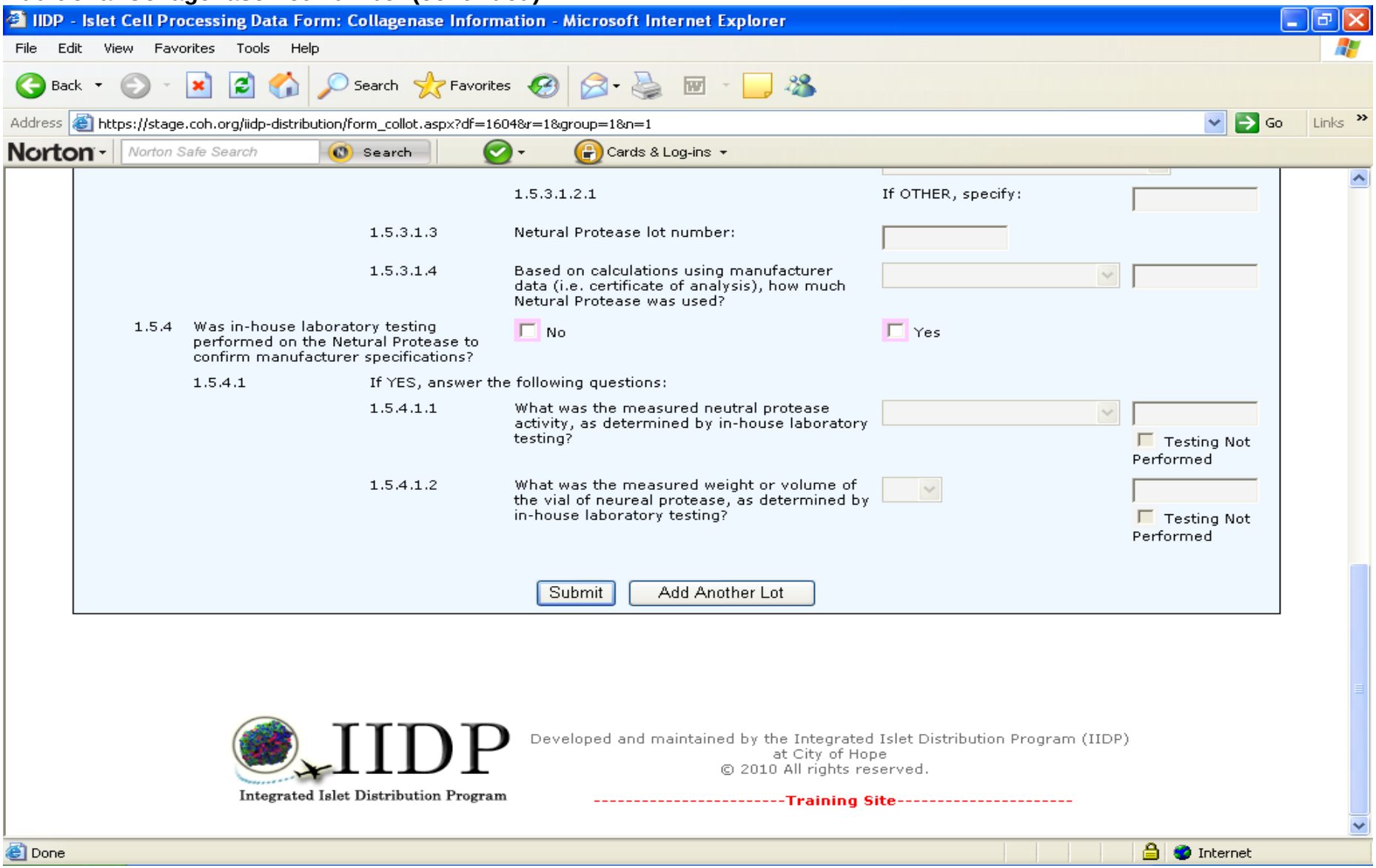
Additional Collagenase Lot Number - Complete the questions for an additional Collagenase Lot Number. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Additional Collagenase Lot Number (continued)



Additional Collagenase Lot Number (continued)

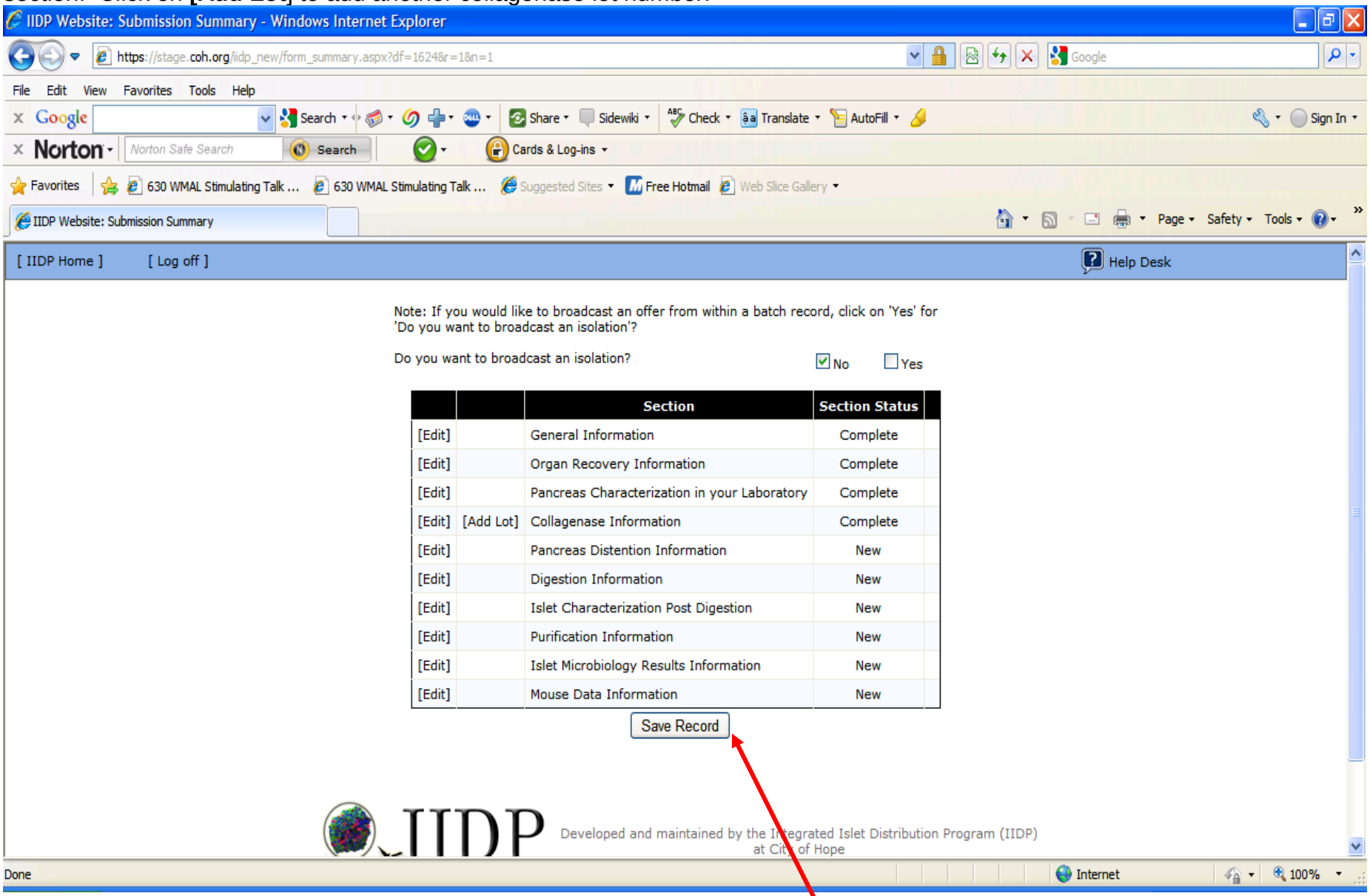


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

OR

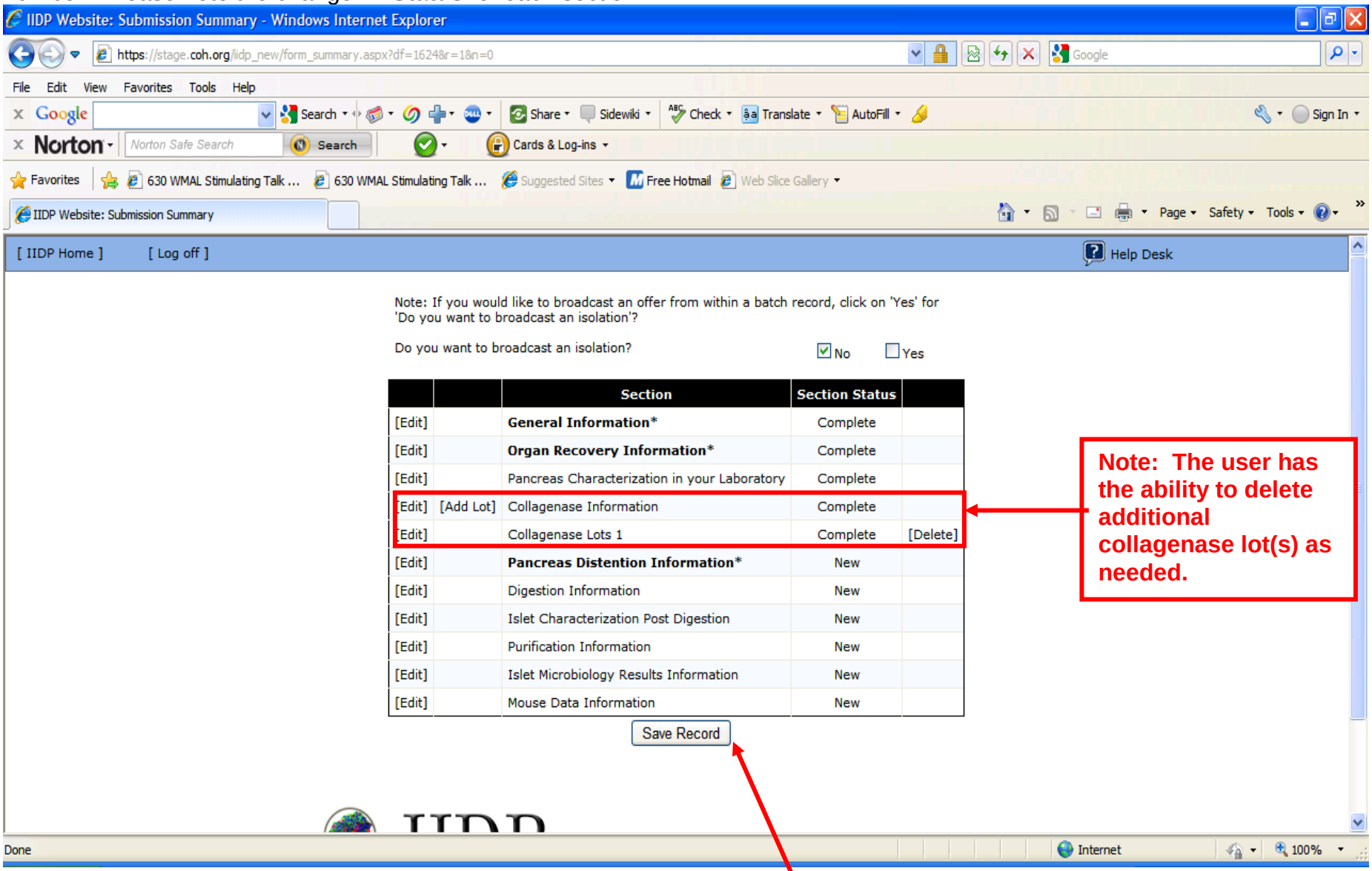
Click on **[Add Another Lot]** to complete the questions for an additional Collaganese Lot number. Repeat the process as many times as needed.

Distribution Record Detail Summary WITHOUT an additional collagenase lot number – Click on **[Edit]** to complete the next section. Click on **[Add Lot**] to add another collagenase lot number.



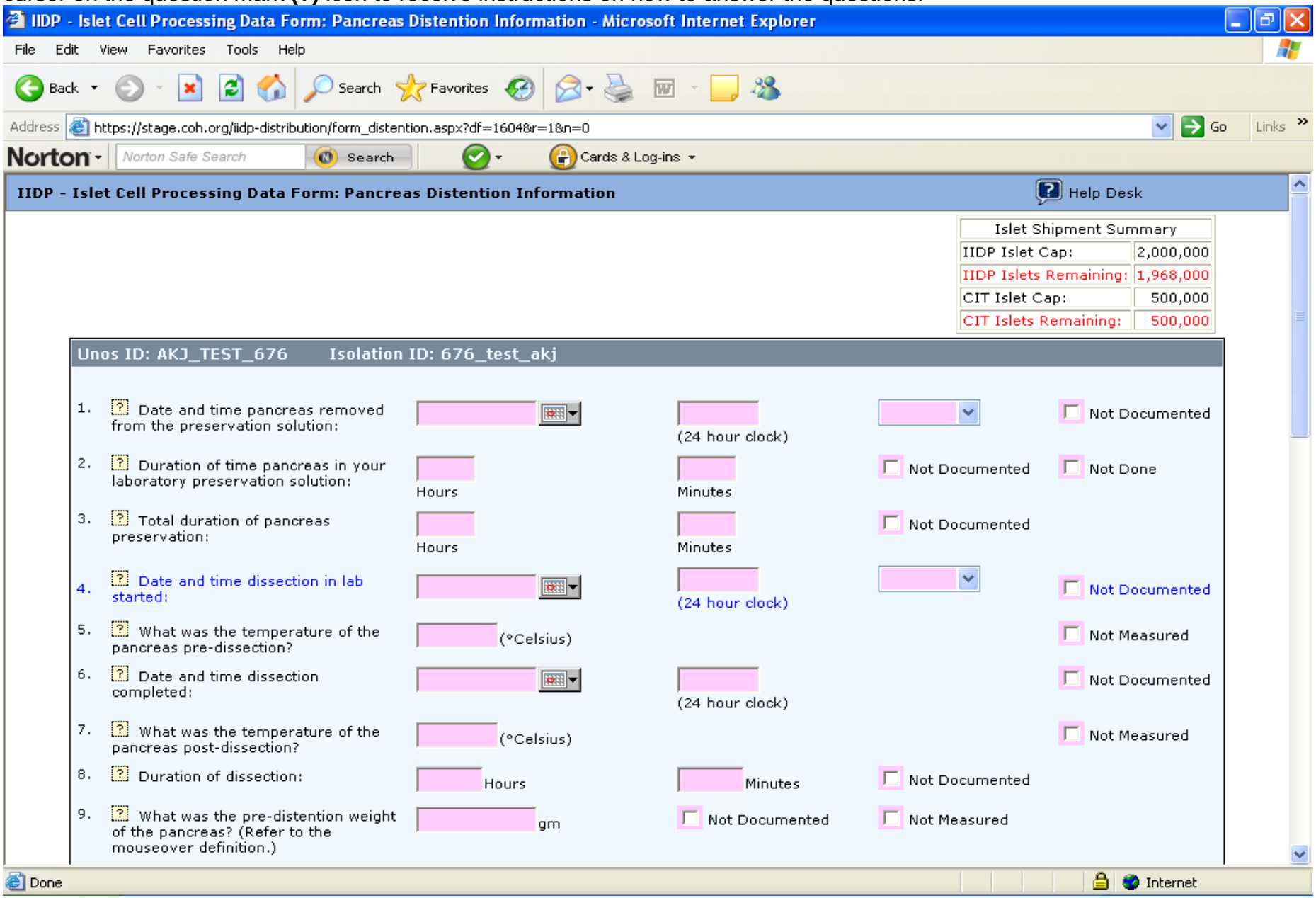
The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a **'Complete'** status.

Distribution Record Detail Summary WITH an additional collagenase lot number – Click on **[Edit]** to complete the next section. Click on **[Add Lot**] to add another collagenase lot number. Click on **[Delete**] to remove an additional collagenase lot number. Please note the change in **'Status'** of each section.

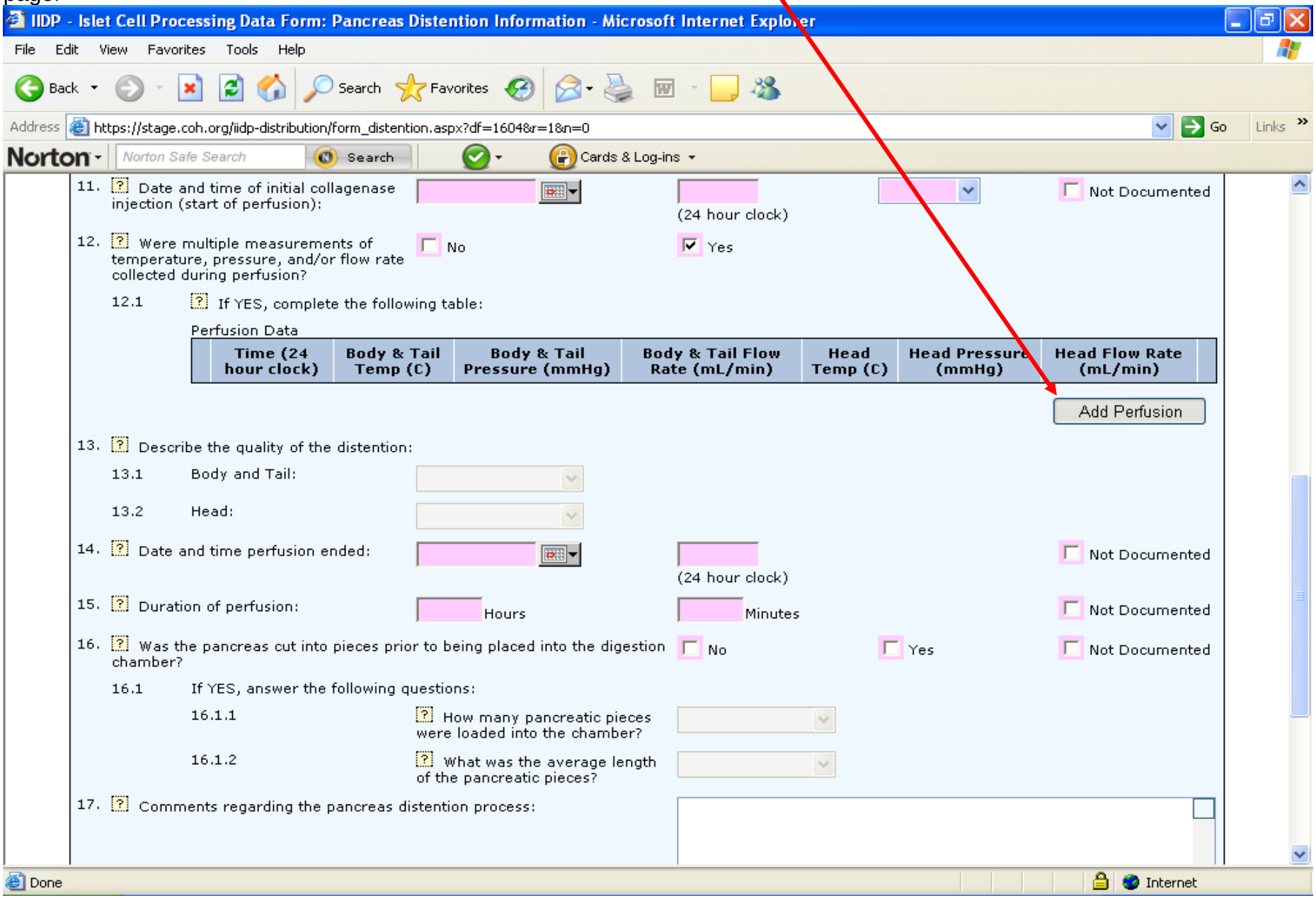


The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a **'Complete'** status.

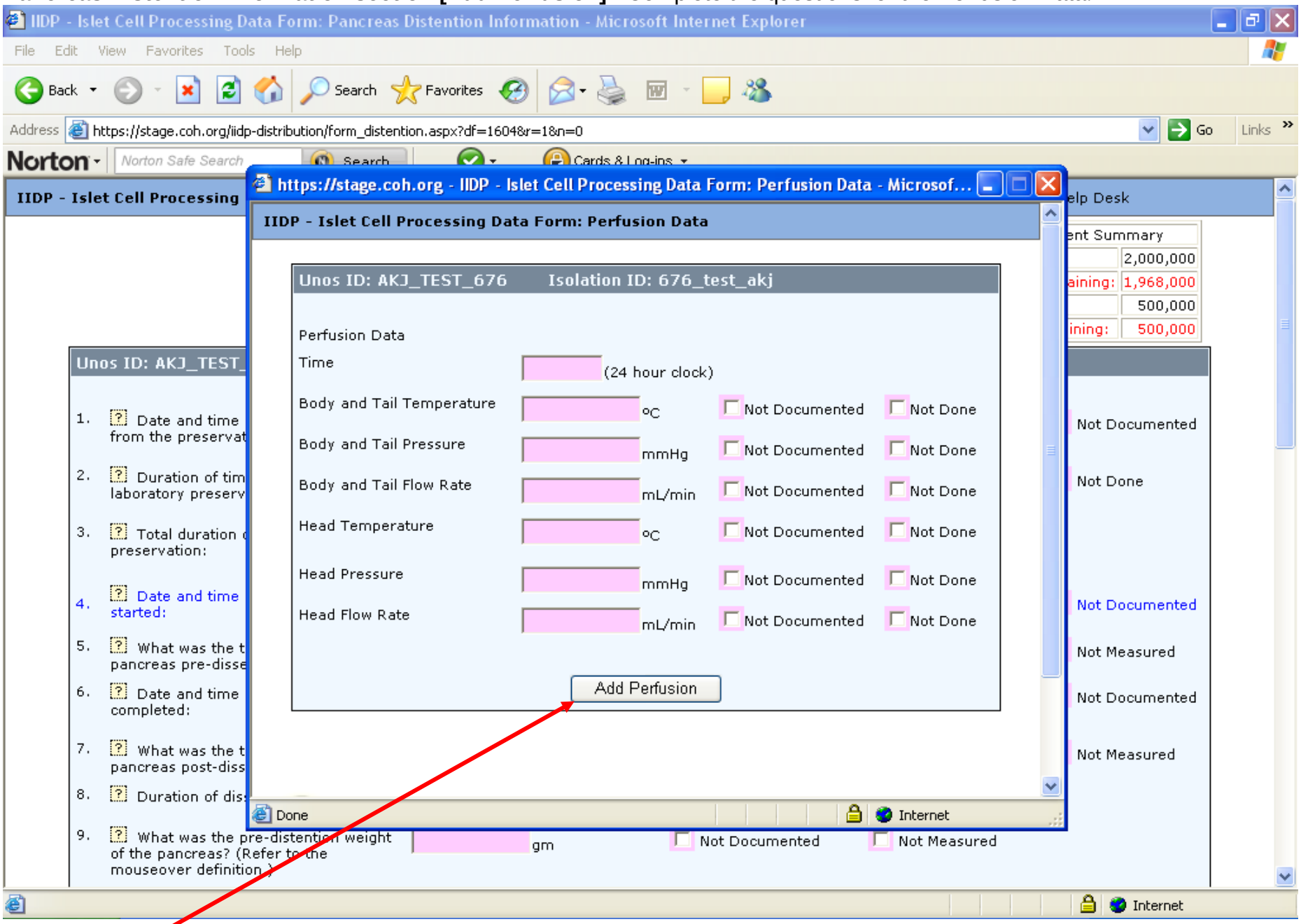
Pancreas Distention Information section – Complete the questions in the Pancreas Distention Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Pancreas Distention Information section (continued) - Click on **[Add Perfusion]** to add Perfusion Data - refer to the next page.

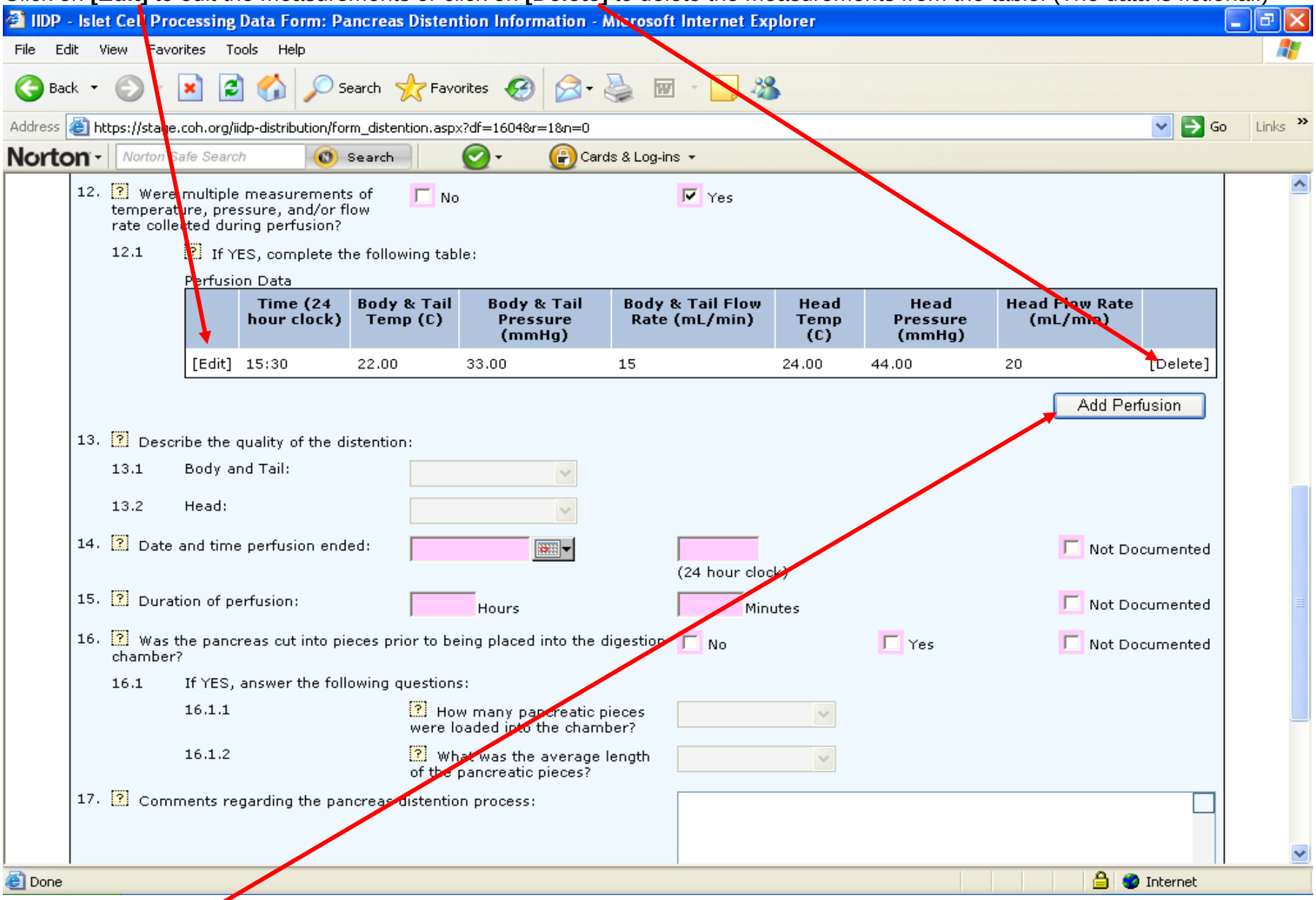


Pancreas Distention Information section [Add Perfusion] - Complete the questions for the Perfusion Data.



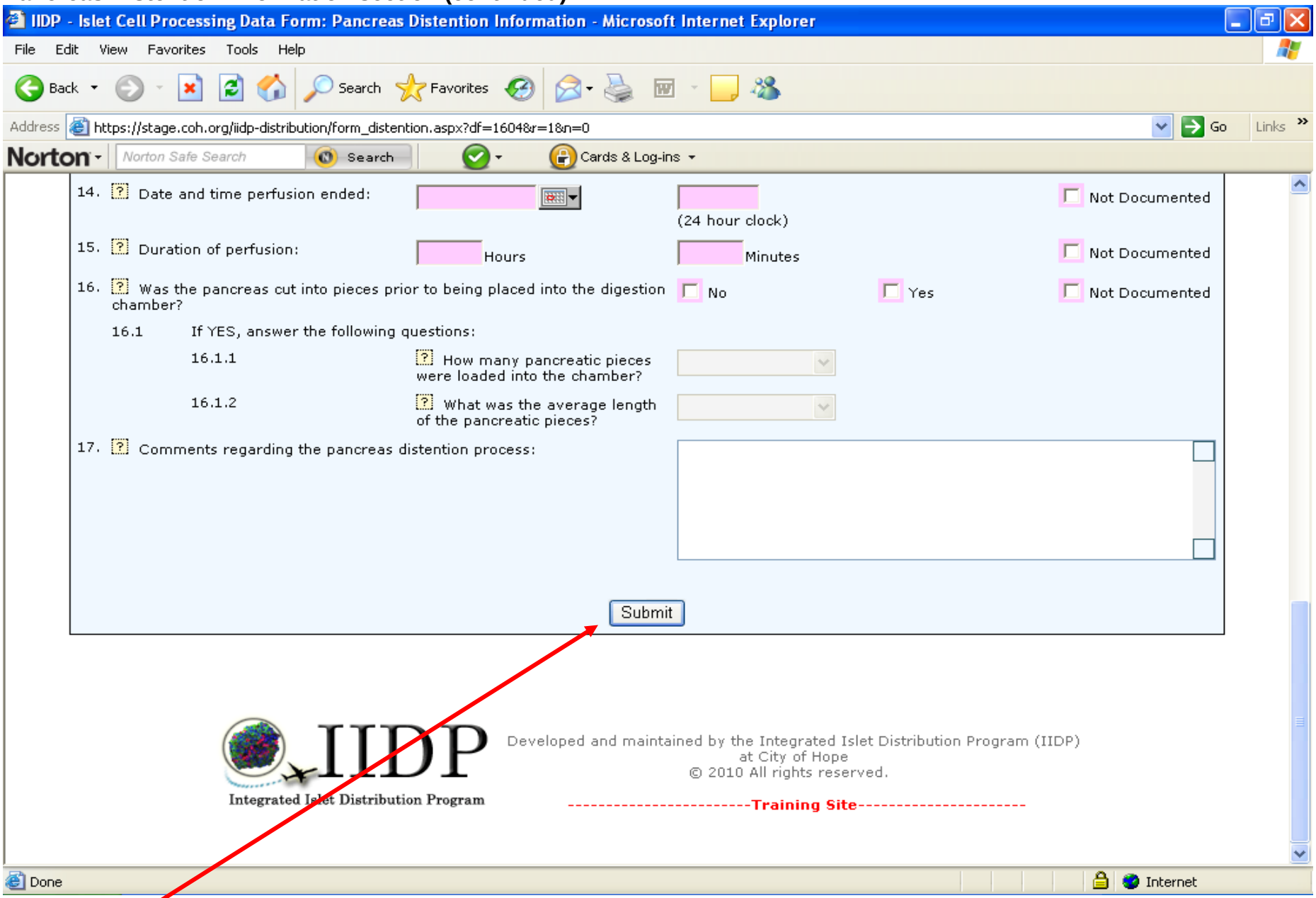
Click on **[Add Perfusion]** to add Perfusion Data - refer to the next page.

Pancreas Distention Information section (continued) - The system adds the measurements to the table.
Click on **[Edit]** to edit the measurements or click on **[Delete]** to delete the measurements from the table. (The data is fictional.)



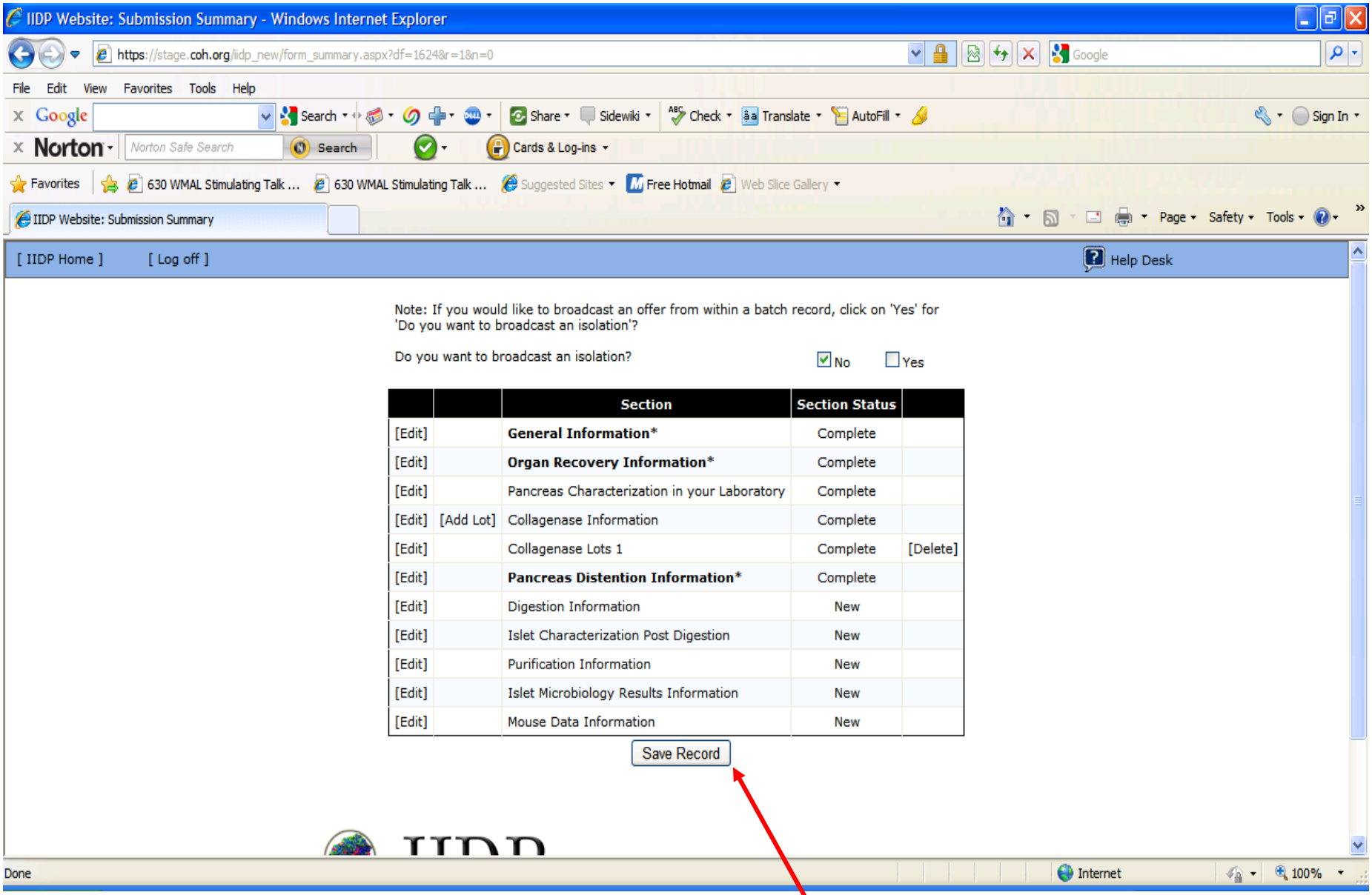
Repeat the **[Add Perfusion]** process as needed to enter all the measurements collected.

Pancreas Distention Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

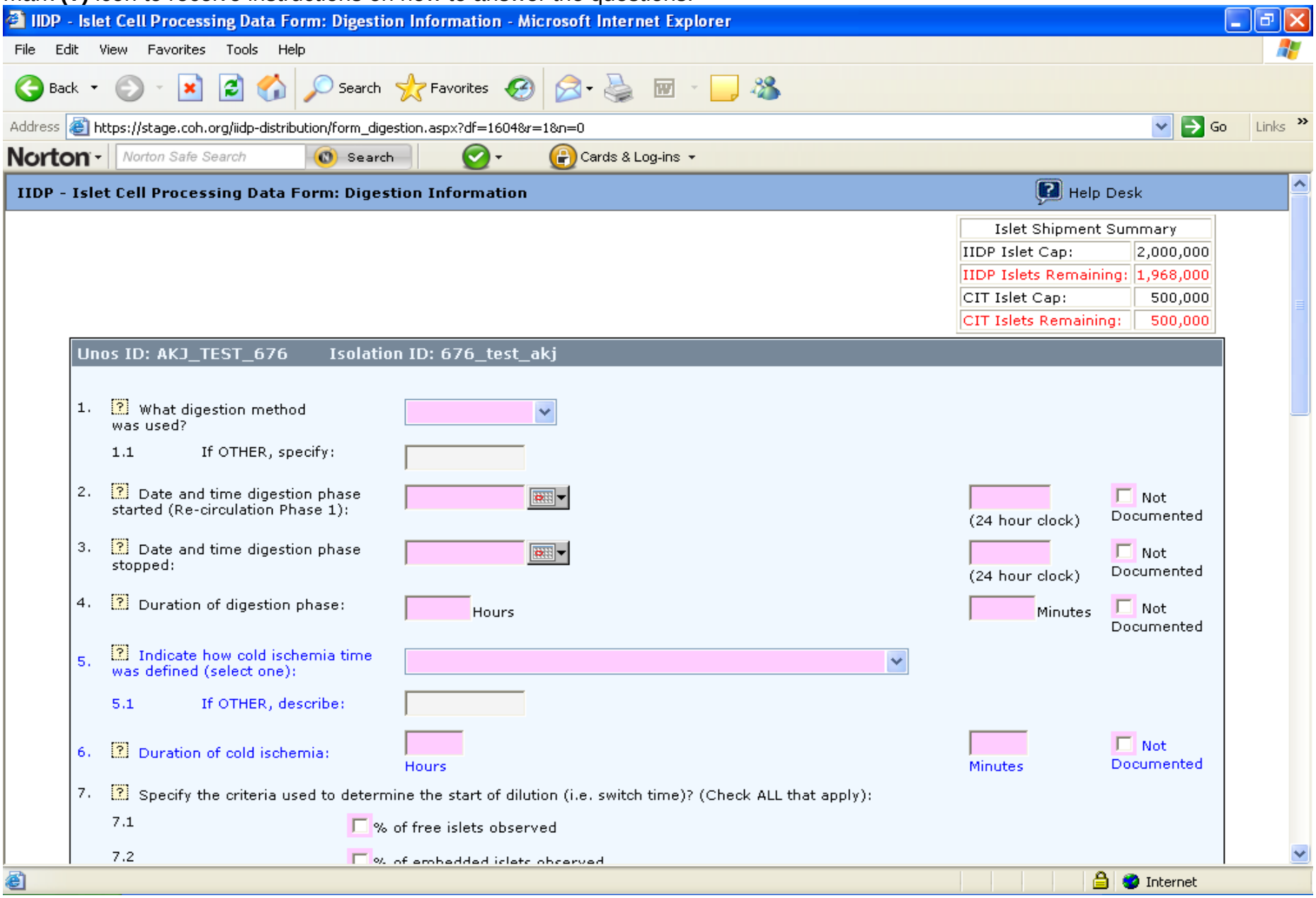
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



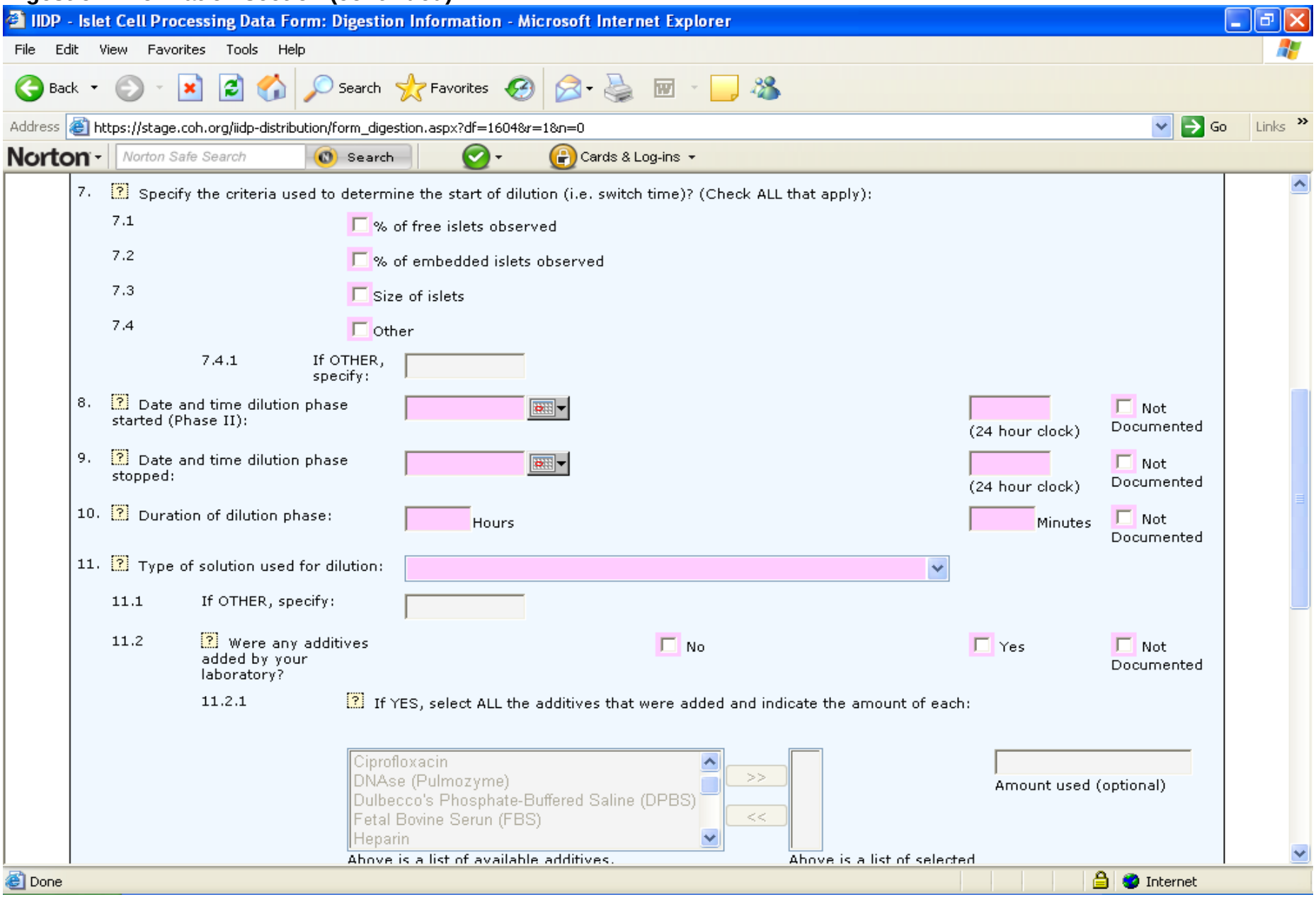
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	New	
[Edit]		Islet Characterization Post Digestion	New	
[Edit]		Purification Information	New	
[Edit]		Islet Microbiology Results Information	New	
[Edit]		Mouse Data Information	New	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

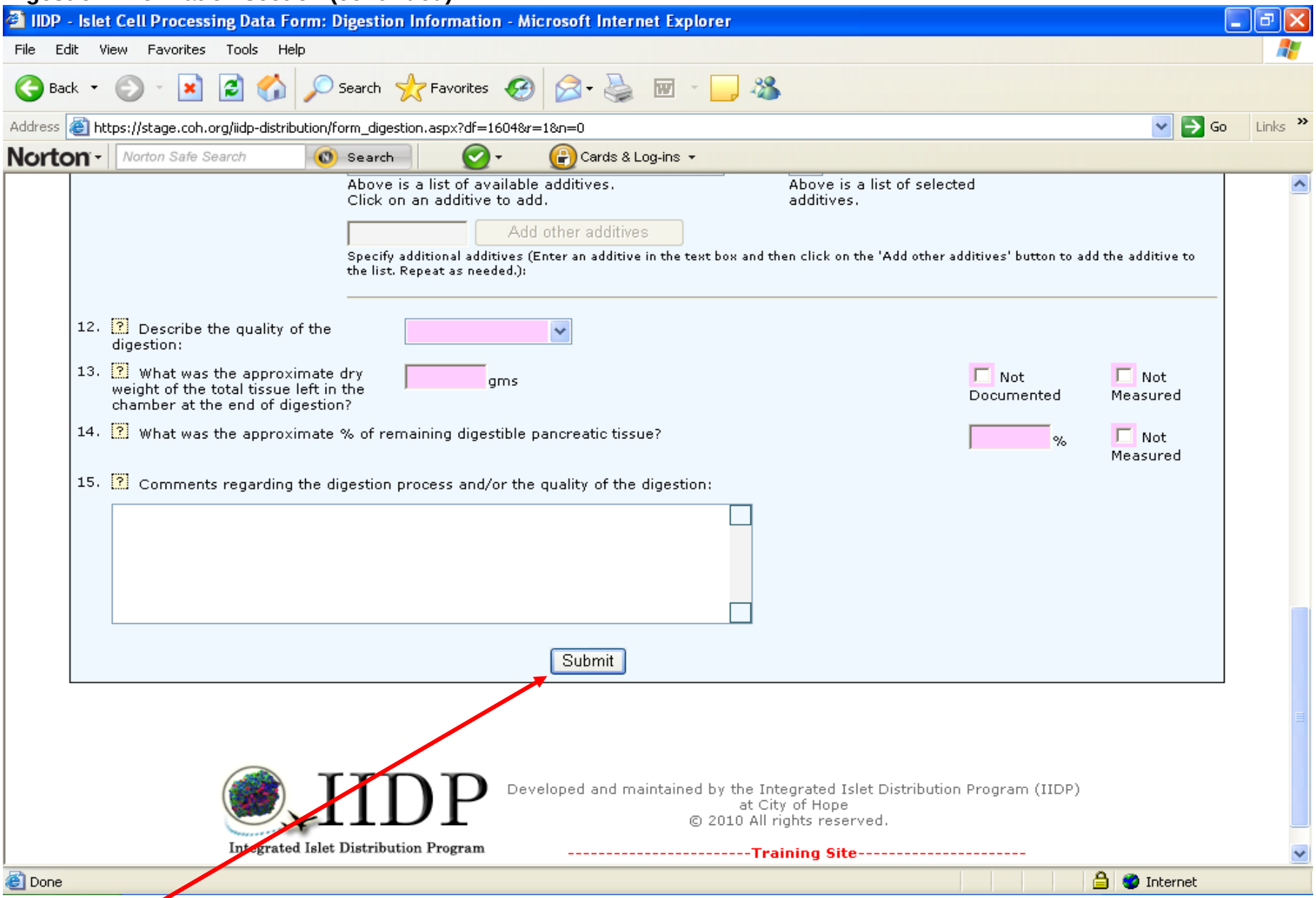
Digestion Information section – Complete the questions in the Digestion Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Digestion Information section (continued)

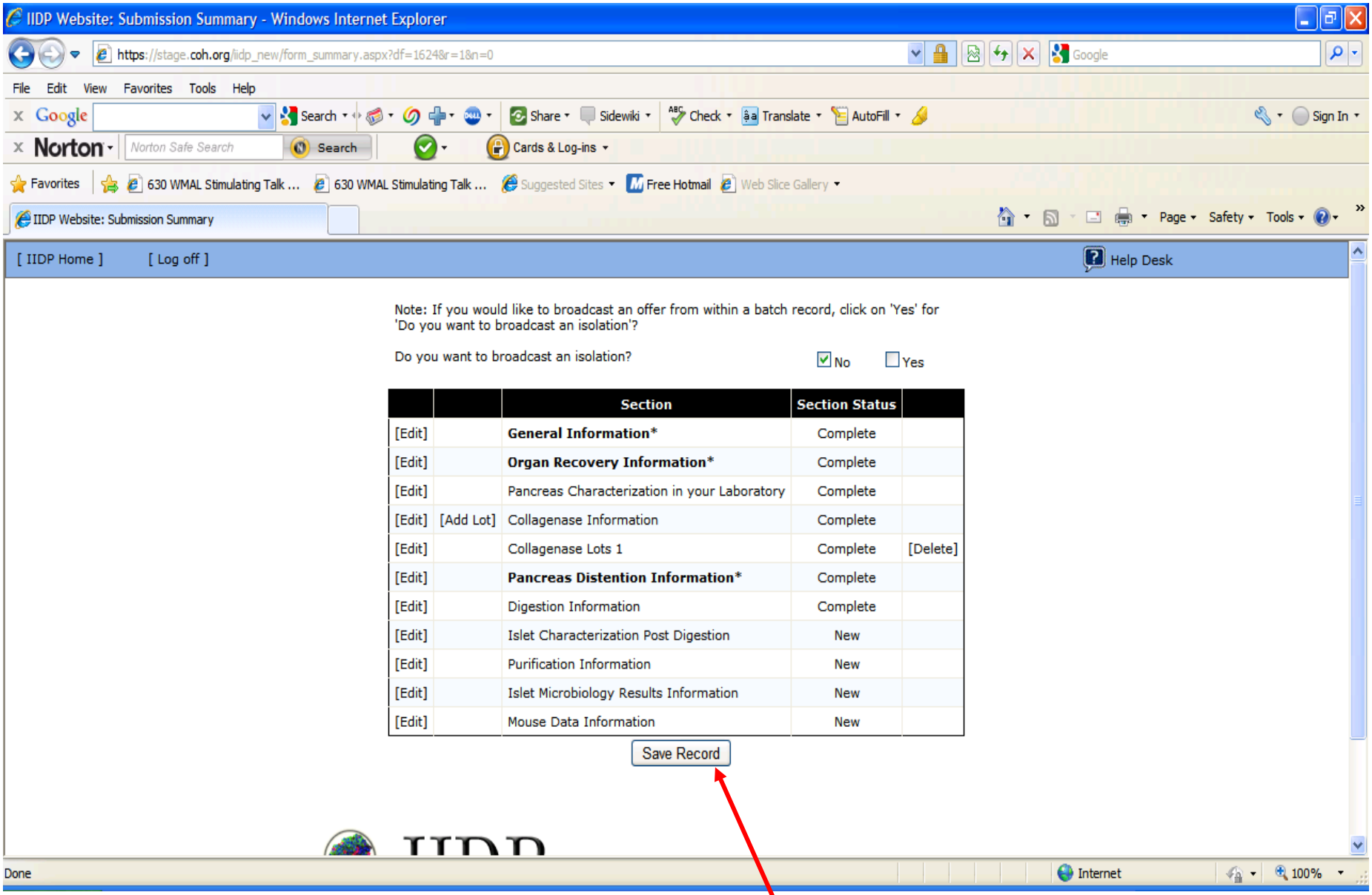


Digestion Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

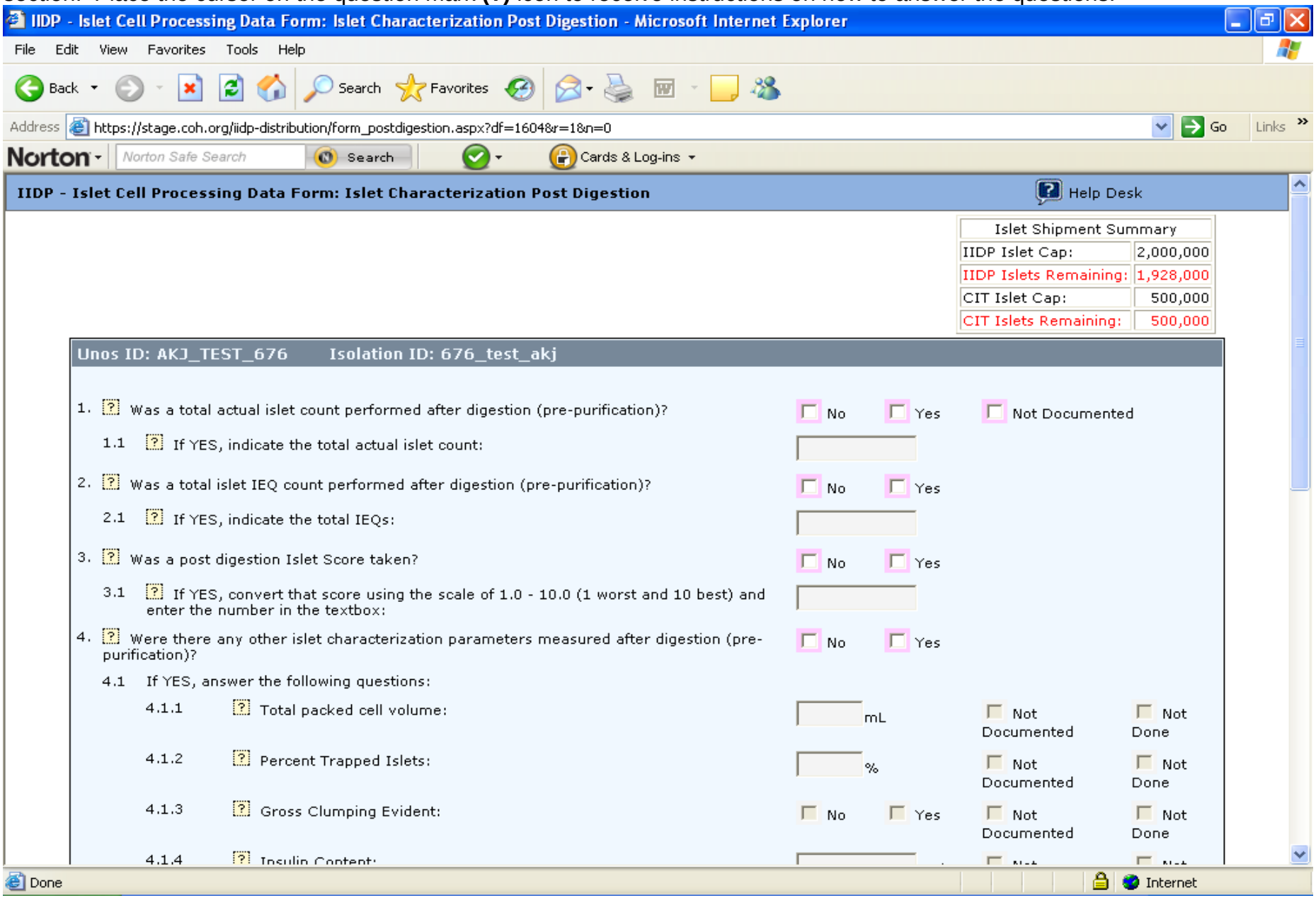
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



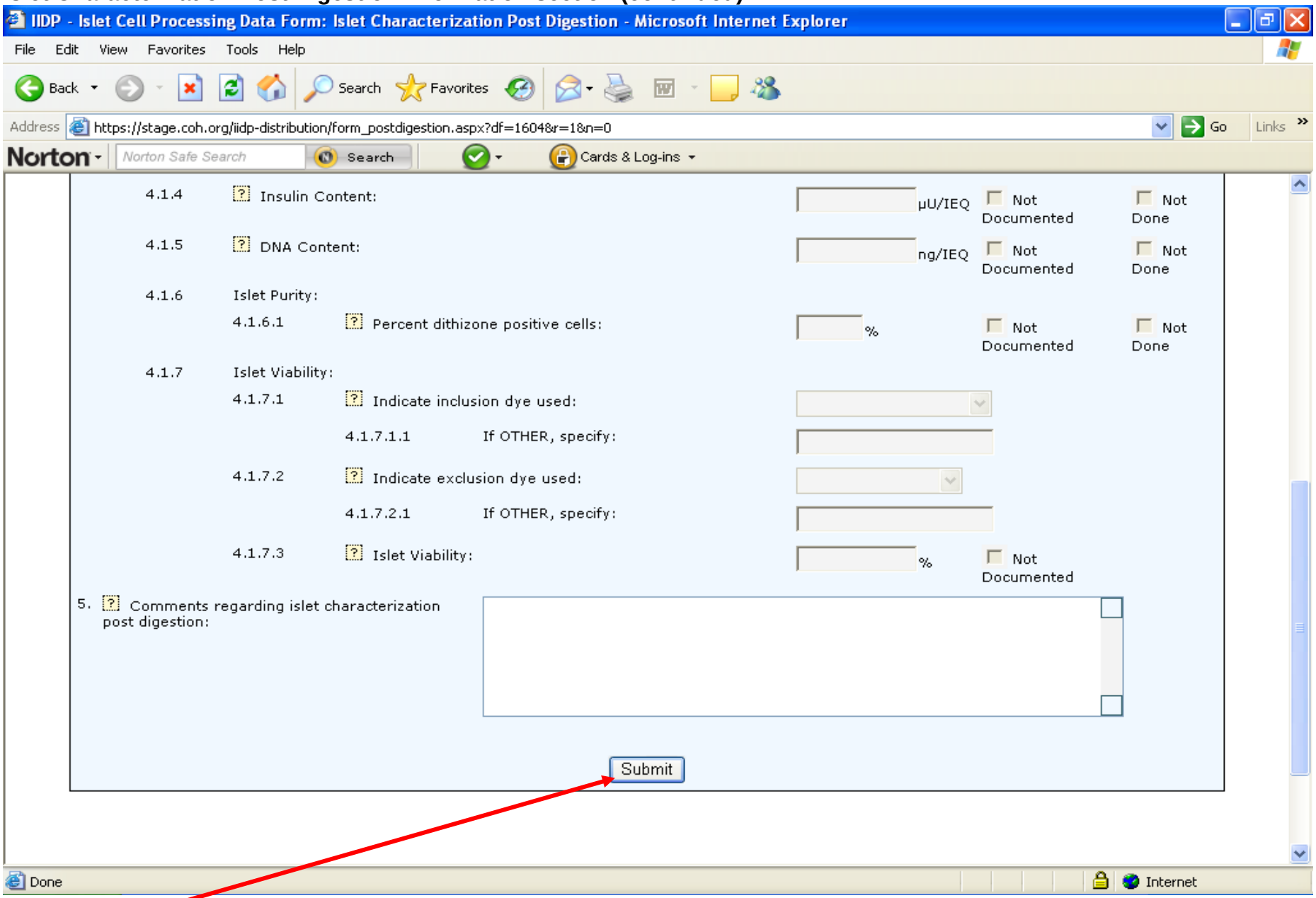
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	New	
[Edit]		Purification Information	New	
[Edit]		Islet Microbiology Results Information	New	
[Edit]		Mouse Data Information	New	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Islet Characterization Post Digestion Information section – Complete the questions in the Islet Characterization Post Digestion section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.

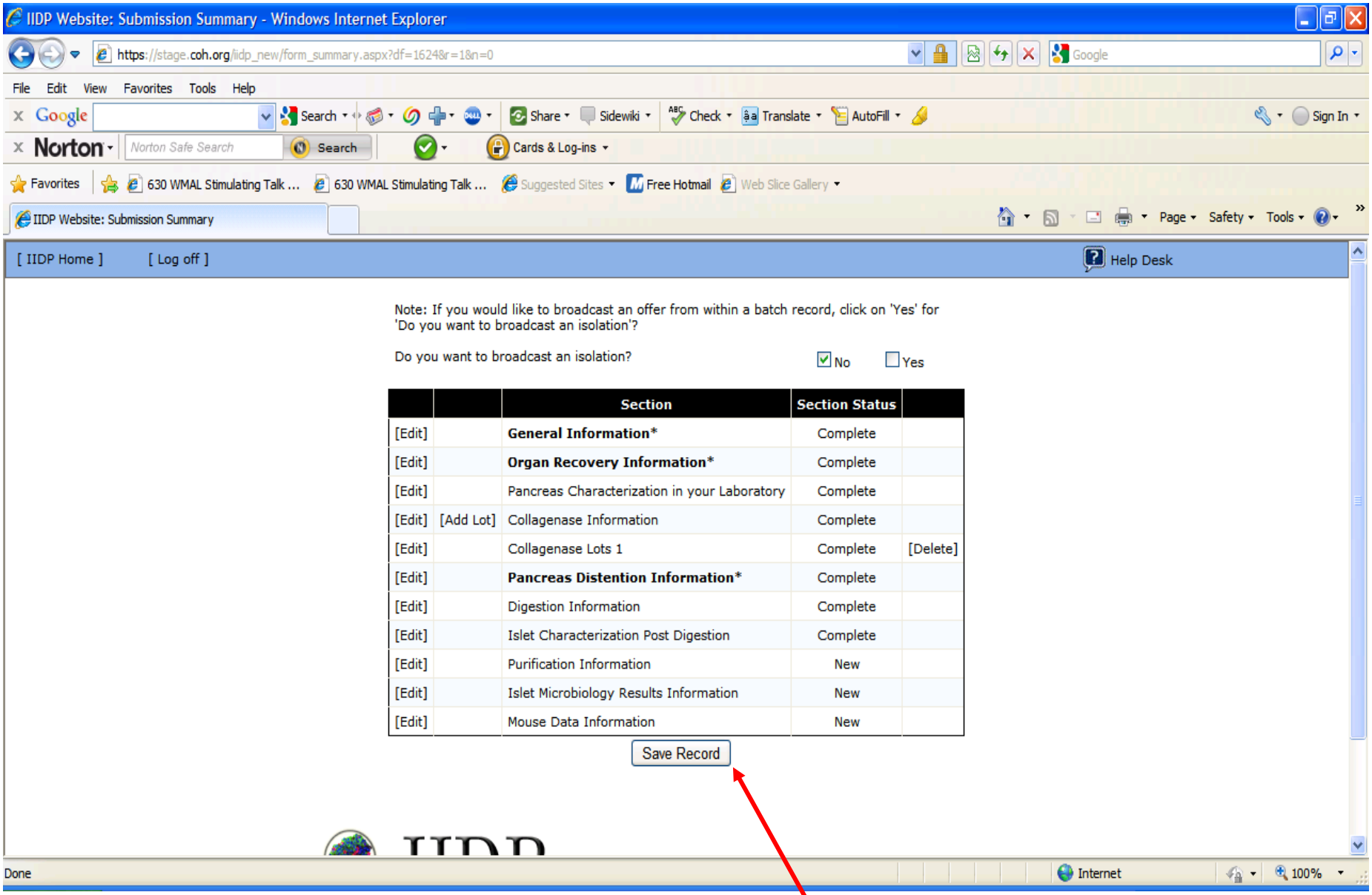


Islet Characterization Post Digestion Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

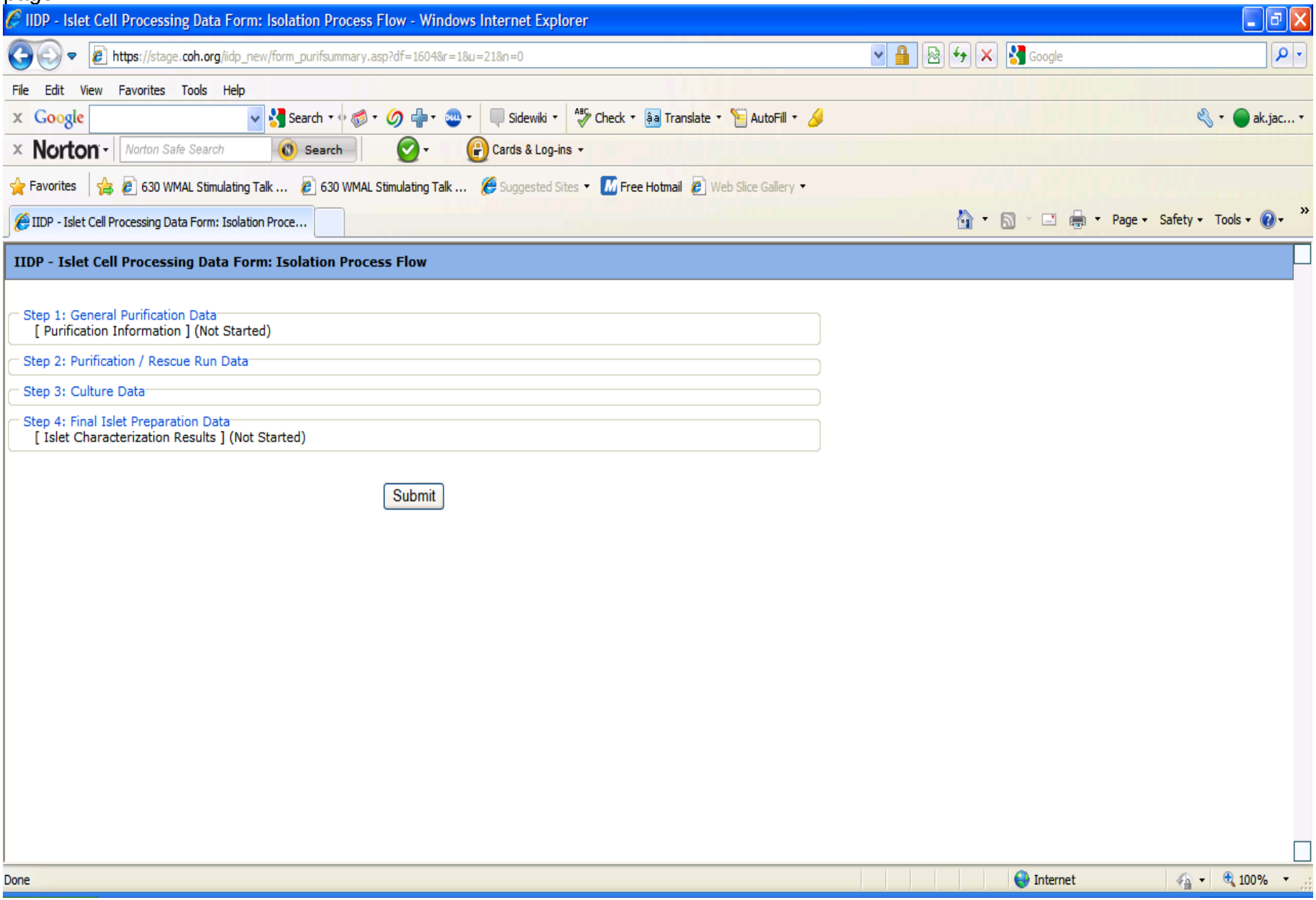
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



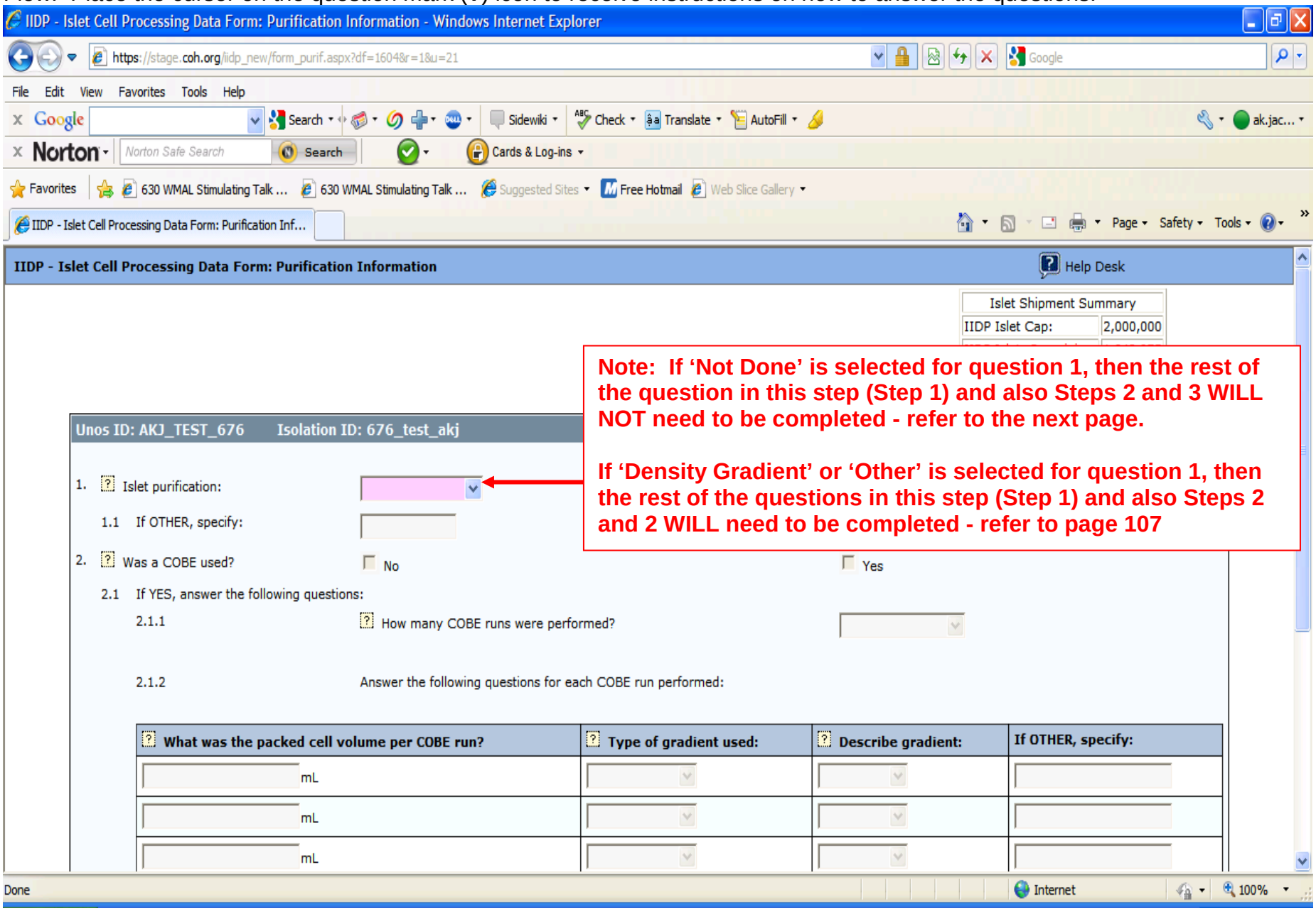
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	New	
[Edit]		Islet Microbiology Results Information	New	
[Edit]		Mouse Data Information	New	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

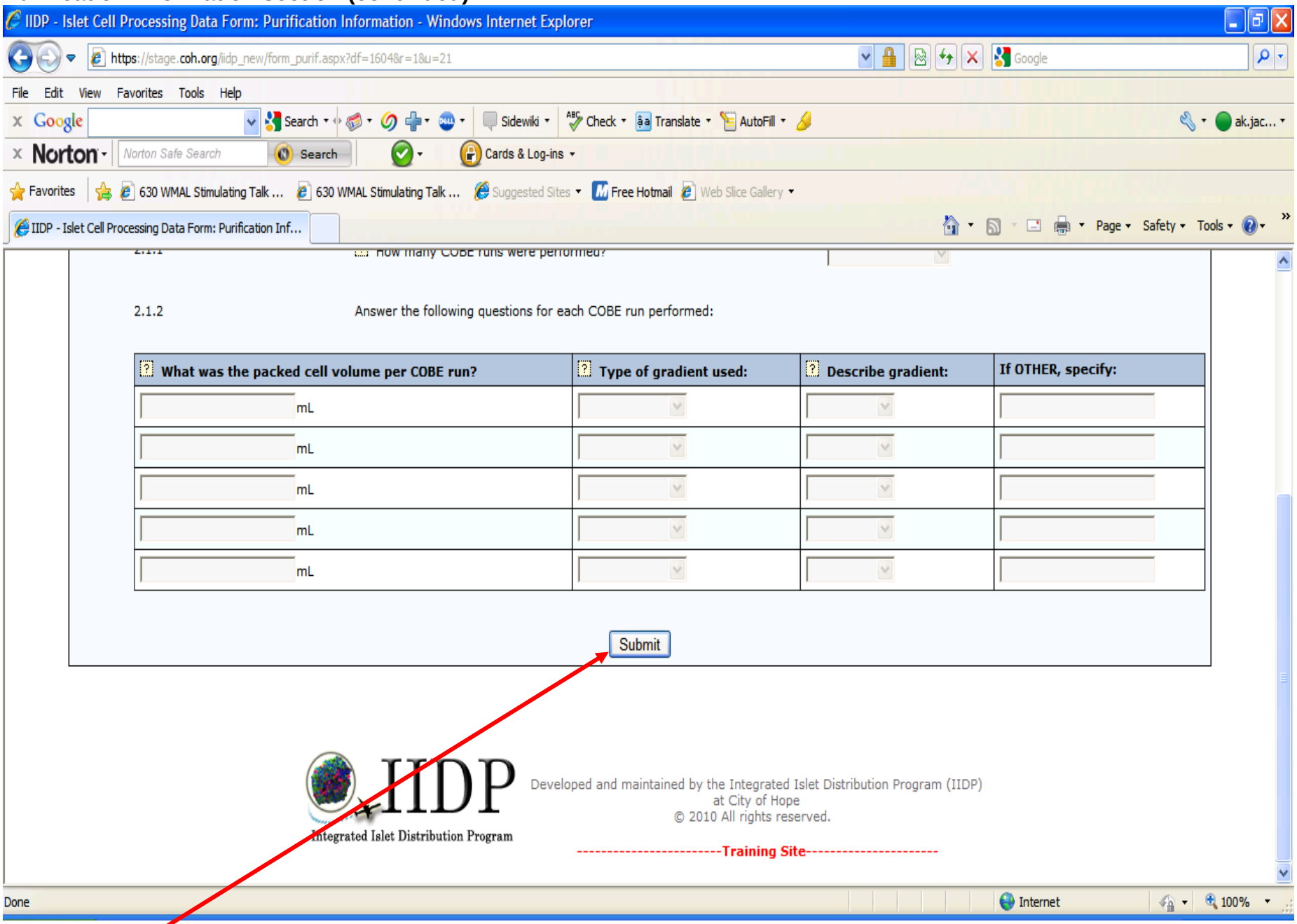
Purification Information section - Isolation Process Flow section – Complete Steps 1 and 4 in the Isolation Process Flow. Step 2 and Step 3 are conditional based on the answer to question 1 in Step 1 – General Purification Data. Refer to the next page.



Purification Information section - Complete the answers in Step 1 - Purification Information section of the Isolation Process Flow. Place the cursor on the question mark (**?**) icon to receive instructions on how to answer the questions.

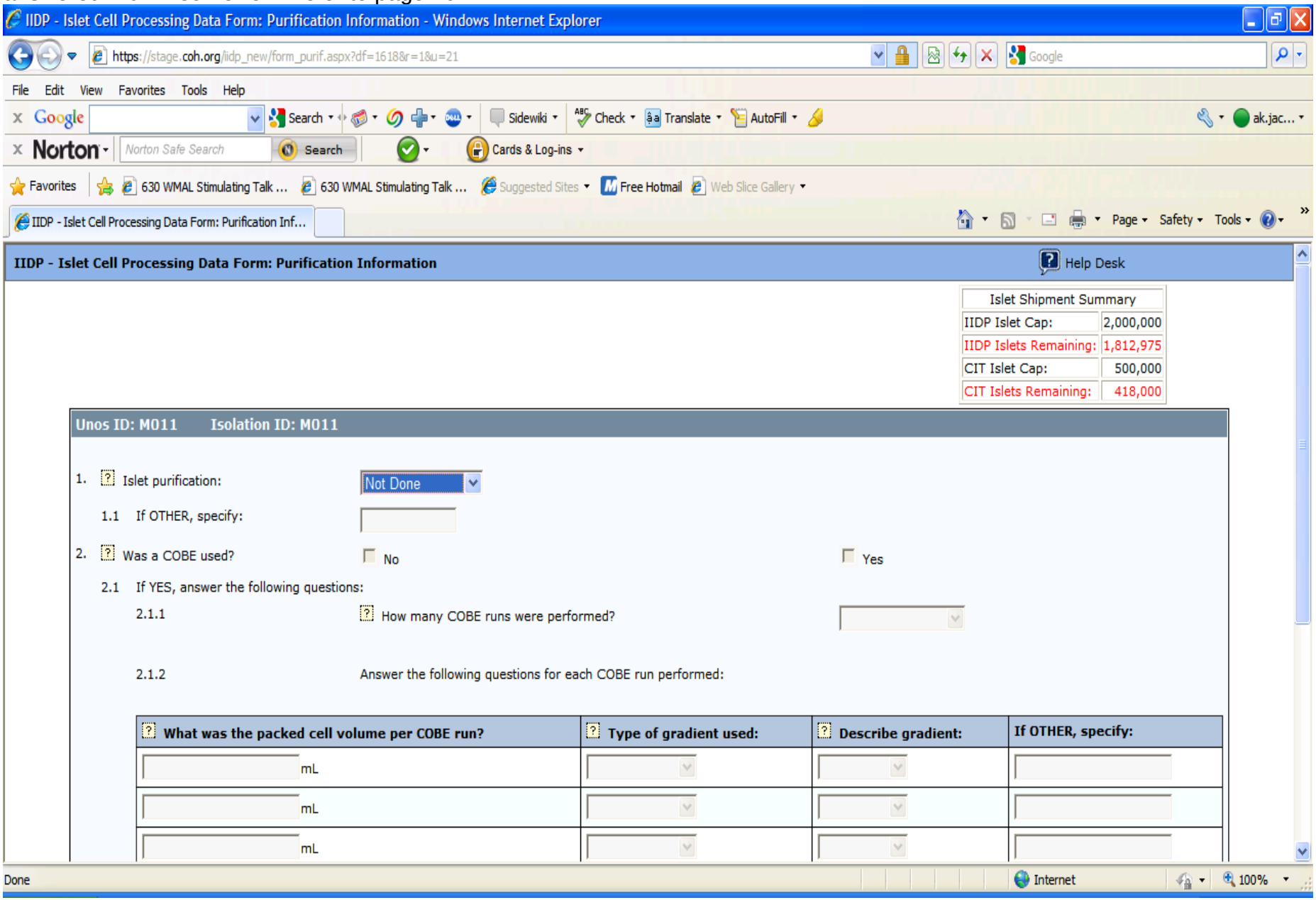


Purification Information section (continued)

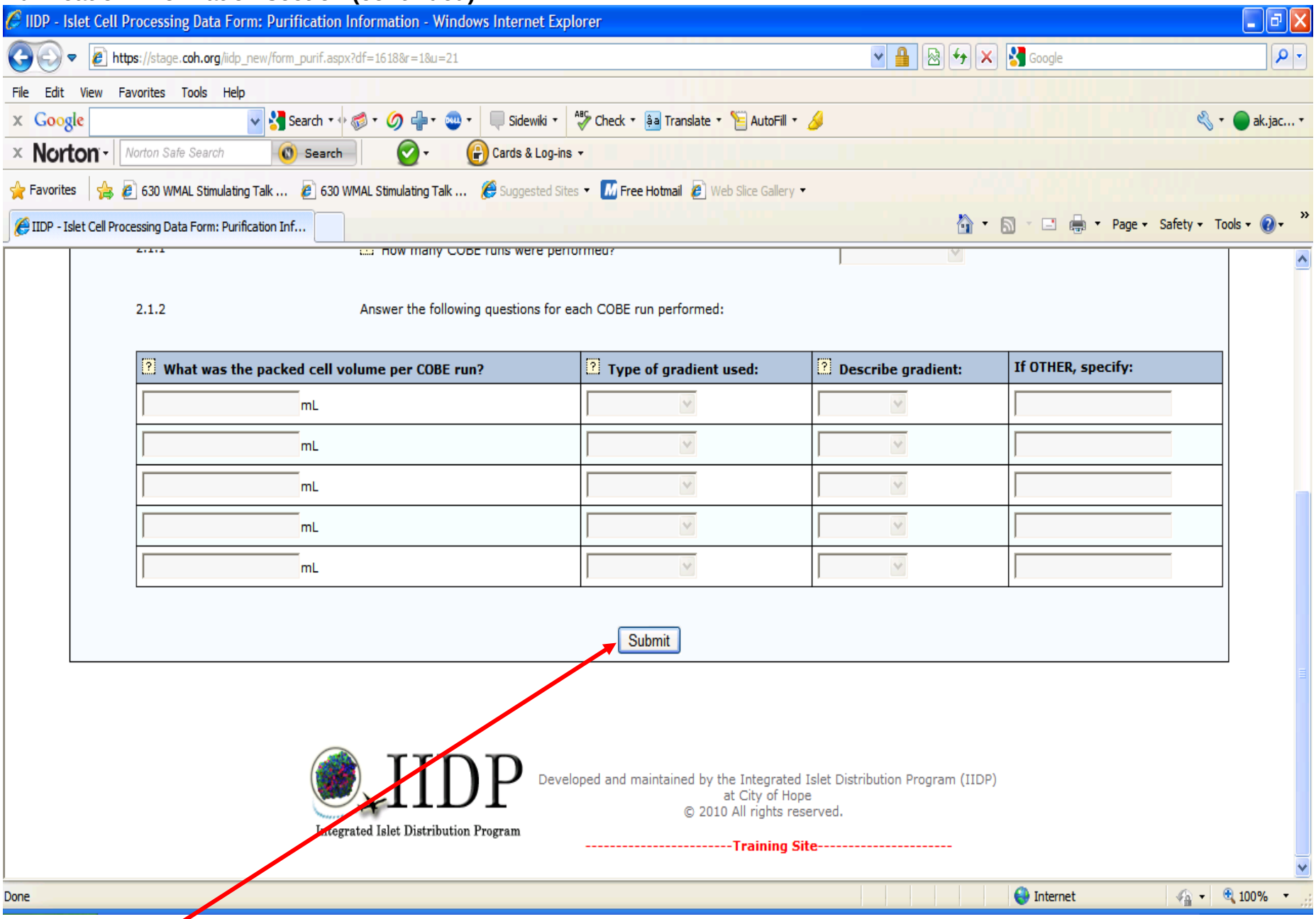


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

This is an example of the conditional answer in Step 1 that will determine if Step 2 and Step 3 need to be completed or not. Step 2 and Step 3 of the Isolation Process Flow will NOT NEED to be completed if question 1 of the Purification Information section is answered with **'Not Done'.** Refer to page 107

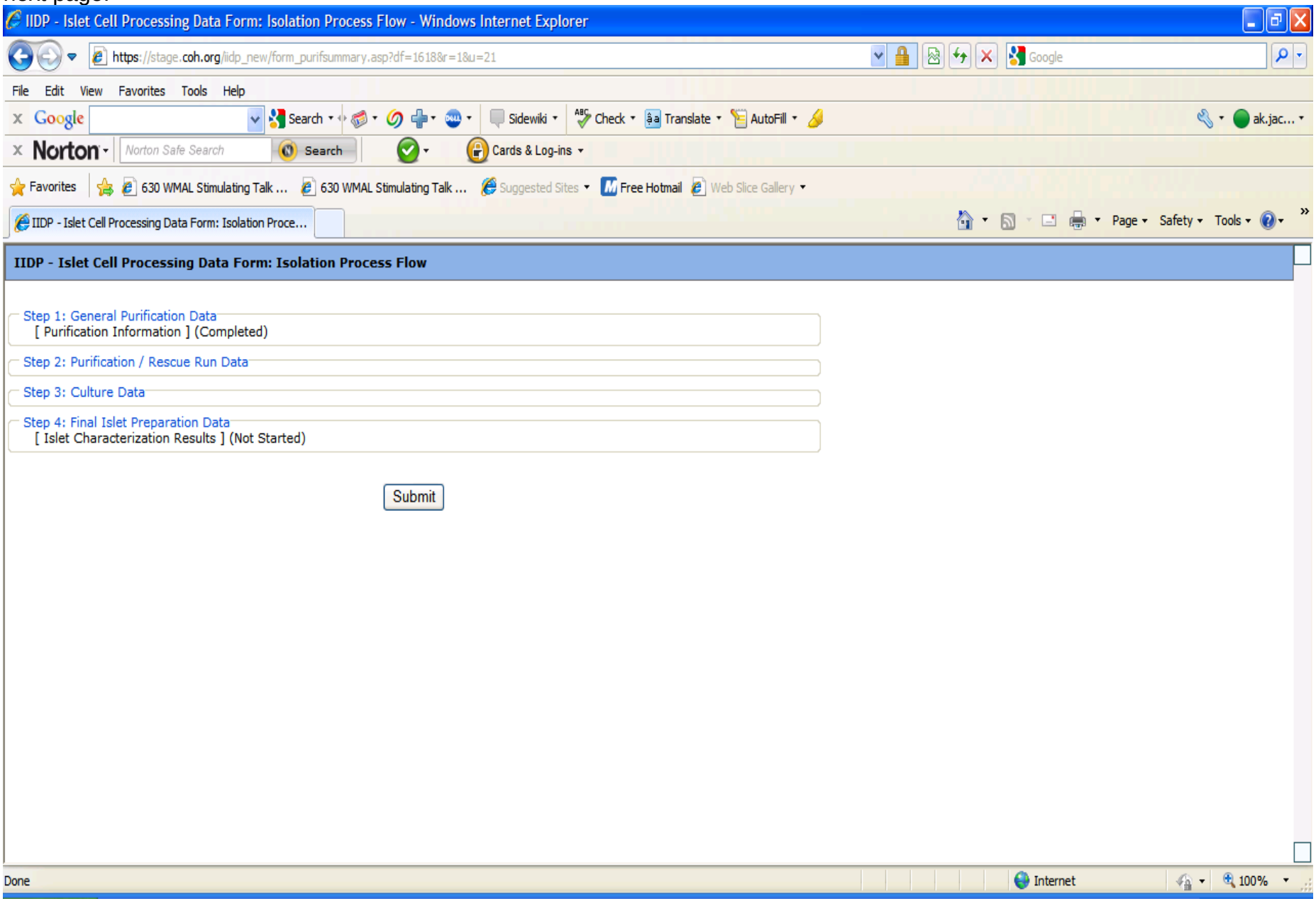


Purification Information section (continued)

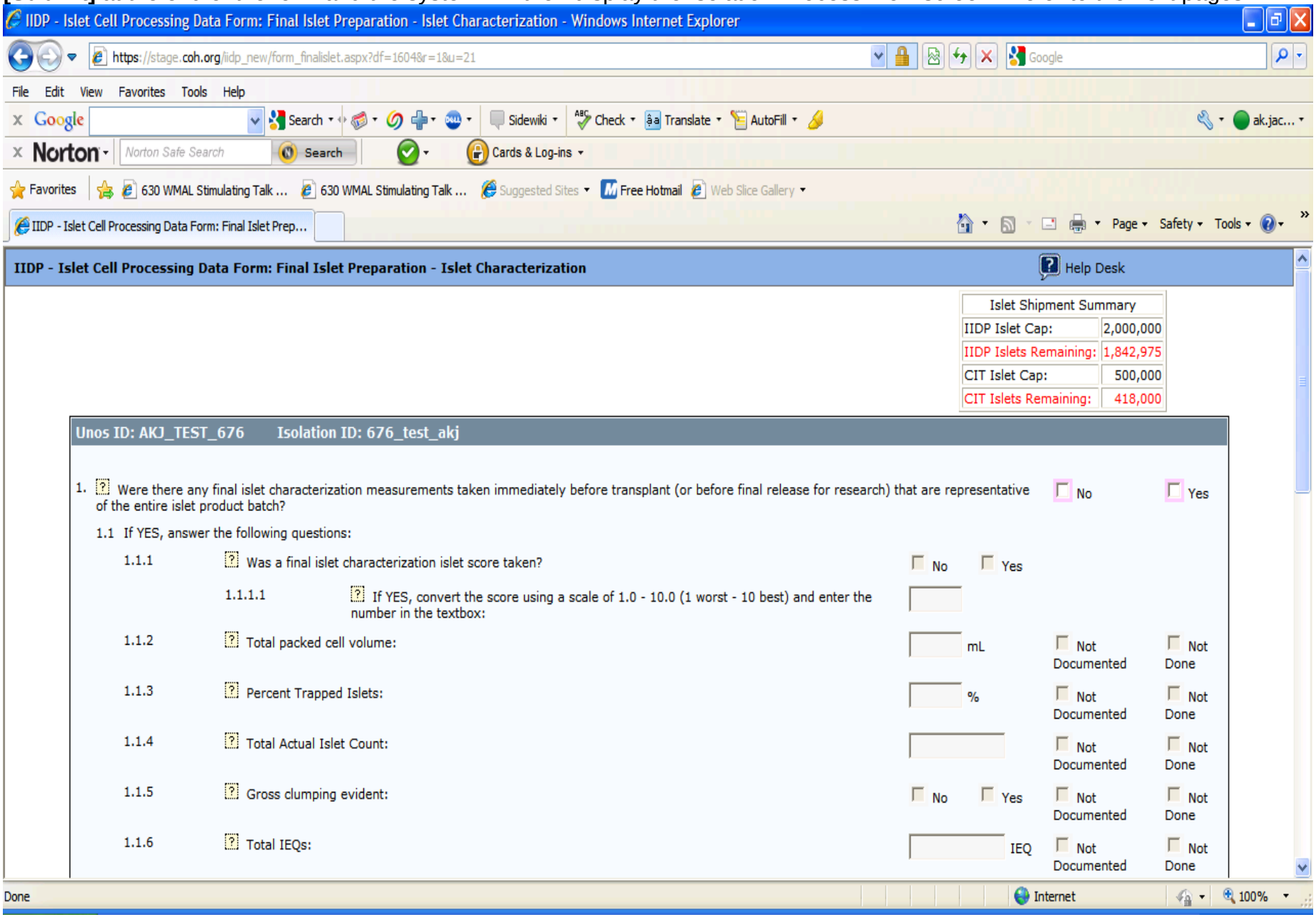


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

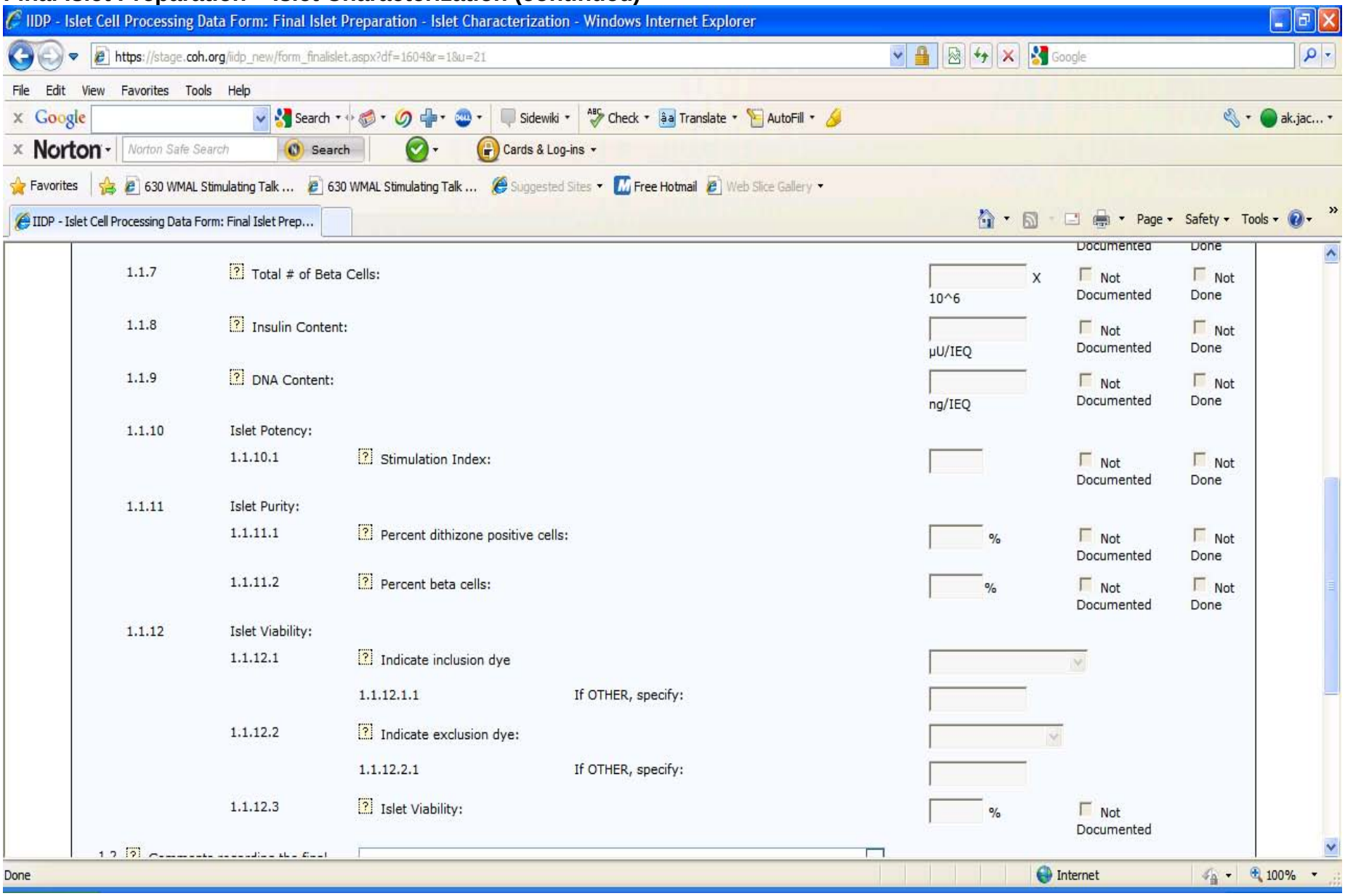
Isolation Process Flow screen - The user WILL NOT need to complete Step 2 or Step 3 and can proceed to Step 4 – refer to the next page.



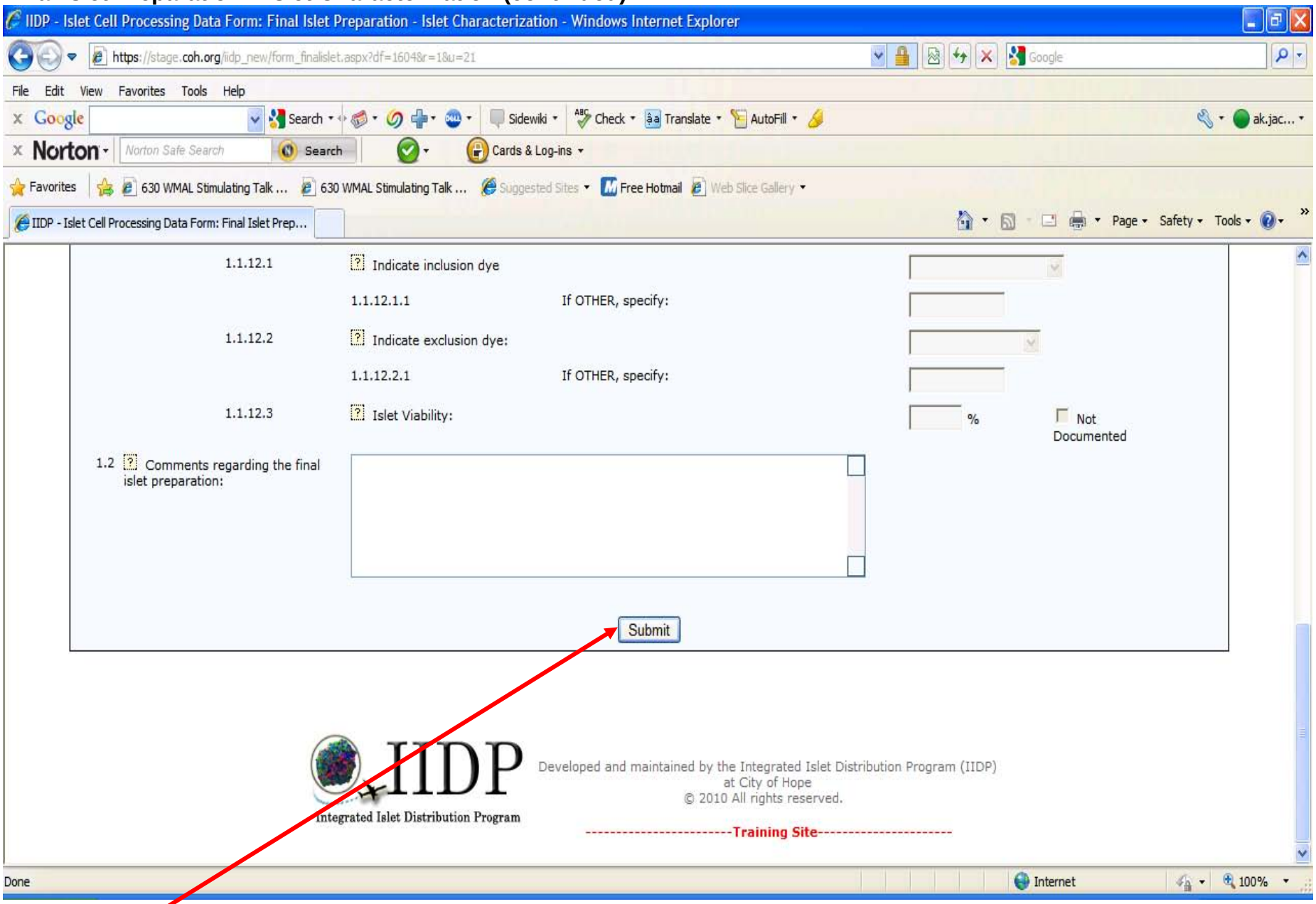
Final Islet Preparation – Islet Characterization – If 'No' is selected for Question 1, then the rest of the questions in this form do not need to be completed. However, if 'Yes' is selected for Question 1, then complete the applicable questions then click on **[Submit]** at the end of the form and the system will then display the Isolation Process Flow screen – refer to the next pages.



Final Islet Preparation – Islet Characterization (continued)

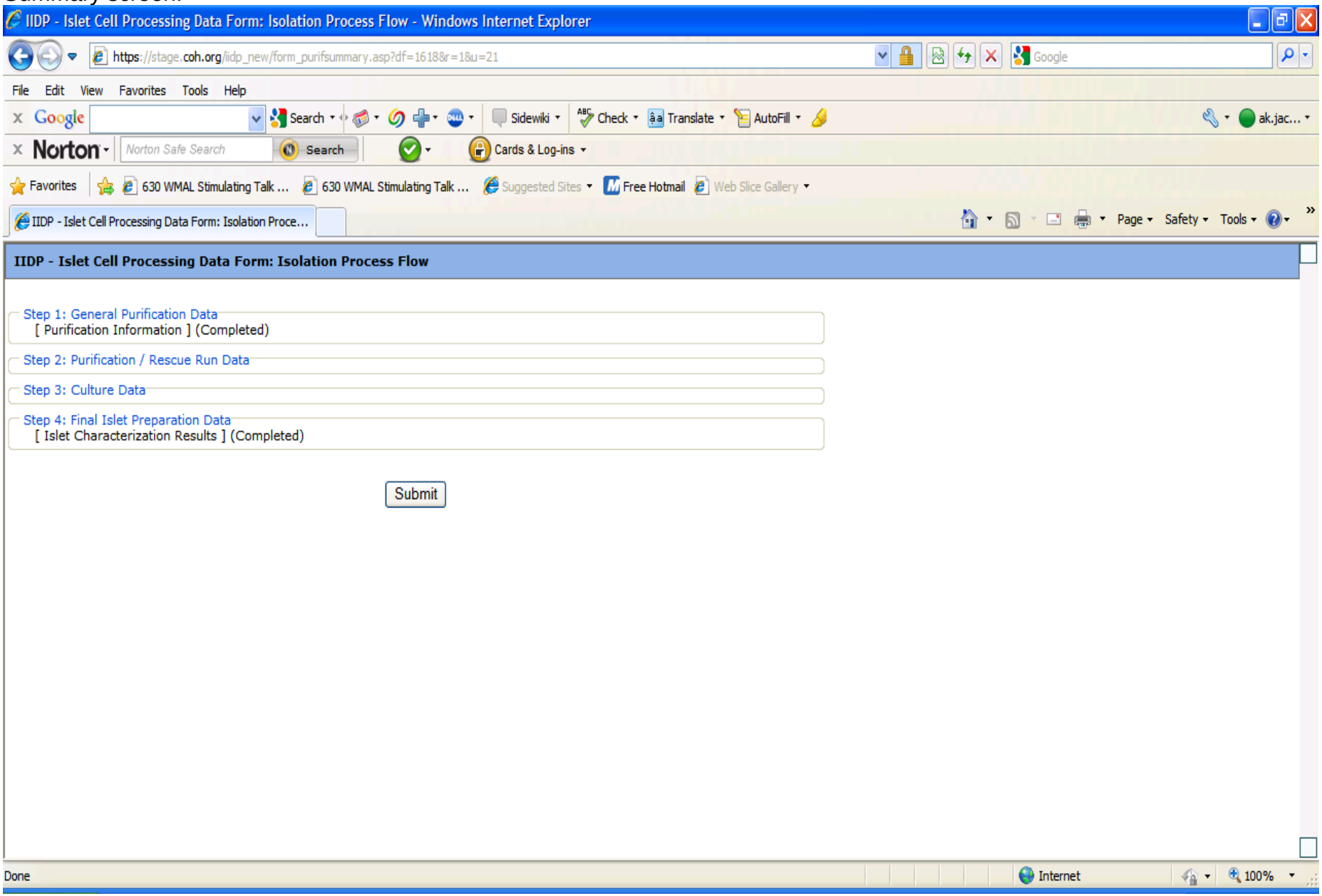


Final Islet Preparation – Islet Characterization (continued)

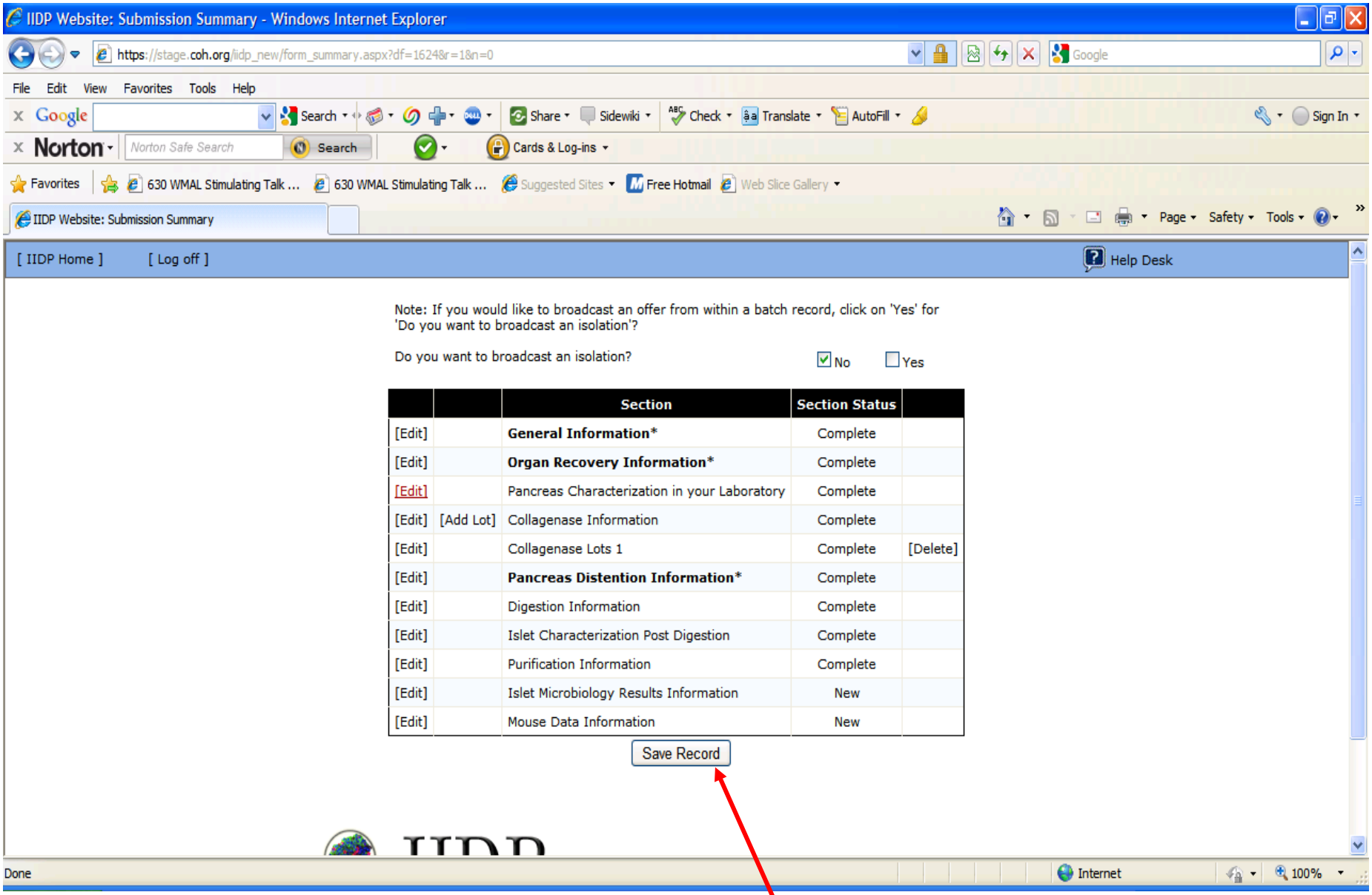


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

Isolation Process Flow screen - This section is now complete. Click on **[Submit]** to return to the Distribution Record Detail Summary screen.



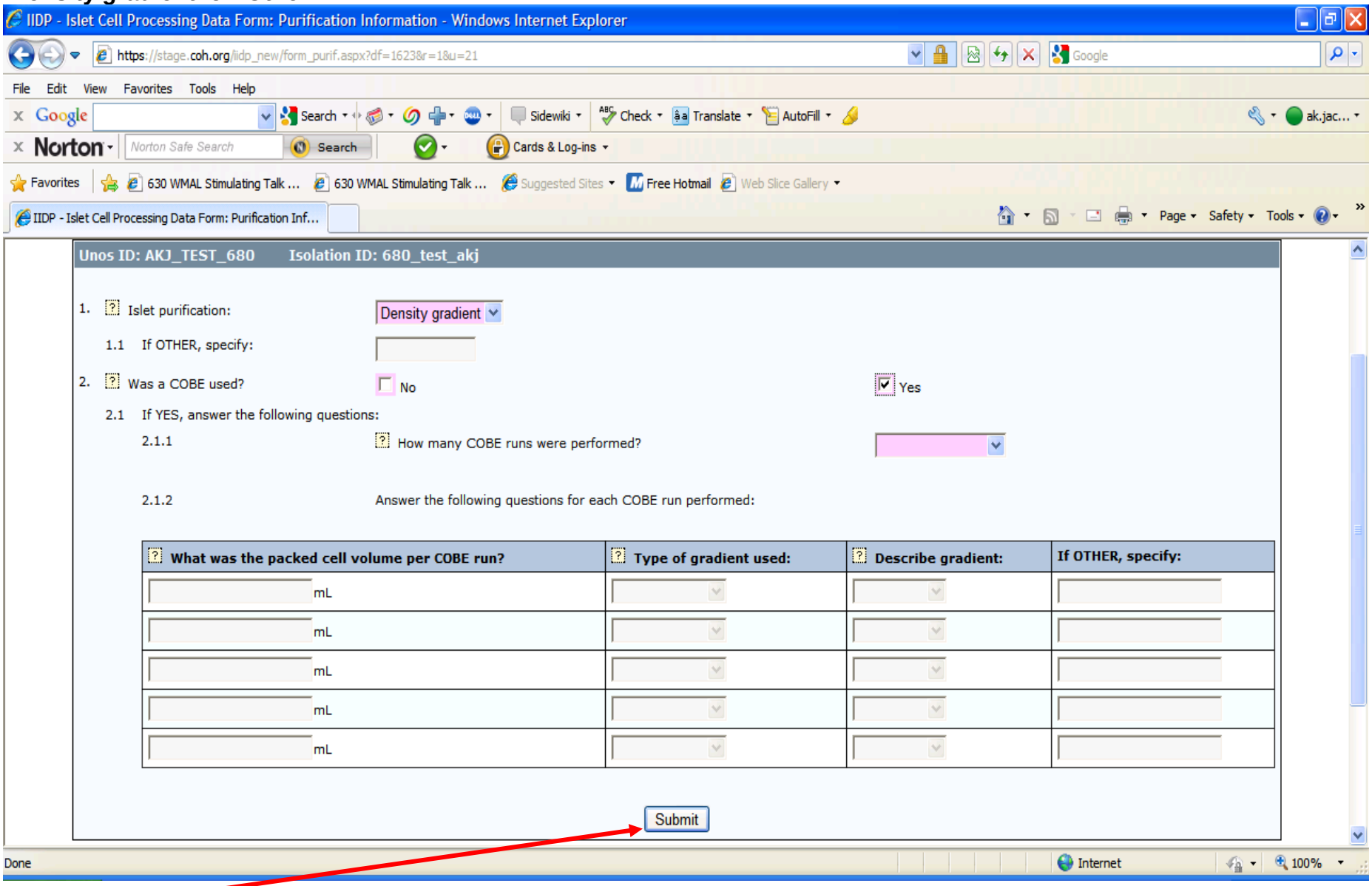
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	New	
[Edit]		Mouse Data Information	New	

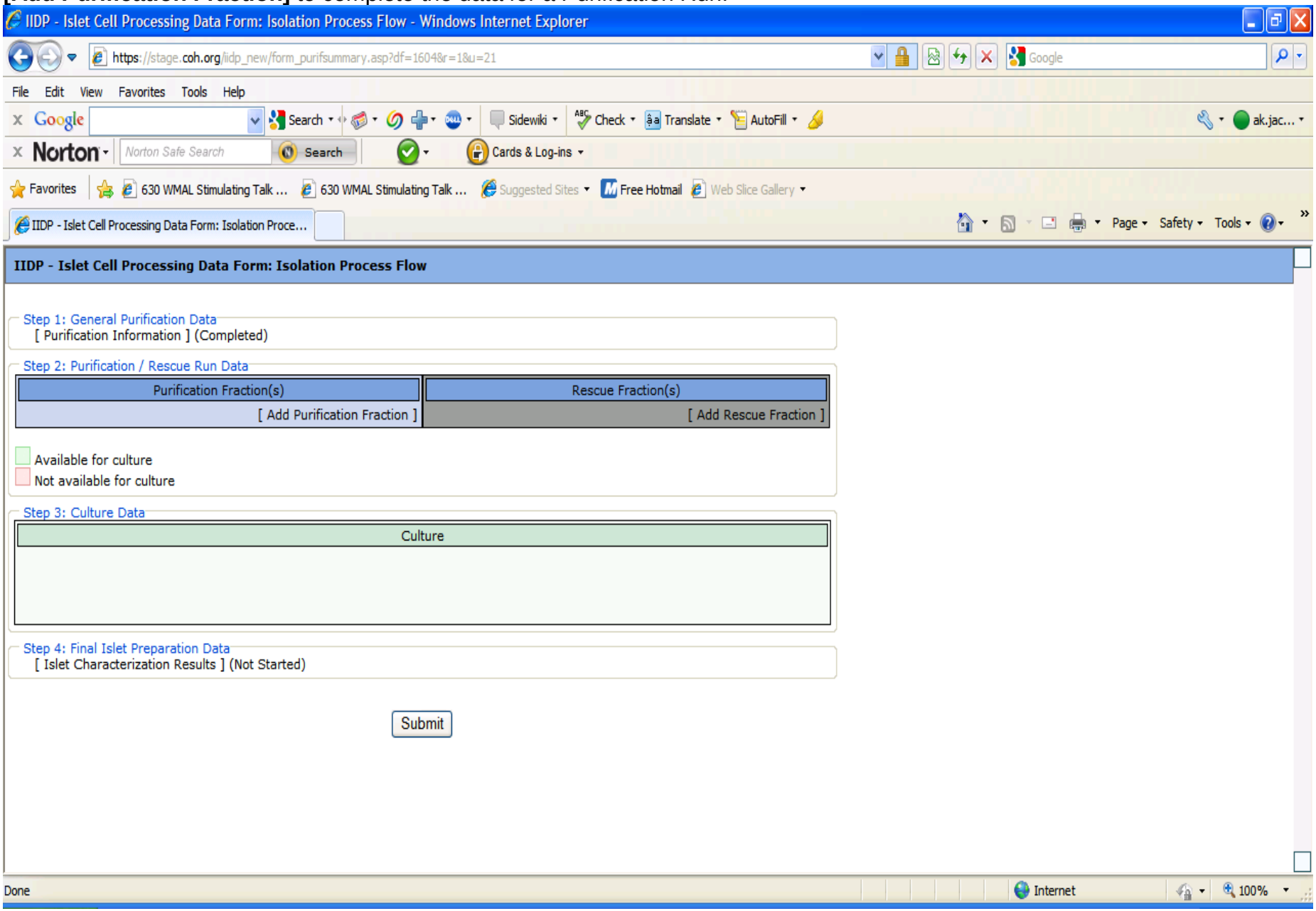
The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a **'Complete'** status.

This is an example of the conditional answer in Step 1 that will determine if Step 2 and Step 3 need to be completed or not. Step 2 and Step 3 of the Isolation Process Flow will NEED to be completed if Question 1 of the Purification Information is answered with **'Density gradient' or 'Other'.**

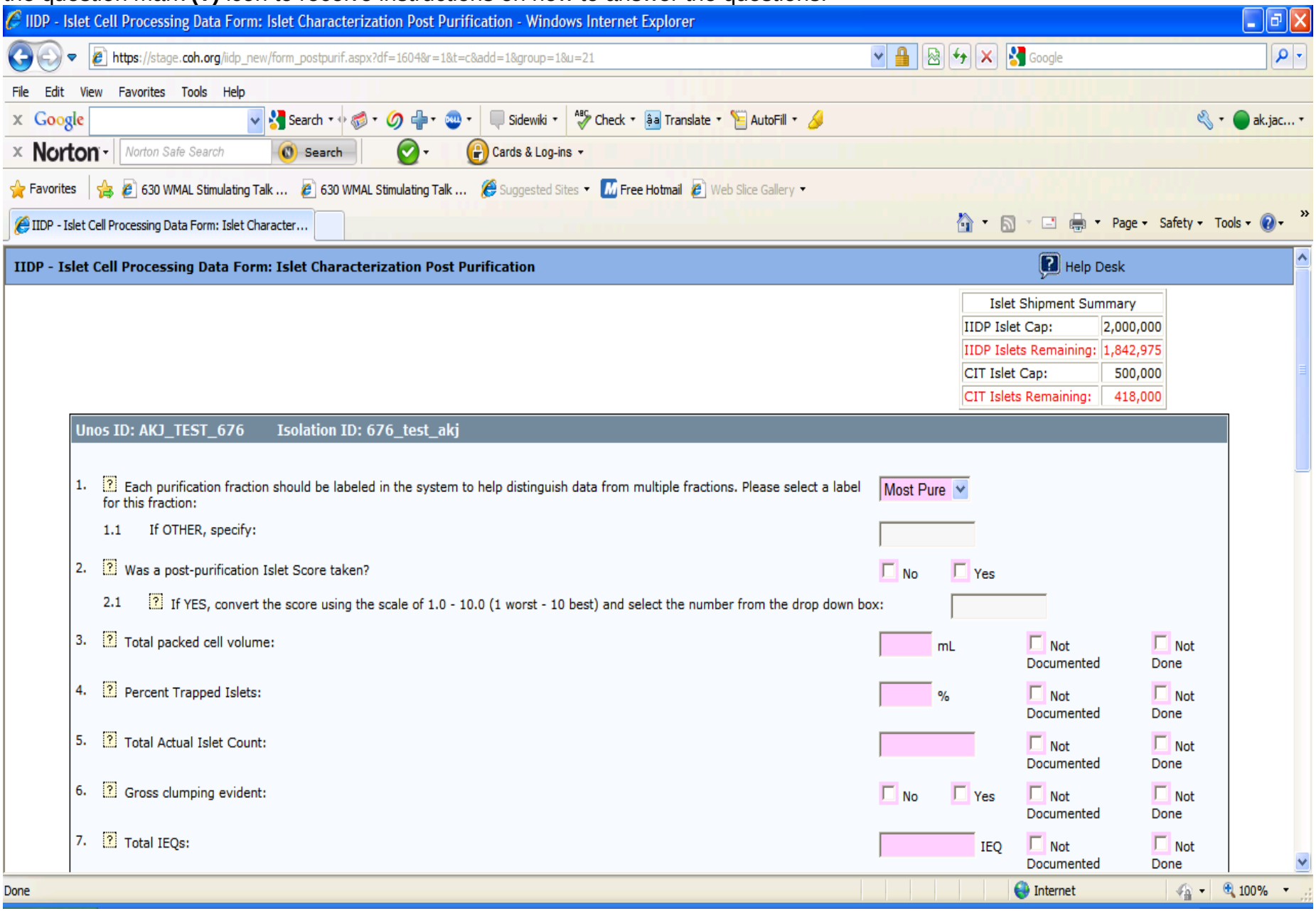


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

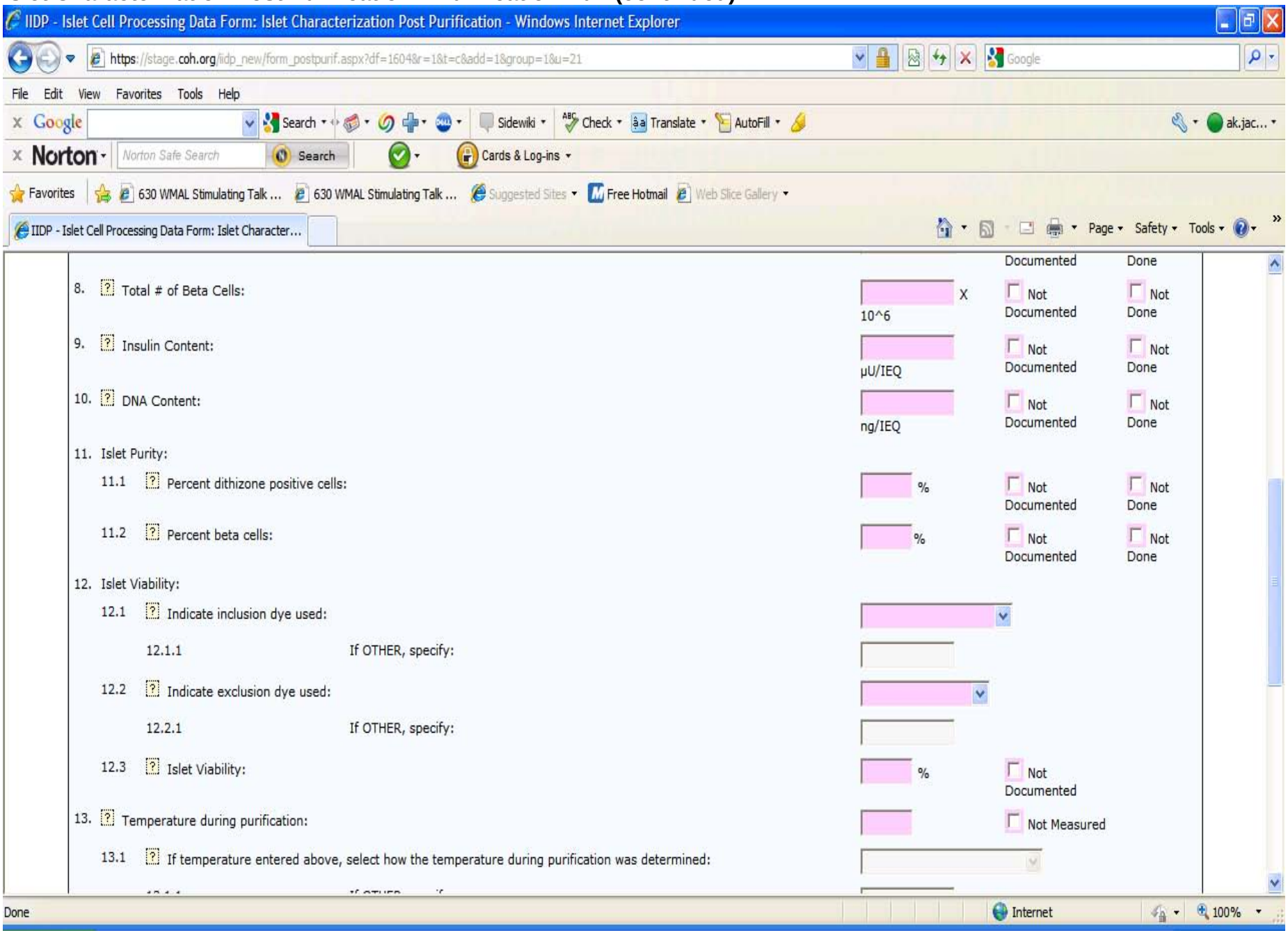
Isolation Process Flow screen - The user will need to complete Step 2 and/or Step 3 of the Isolation Process Flow. Click on **[Add Purification Fraction]** to complete the data for a Purification Run.



Islet Characterization Post Purification – Purification Run - Complete the questions for a Purification Run. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



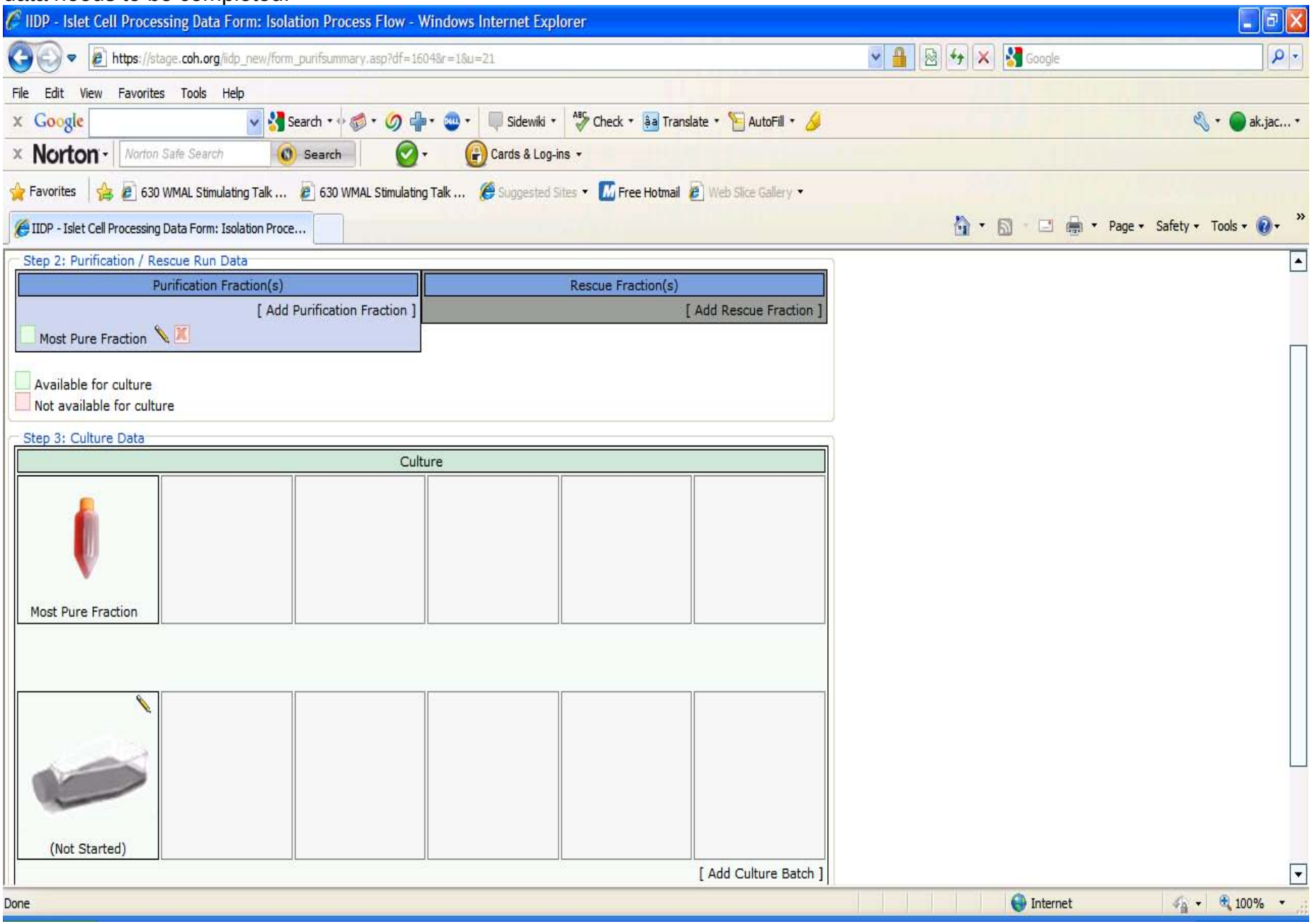
Islet Characterization Post Purification – Purification Run (continued)



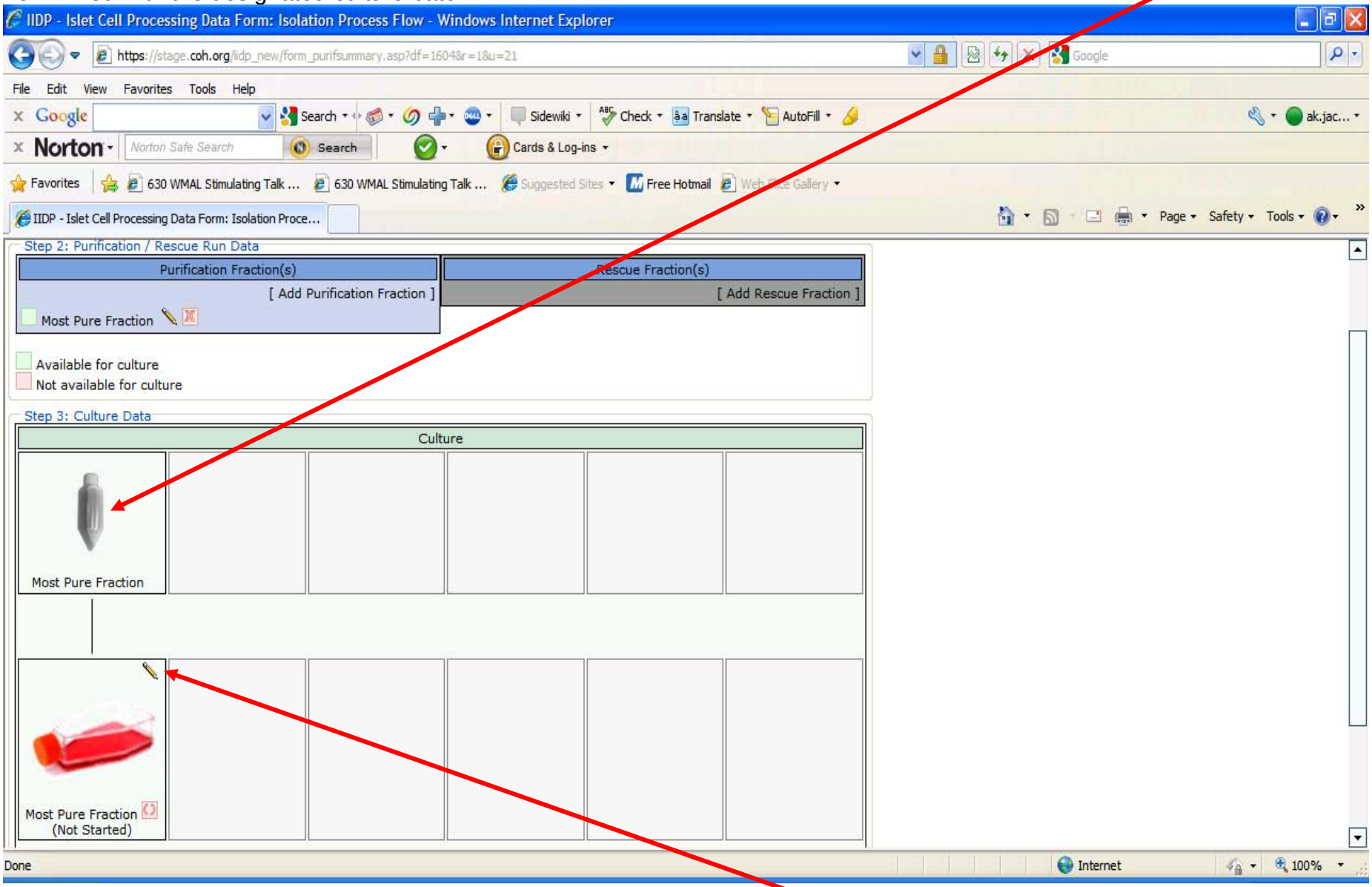
Islet Characterization Post Purification – Purification Run (continued)

Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen. Refer to next page.

Isolation Process Flow screen - The system will display that a Purification Fraction(s) has/have been added and that Culture data needs to be completed.

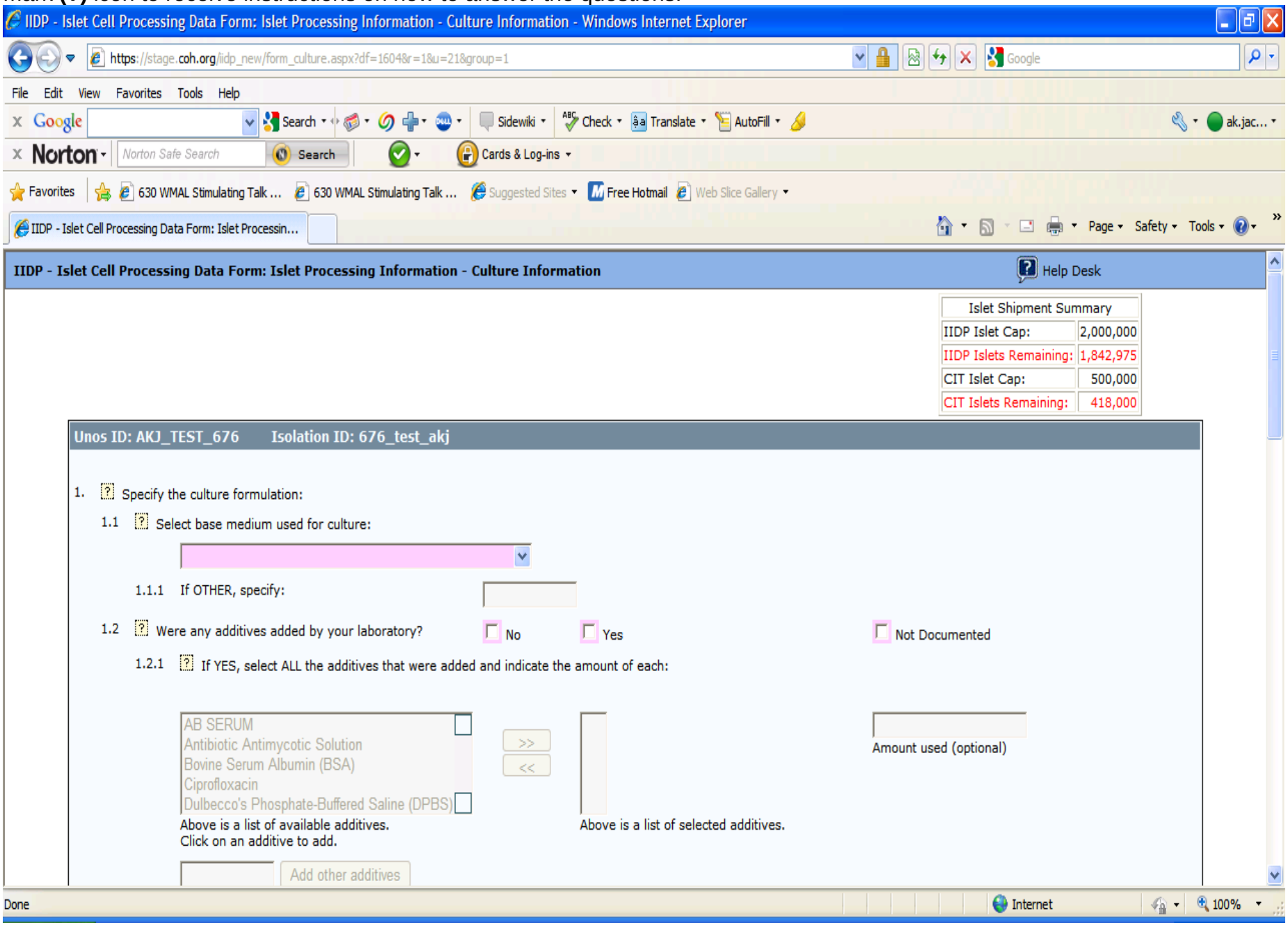


Isolation Process Flow screen - To link the fraction (container) with the culture (culture flask) click on the container in the Purification Fraction box and drag the container down into the culture flask. The Purification Fraction (e.g., Most Pure Fraction) is now linked with the designated culture batch.

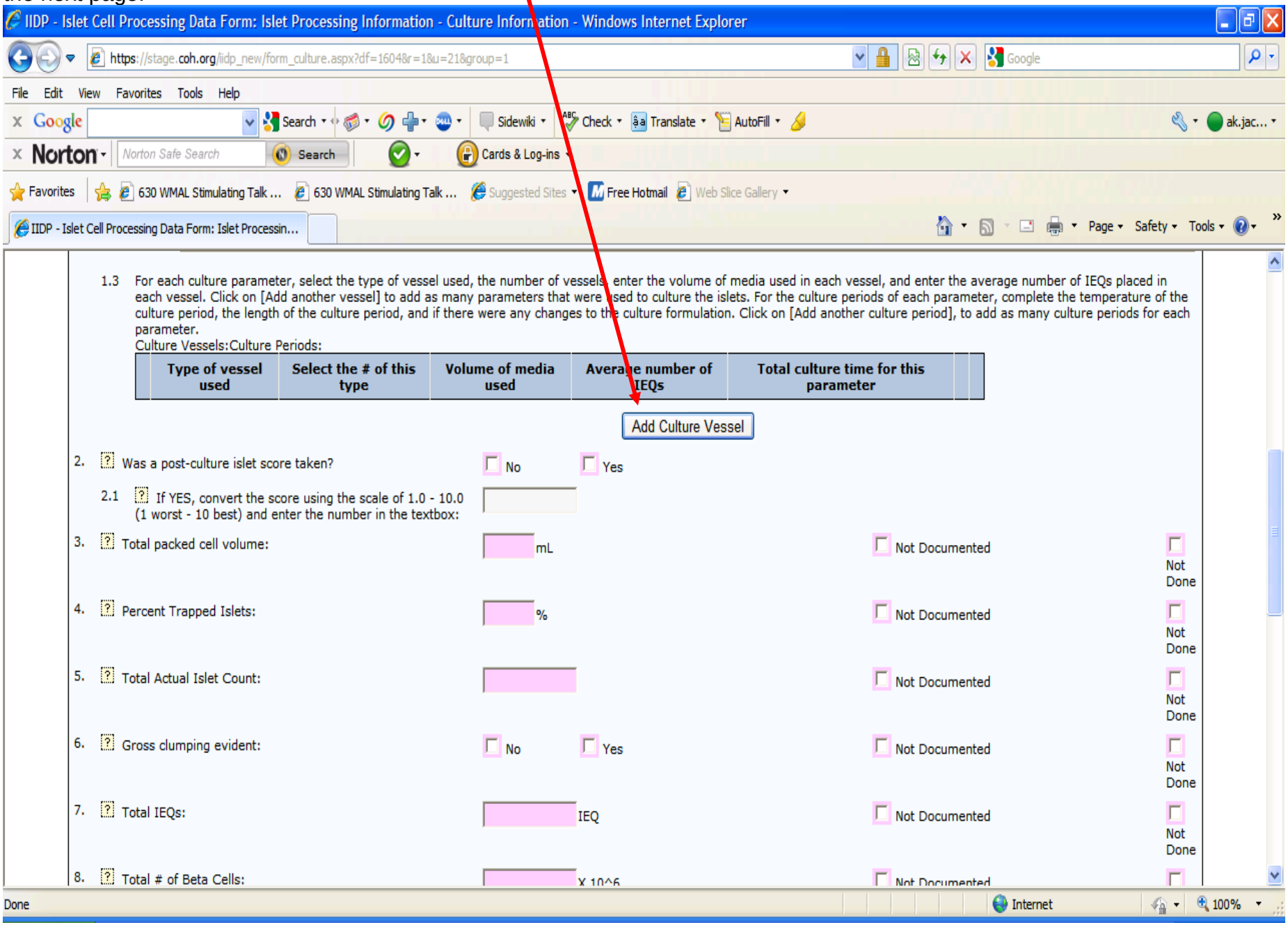


To complete the culture information for the Most Pure Fraction click on the **[Edit]** icon in the top right hand corner of the culture flask box - refer to the next page.

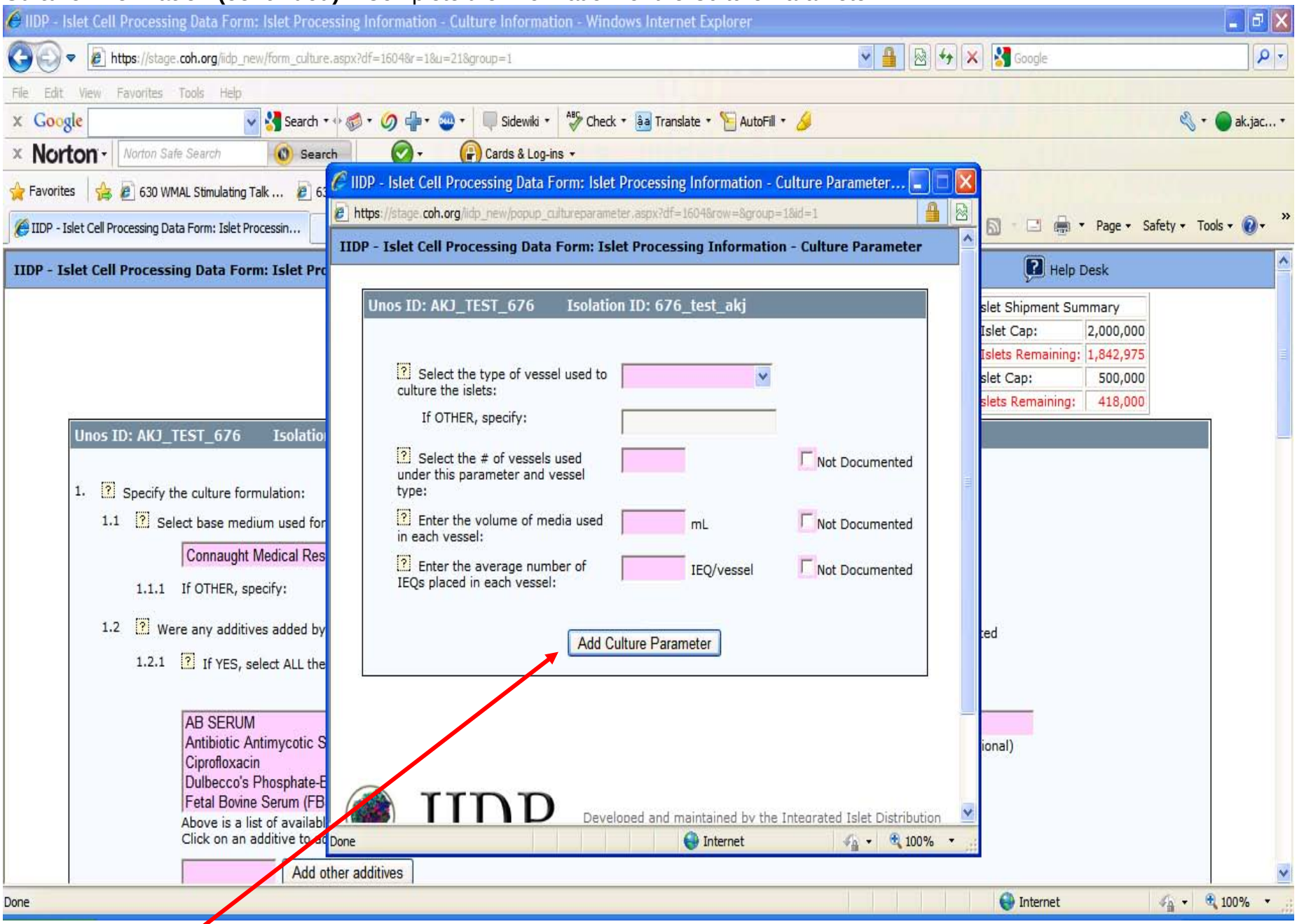
Culture Information - Complete the questions for the culture information for Most Pure Fraction. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Culture Information continued - Click on **[Add Culture Vessel]** to enter Culture Parameter and Culture Period Data - refer to the next page.

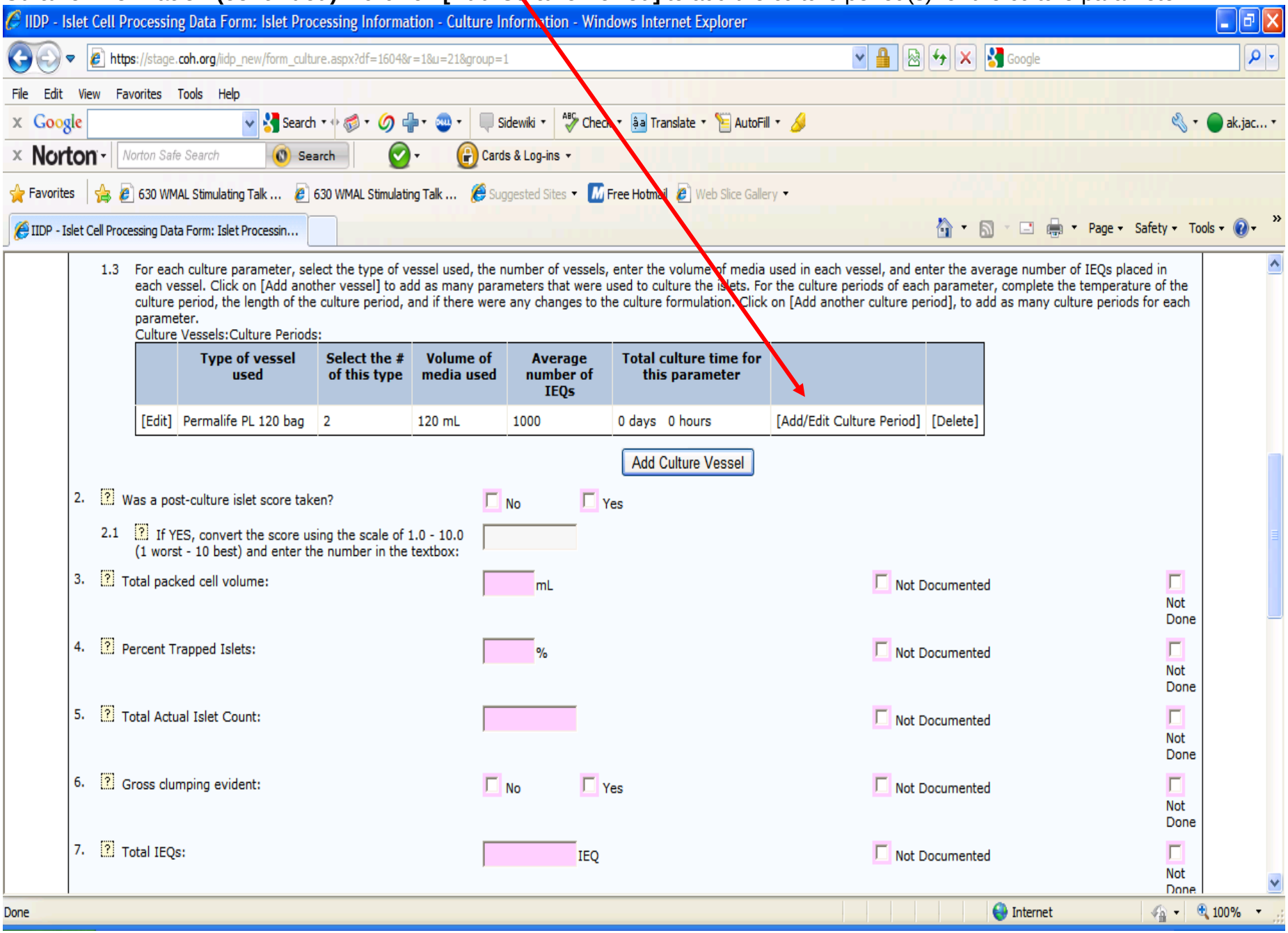


Culture Information (continued) – Complete the information for the Culture Parameter.

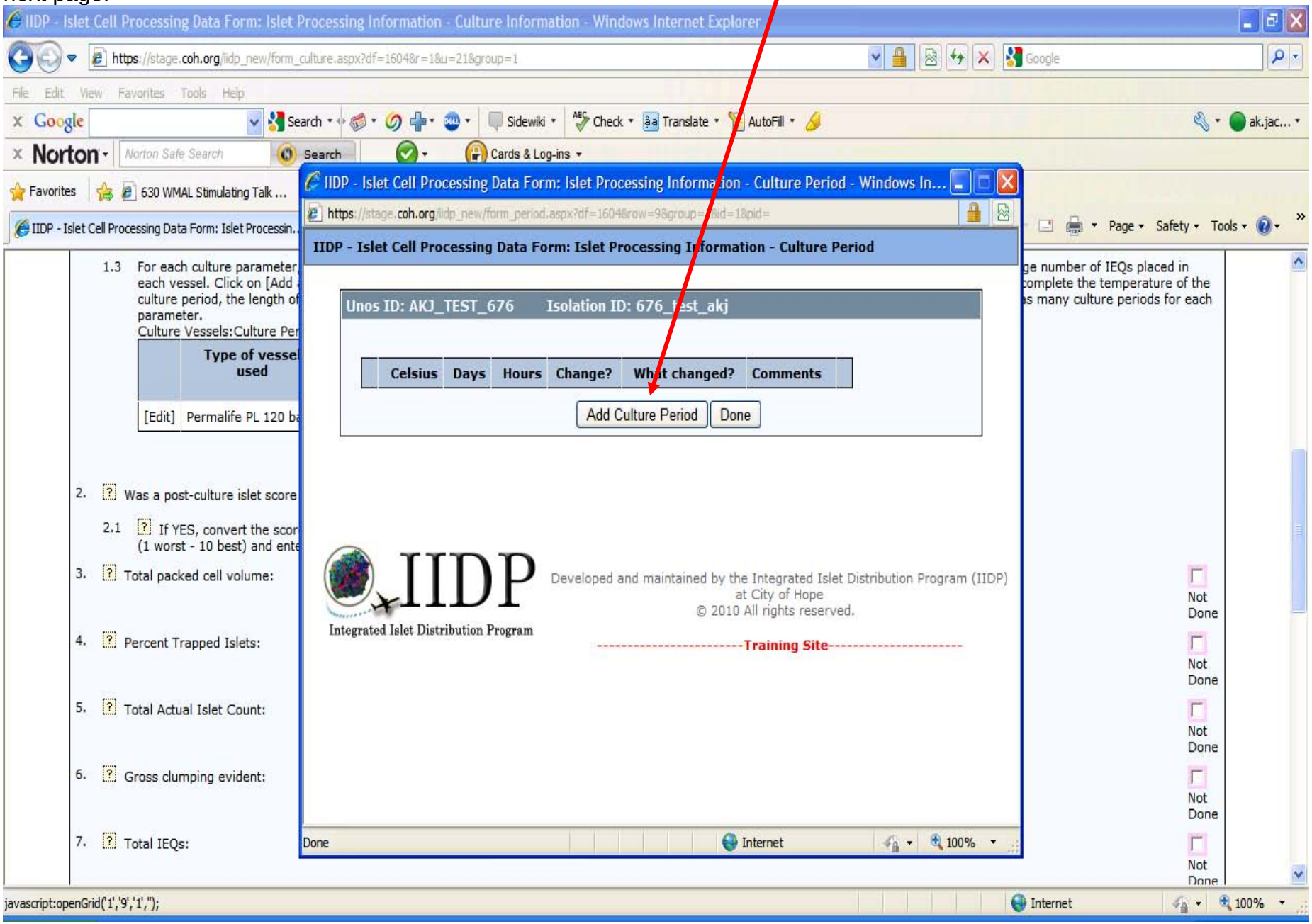


Click on **[Add Culture Parameter] -** refer to the next page. Repeat the process as needed for each culture parameter.

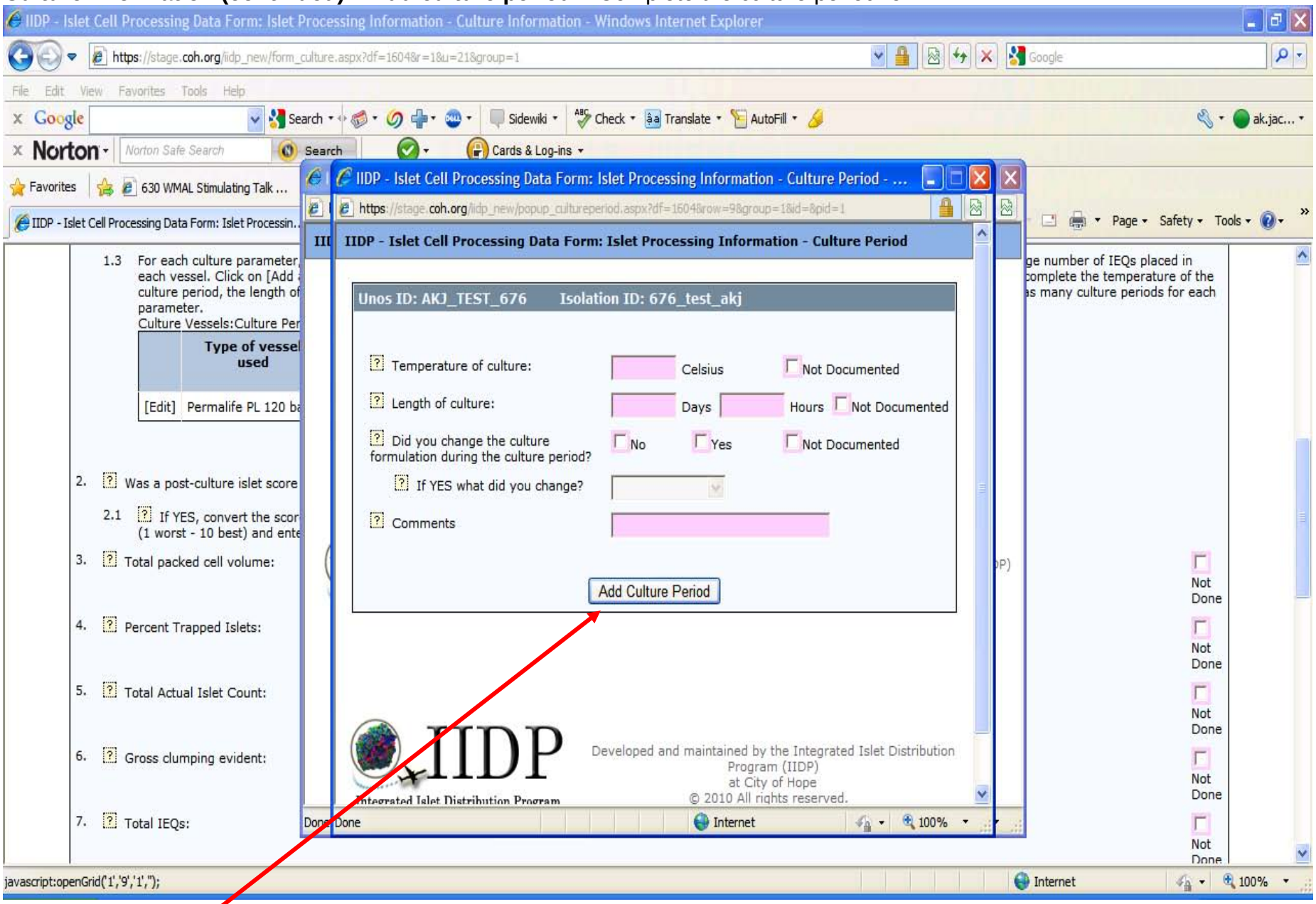
Culture Information (continued) – click on **[Add Culture Period]** to add the culture period(s) for the culture parameter.



Culture Information (continued) – Add culture period – Click on **[Add Culture Period]** to add a culture period - refer to the next page.

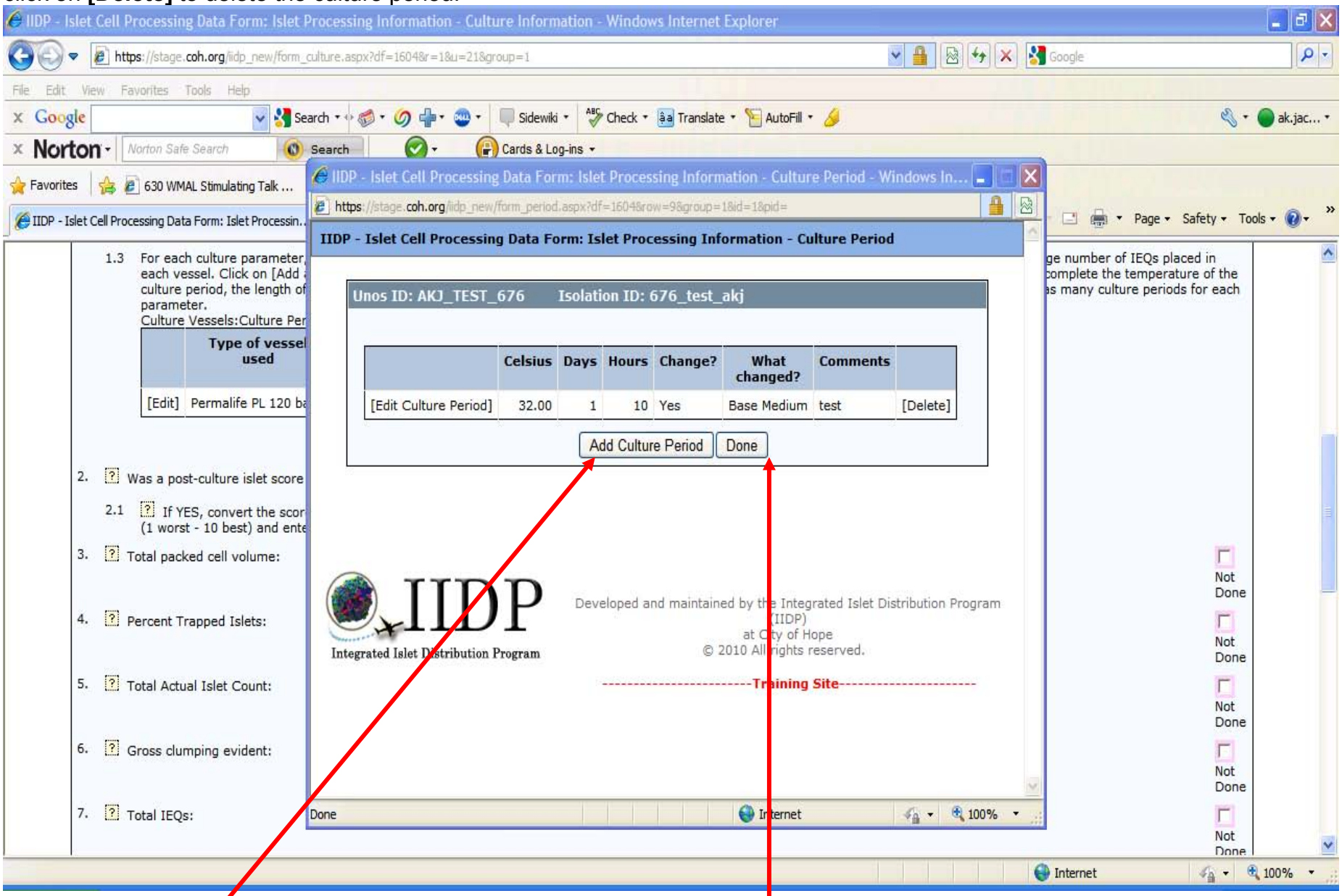


Culture Information (continued) – Add culture period – Complete the culture period form.



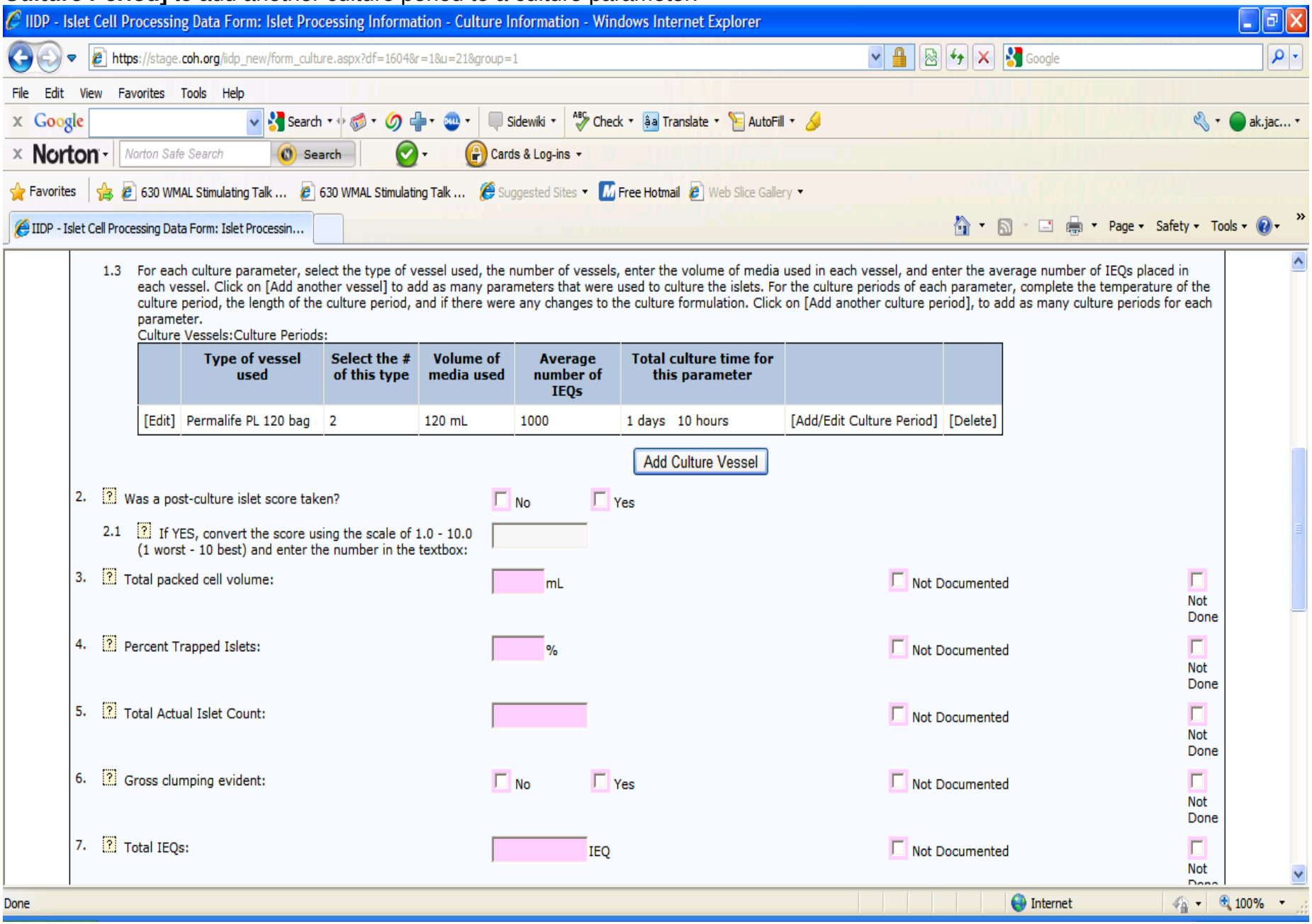
Click on **[Add Culture Period]** to add the culture period to the culture period. Repeat the process as needed to add as many culture periods as applicable to the culture parameter - refer to the next page.

Culture Information (continued) – Add culture period - Click on **[Edit Culture Period]** to edit the culture period information **OR** click on **[Delete]** to delete the culture period.

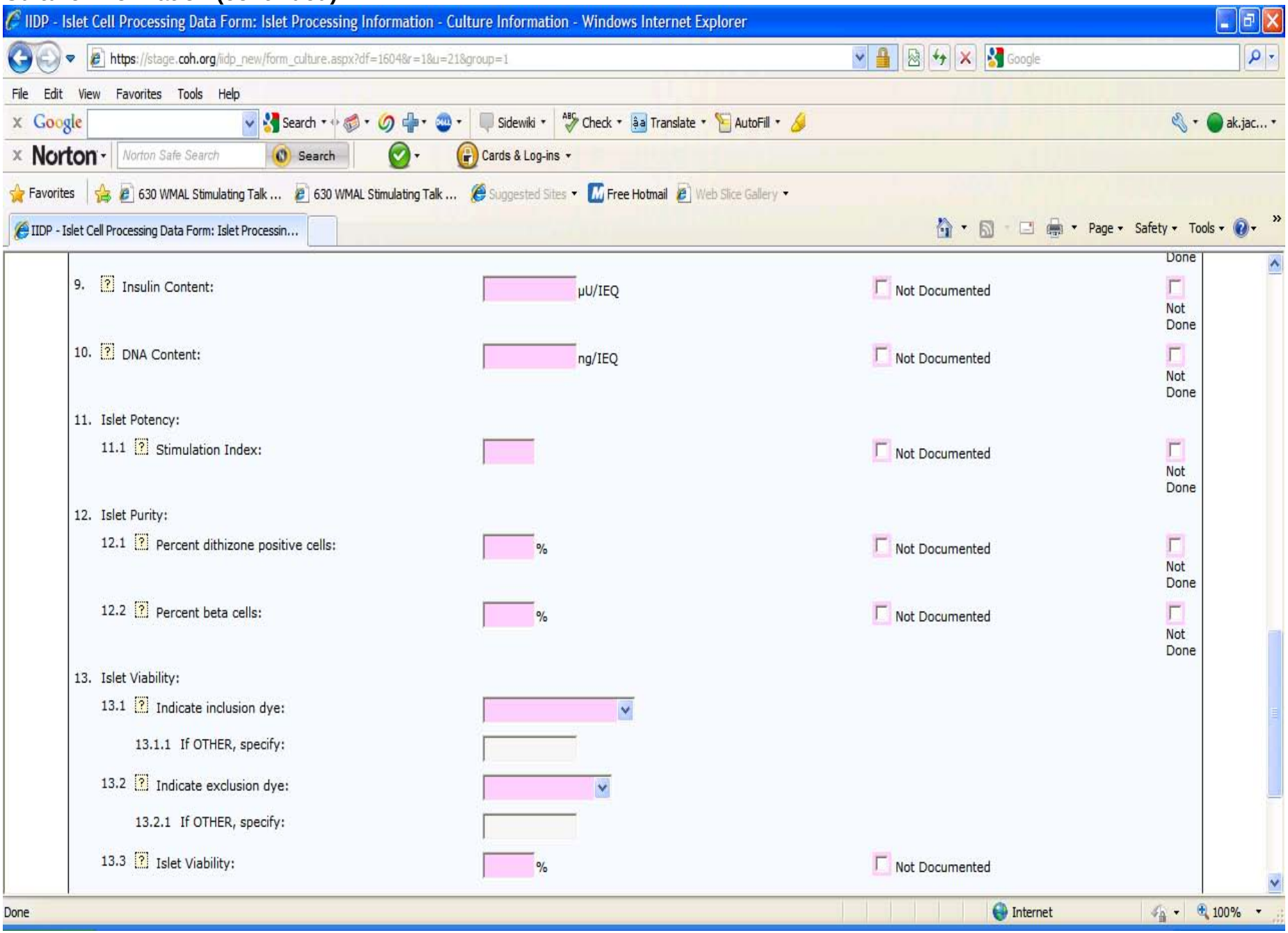


Click on **[Add Culture Period]** to add another culture period **OR** click on **[Done]** to proceed to the next step - refer to the next page.

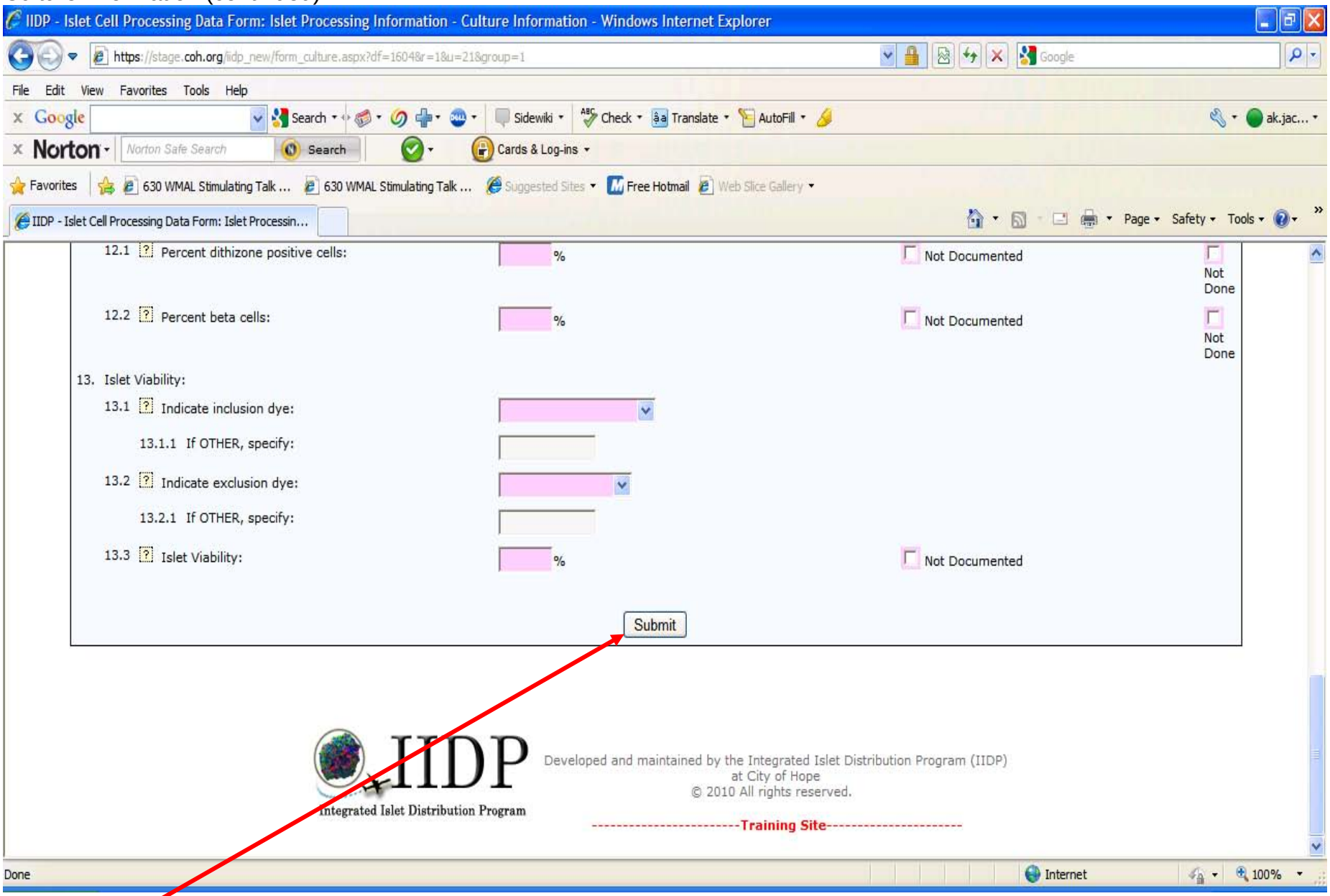
Culture Information (continued) – Click on **[Add Culture Vessel]** to add another culture parameter AND/OR click on **[Add Culture Period]** to add another culture period to a culture parameter.



Culture Information (continued)

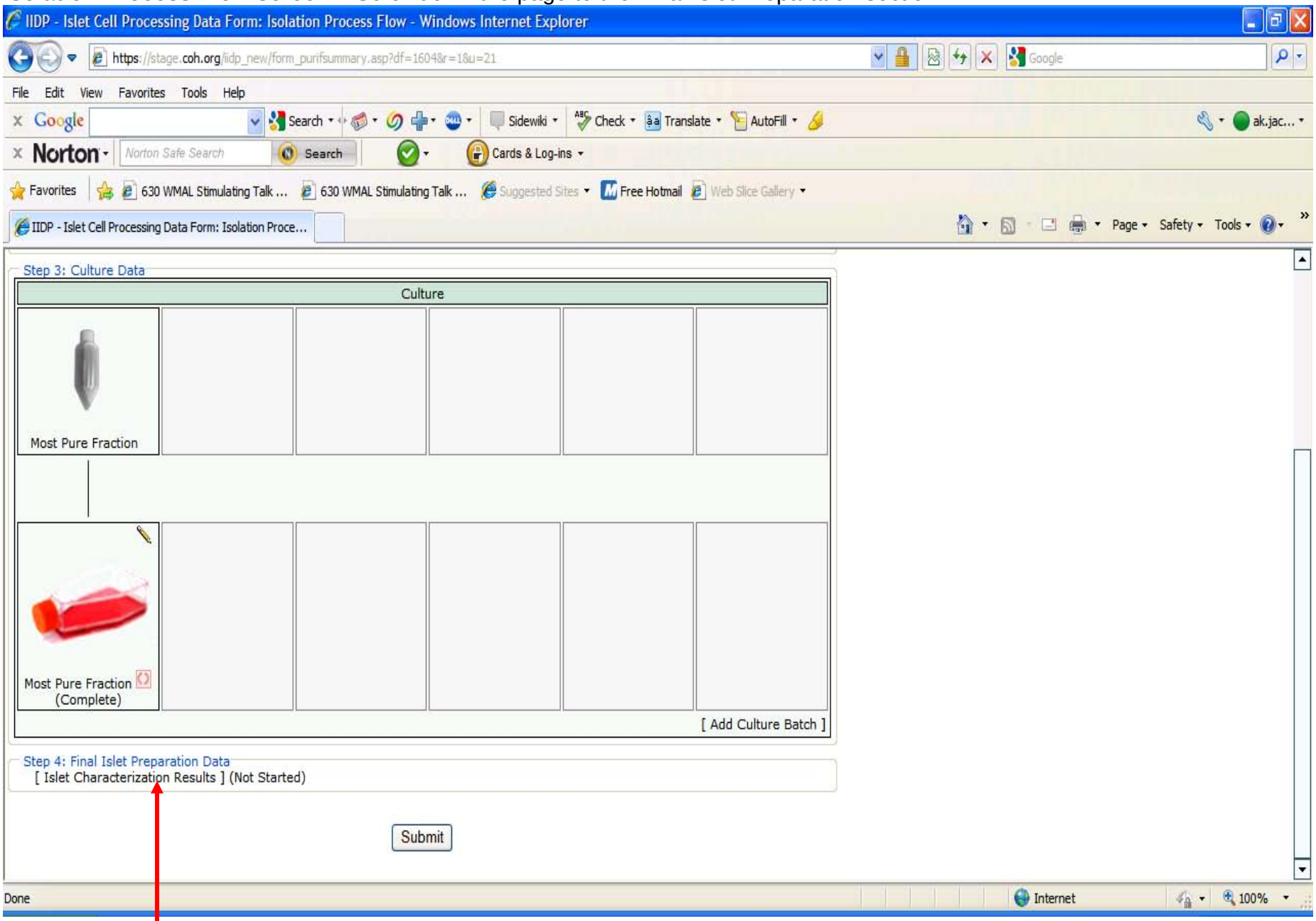


Culture Information (continued)



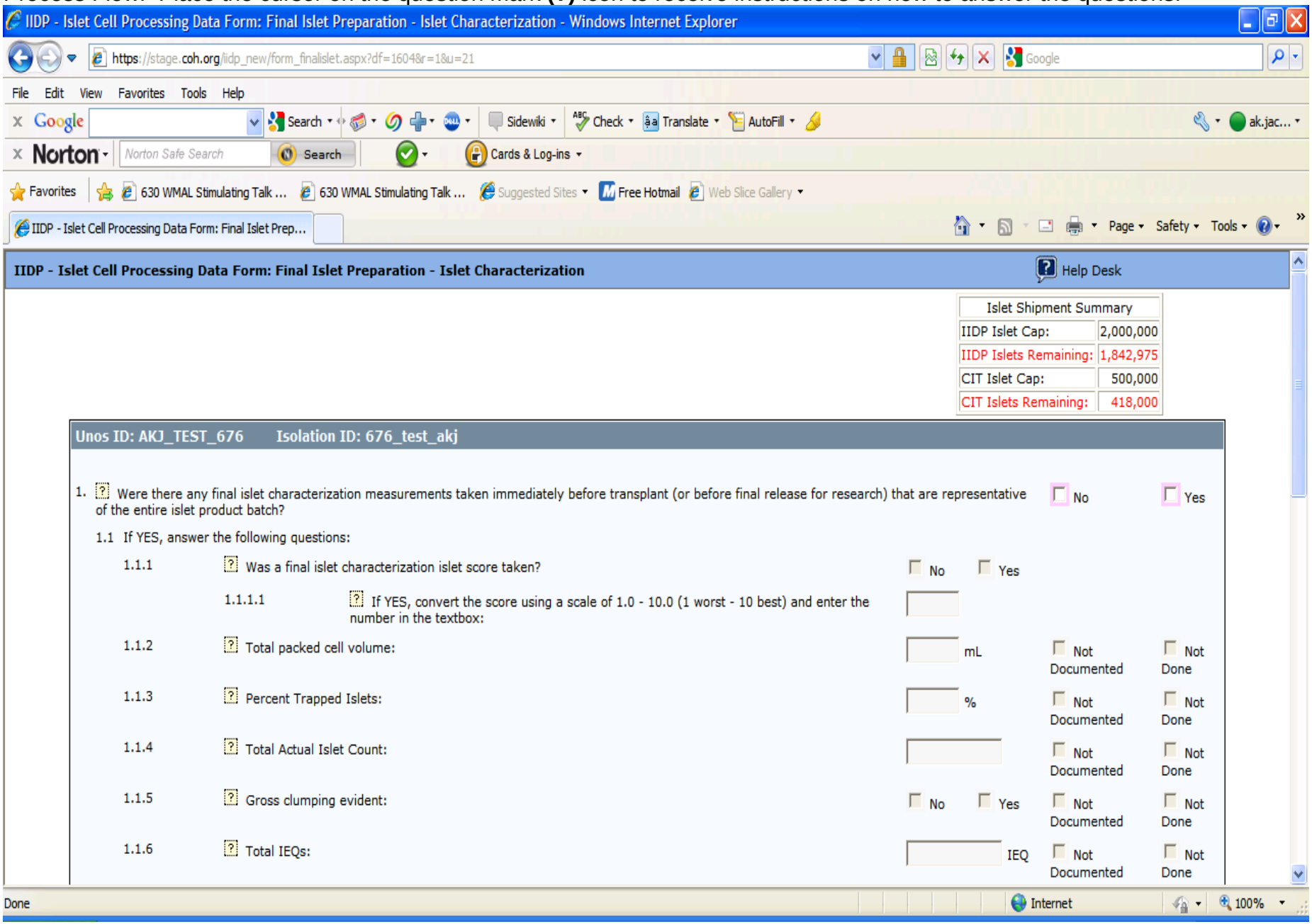
Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen - refer to next page.

Isolation Process Flow screen – Scroll down the page to the Final Islet Preparation section.

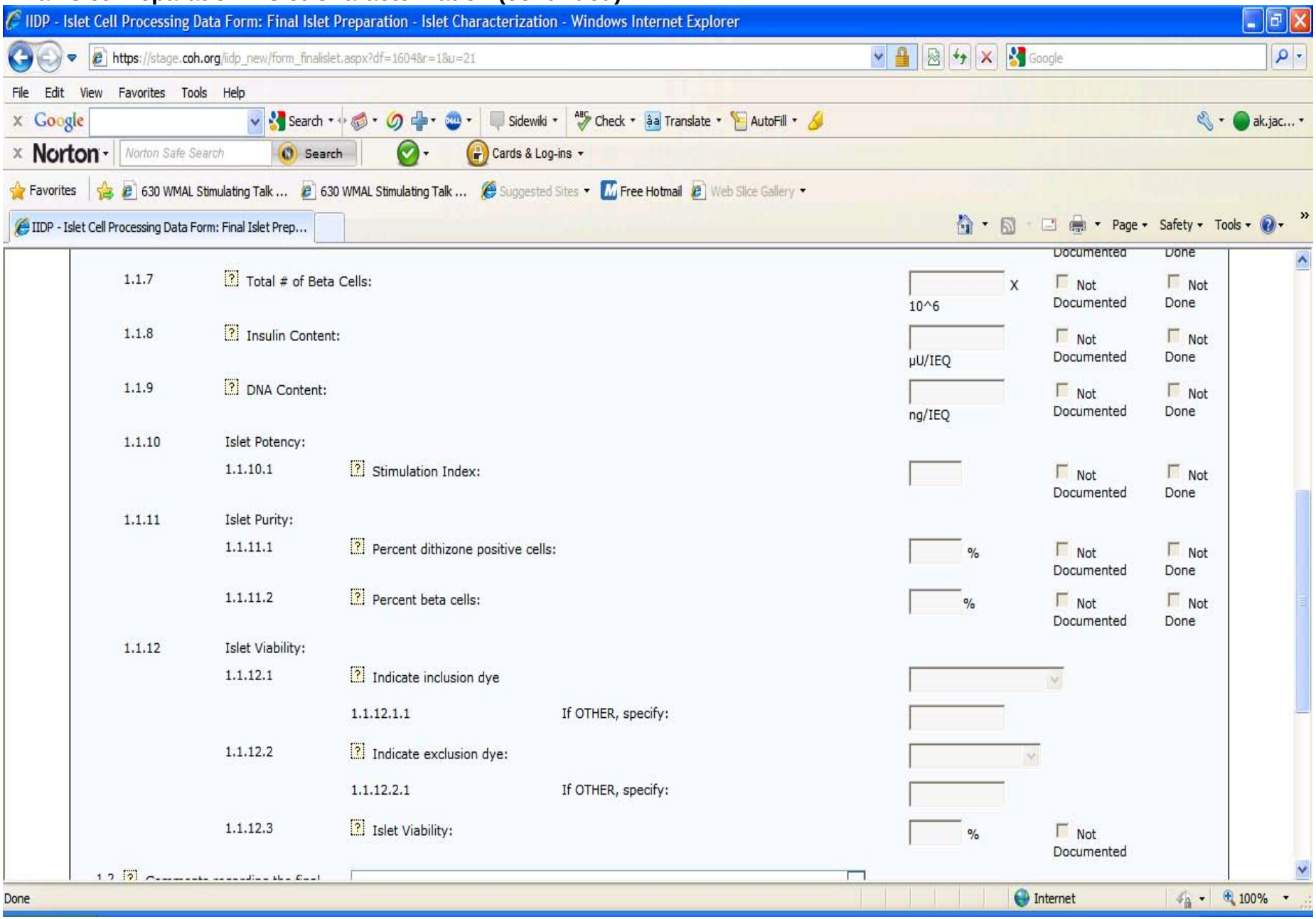


Click on the **[Islet Characterization Results]** to complete Step 4 of the Purification Section - refer to the next page.

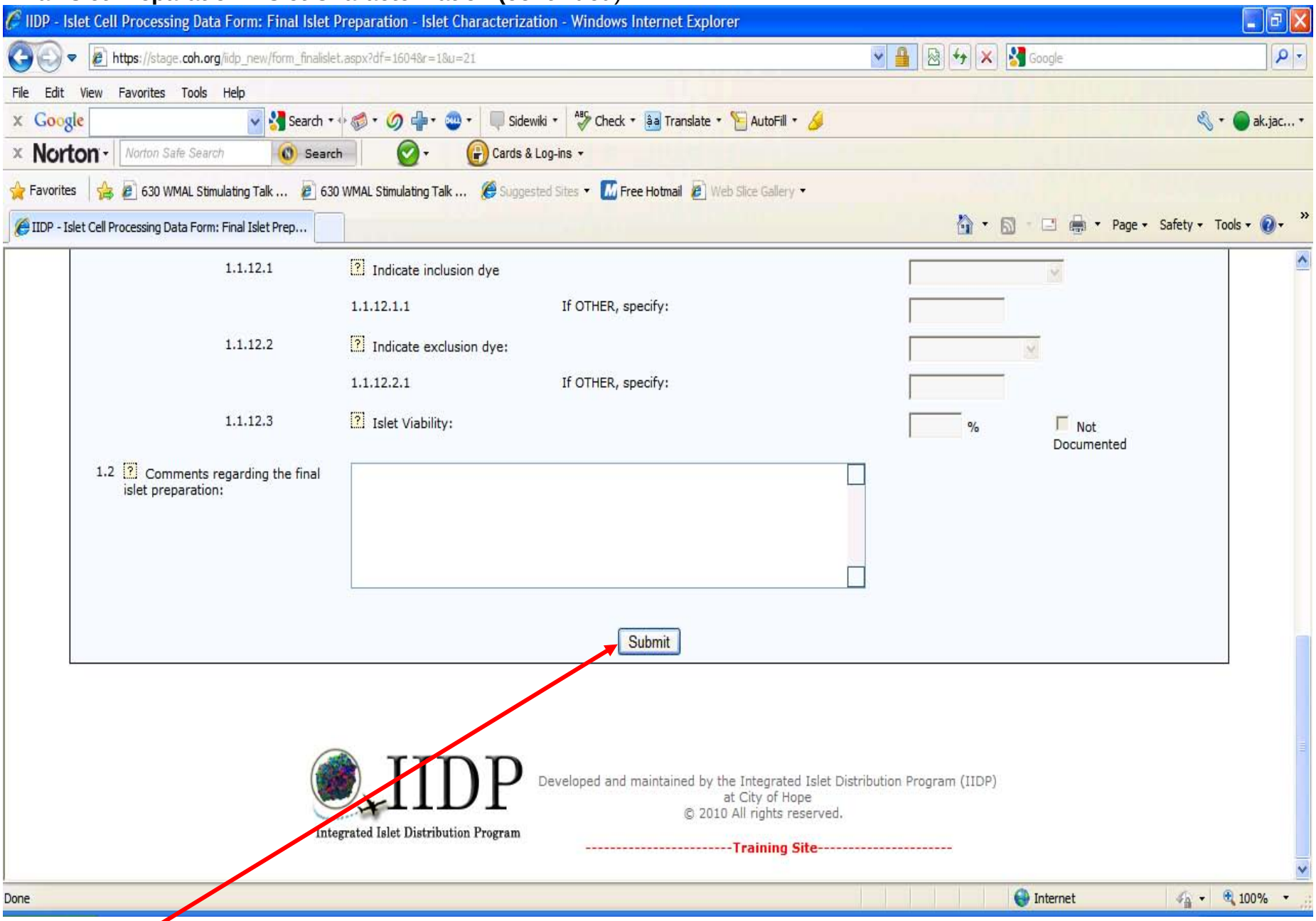
Final Islet Preparation –Islet Characterization - Complete the questions for the Final Islet Preparation - Step 4 of the Isolation Process Flow. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



Final Islet Preparation - Islet Characterization (continued)

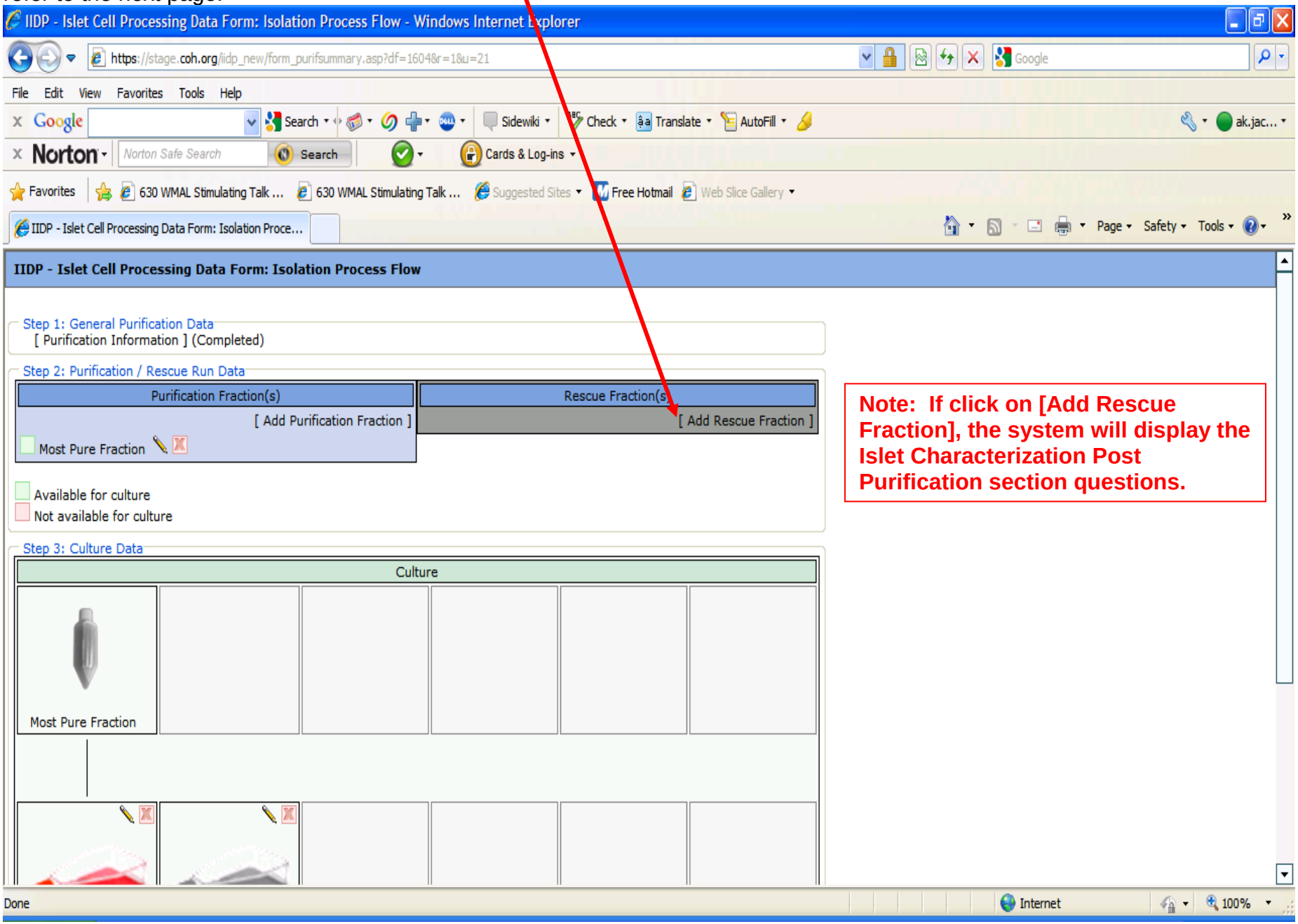


Final Islet Preparation - Islet Characterization (continued)

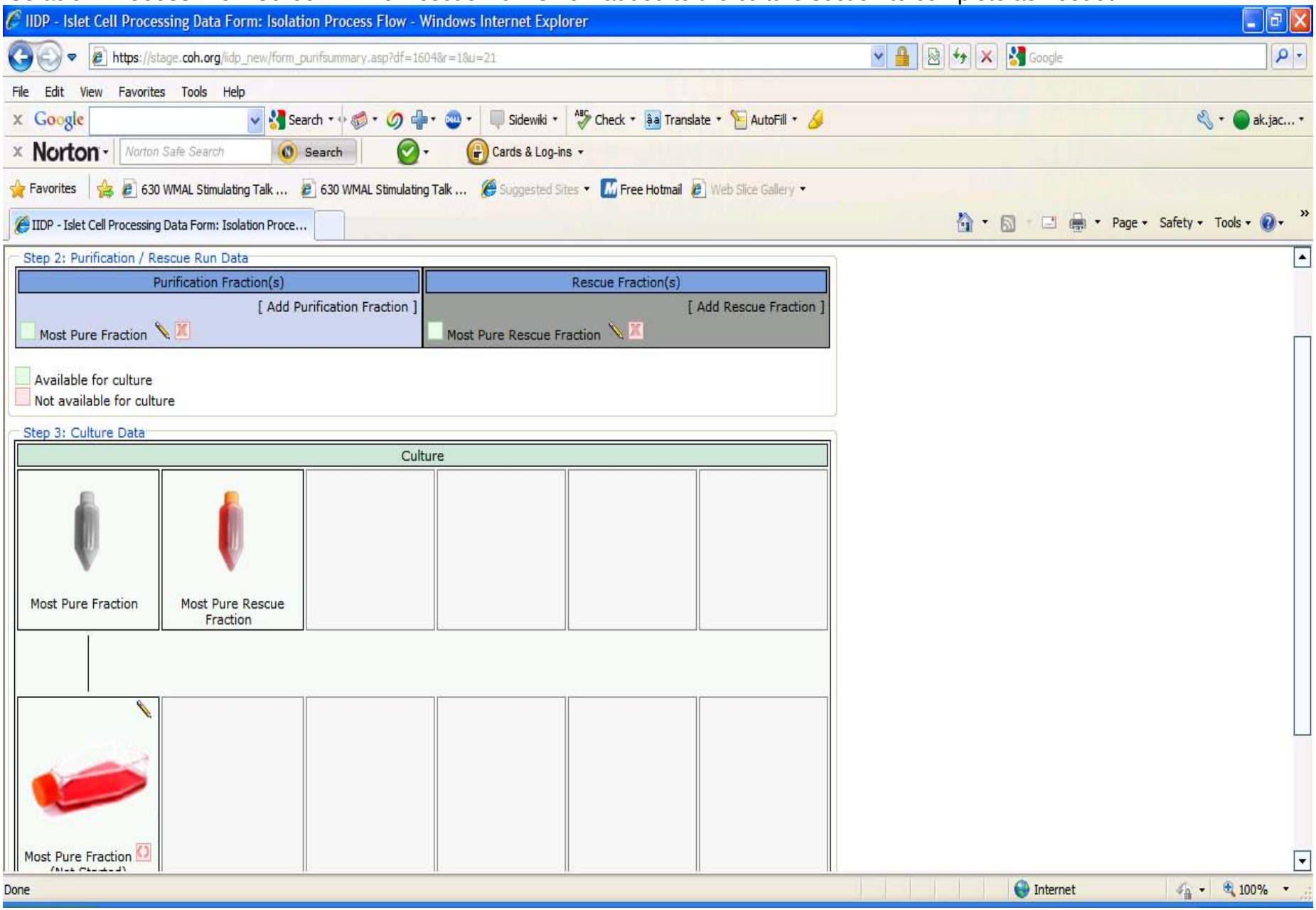


Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen - refer to next page.

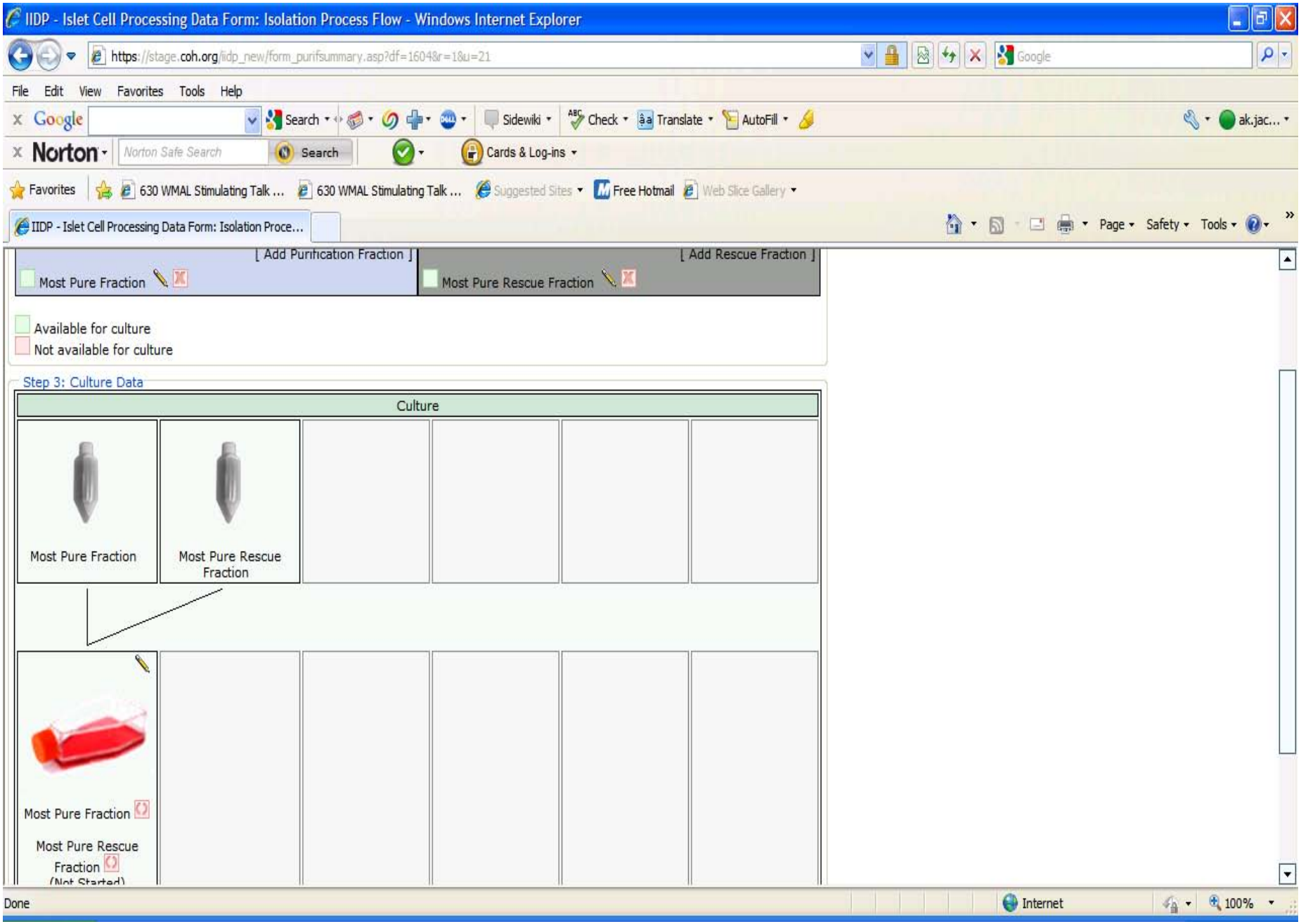
Isolation Process Flow screen - Click on **[Add Rescue Fraction]** if you need to complete the information for a Rescue Run – refer to the next page.



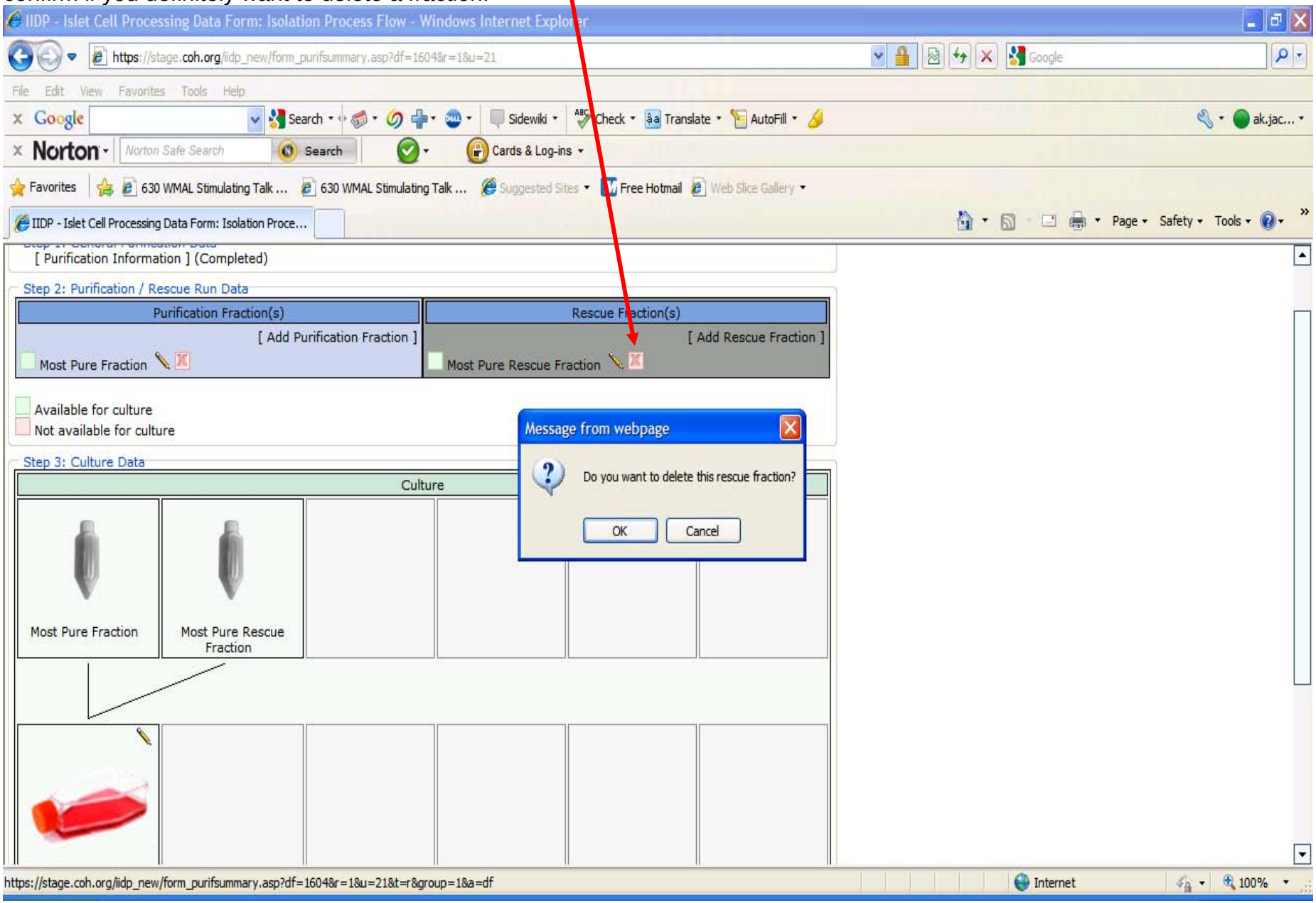
Isolation Process Flow screen – The Rescue Run is now added to the culture section to complete as needed.



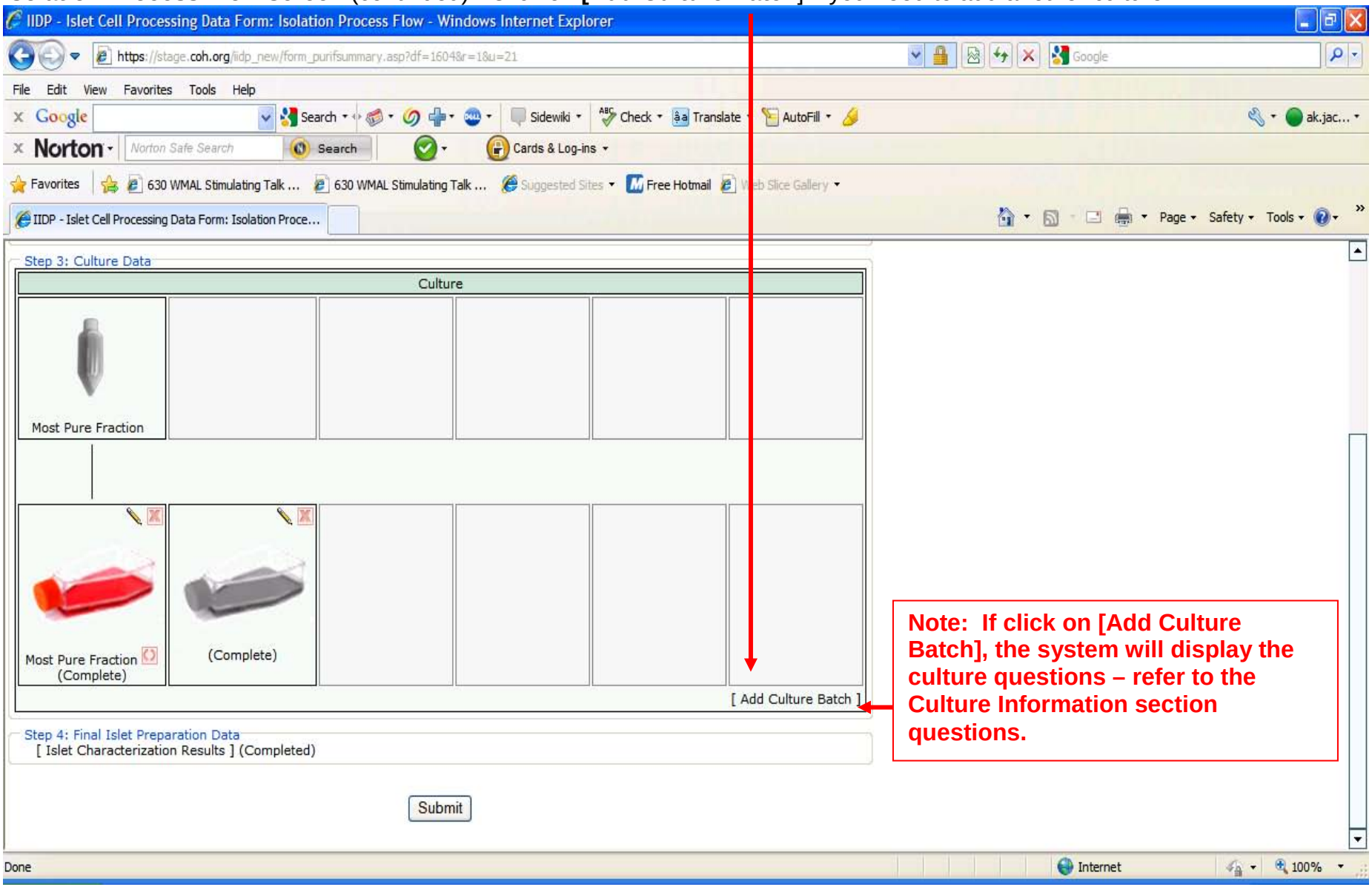
Isolation Process Flow screen – The Rescue Run can be ‘dragged and dropped’ into the culture flask as discussed on page 114.



Isolation Process Flow screen – Click on the [Delete [X]] icon to delete a Purification Fraction and/or Rescue Fraction. Then confirm if you definitely want to delete a fraction.



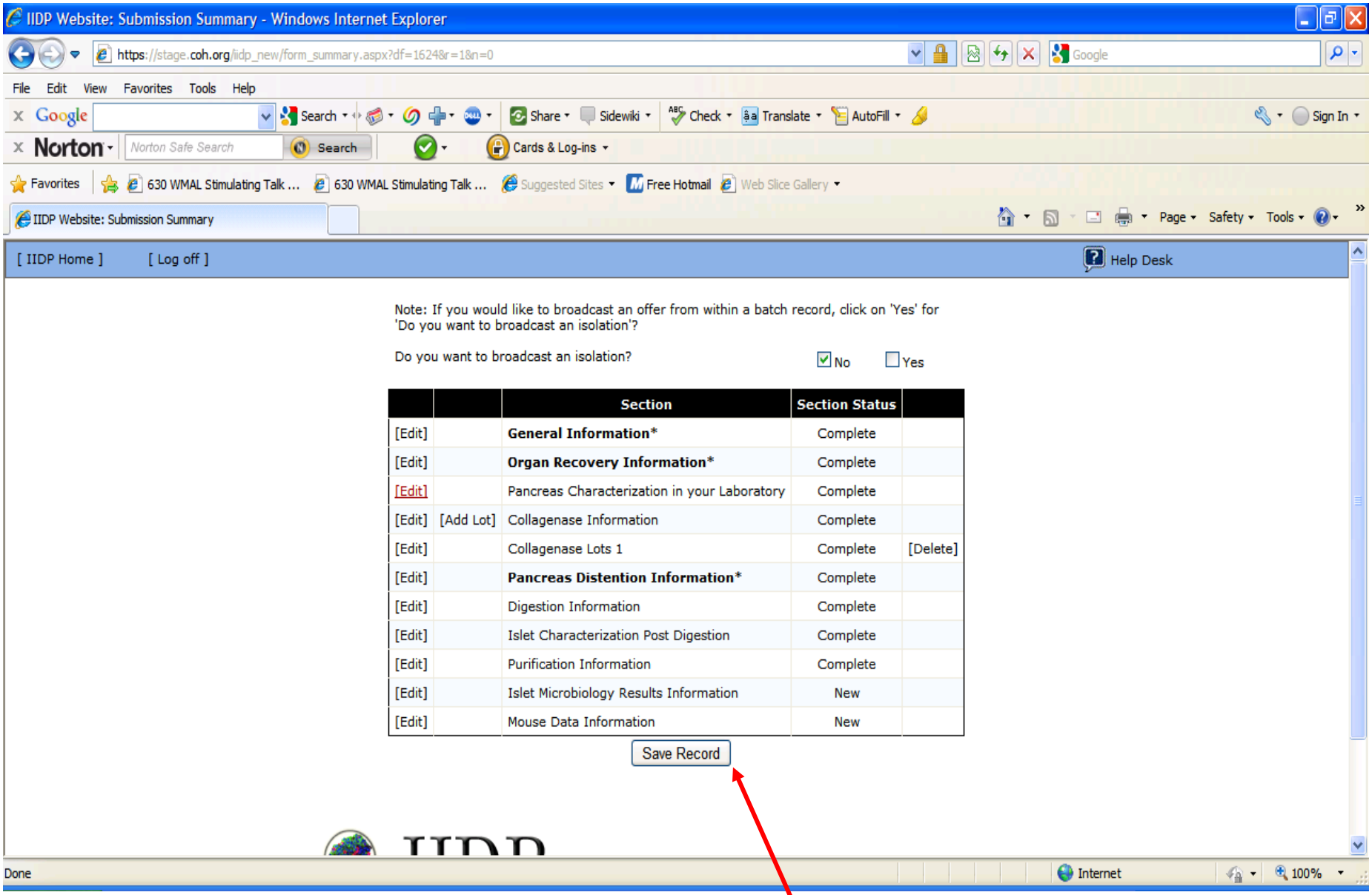
Isolation Process Flow screen (continued) - Click on **[Add Culture Batch]** if you need to add another culture



Note: If click on [Add Culture Batch], the system will display the culture questions – refer to the Culture Information section questions.

Click on the **[Remove ( )]** icon in the bottom right hand corner of the culture flask box to remove a culture as needed.
OR
Click on **[Submit]** to submit/save the Isolation Process Flow (Steps 1 – 4) data to the system. The system will return the user to the Distribution Record Detail Summary.

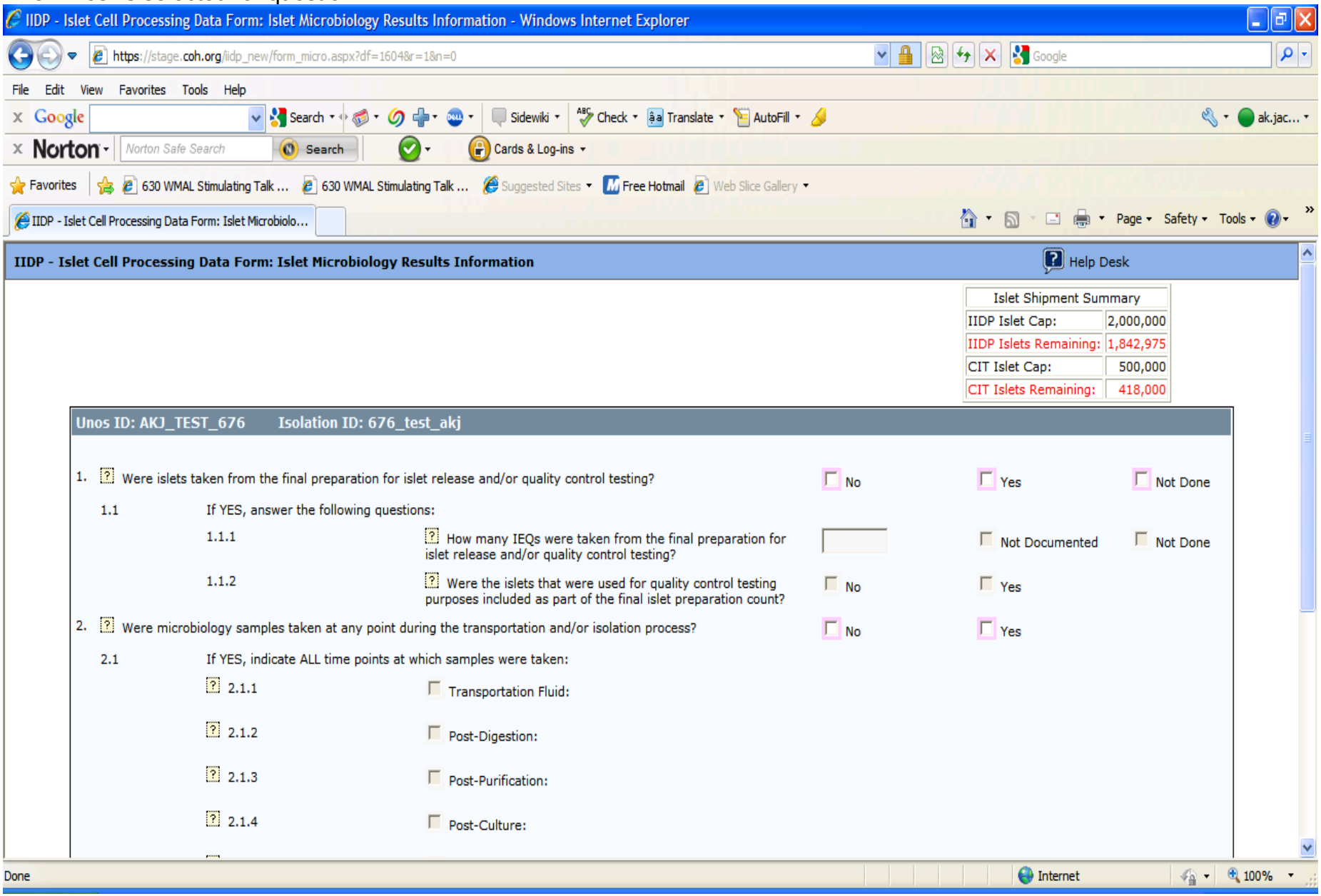
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



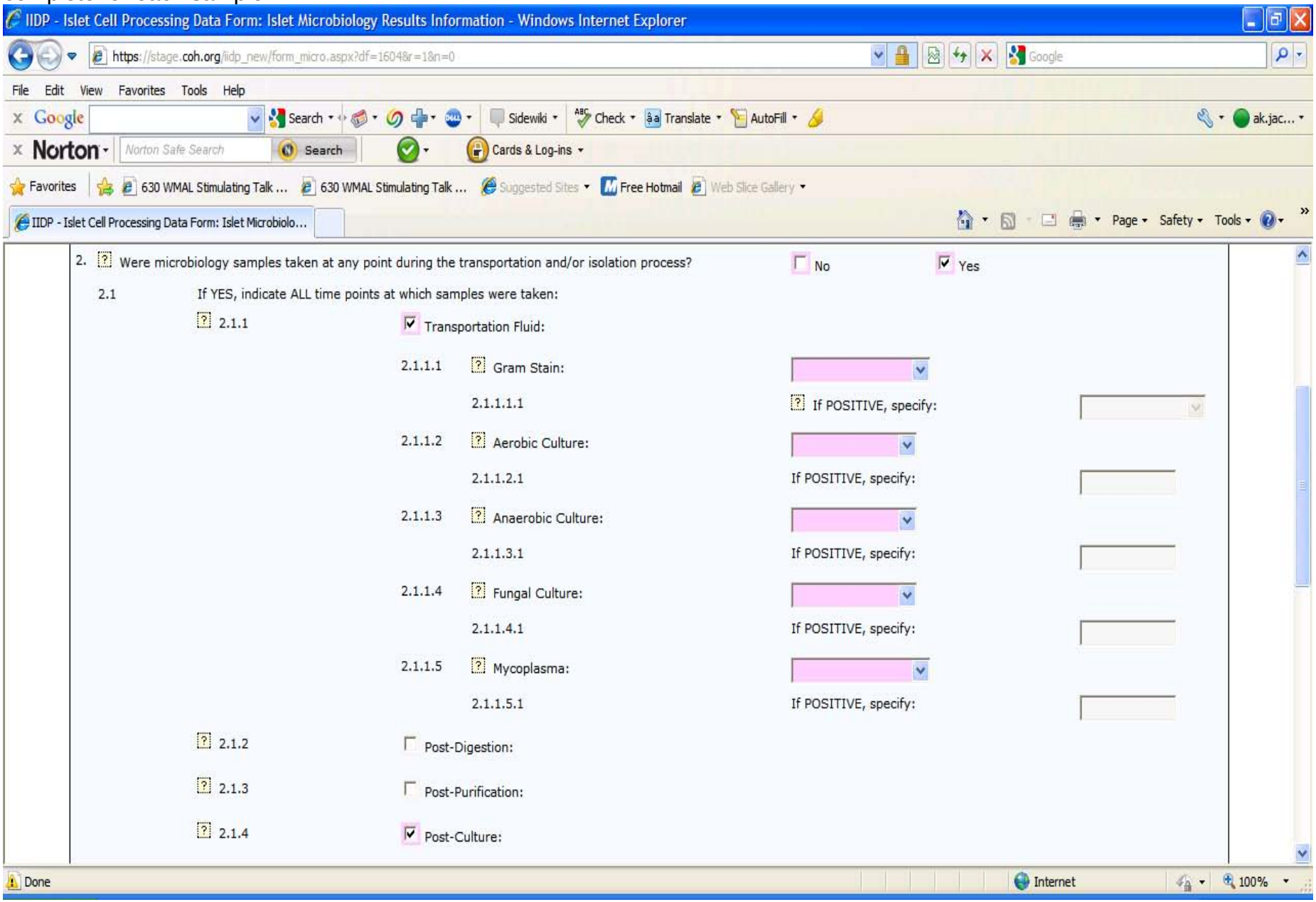
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	New	
[Edit]		Mouse Data Information	New	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

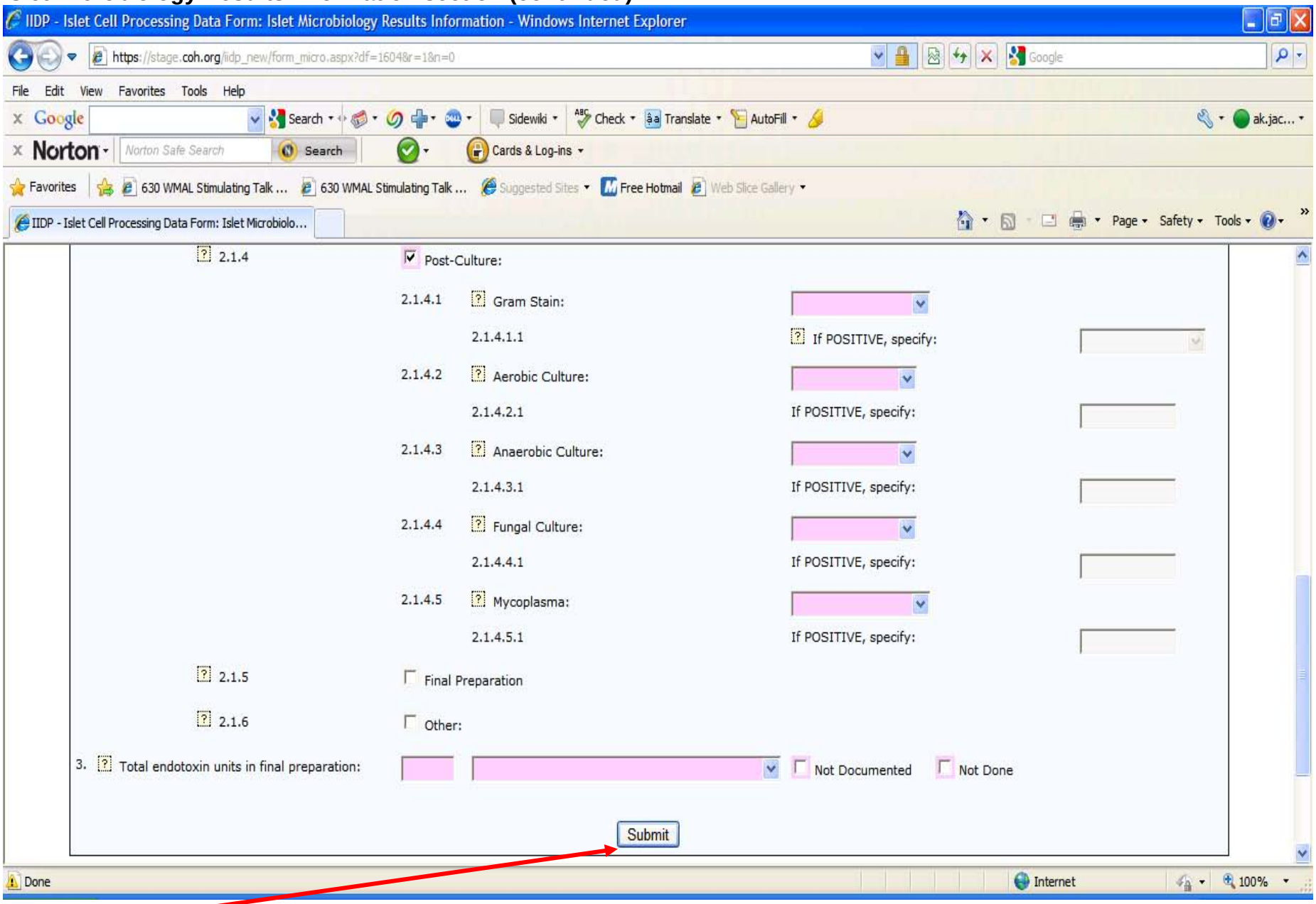
Islet Microbiology Results Information section – Complete the questions in the Islet Microbiology Results Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions. Refer to the next page when 'Yes' is selected for question 2.



Islet Microbiology Results Information section (continued) – When 'Yes' is selected for question 2, then select when the microbiology samples were taken. For those microbiology samples, the system will display the microbiology questions to complete for each sample.

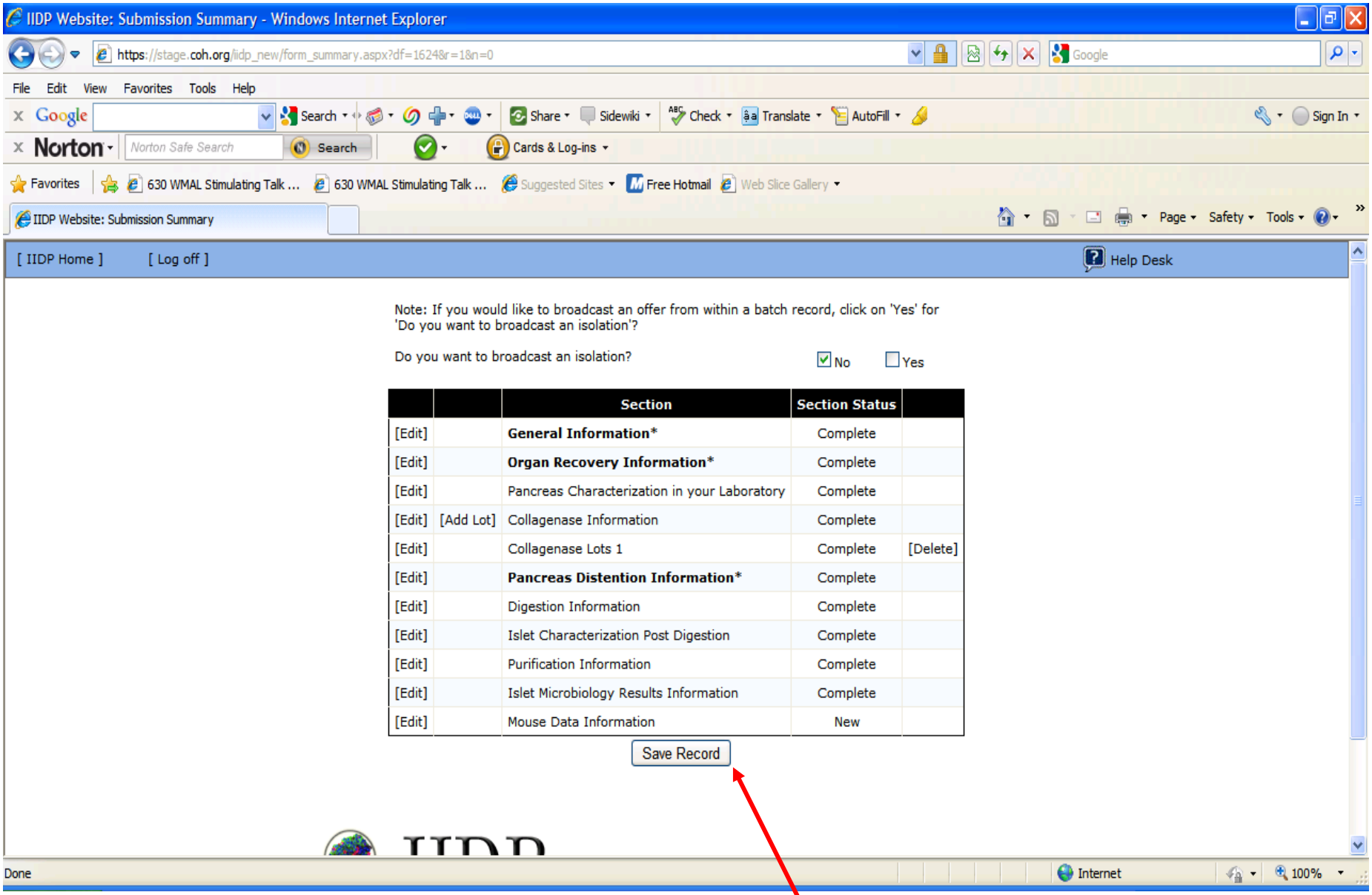


Islet Microbiology Results Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

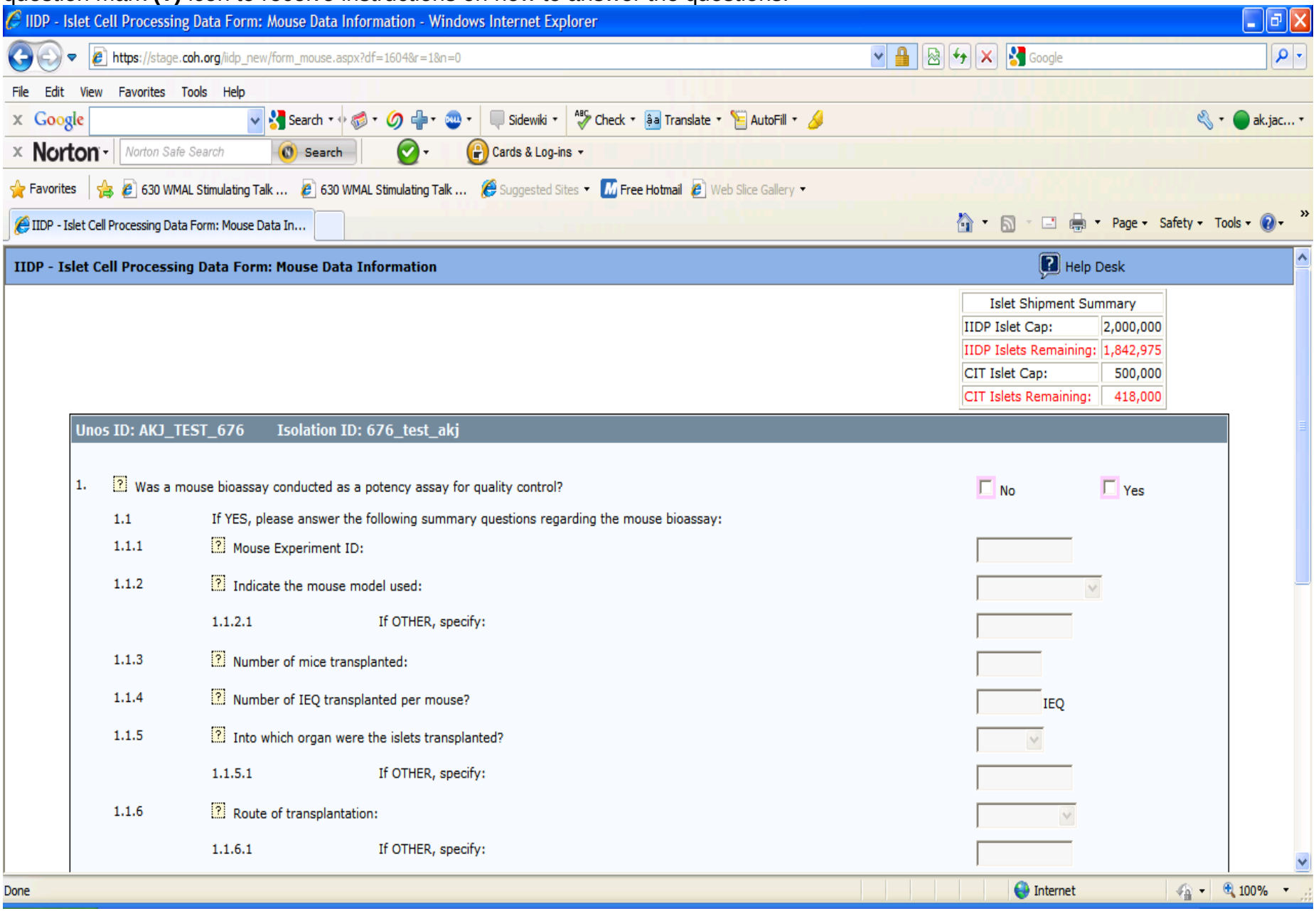
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



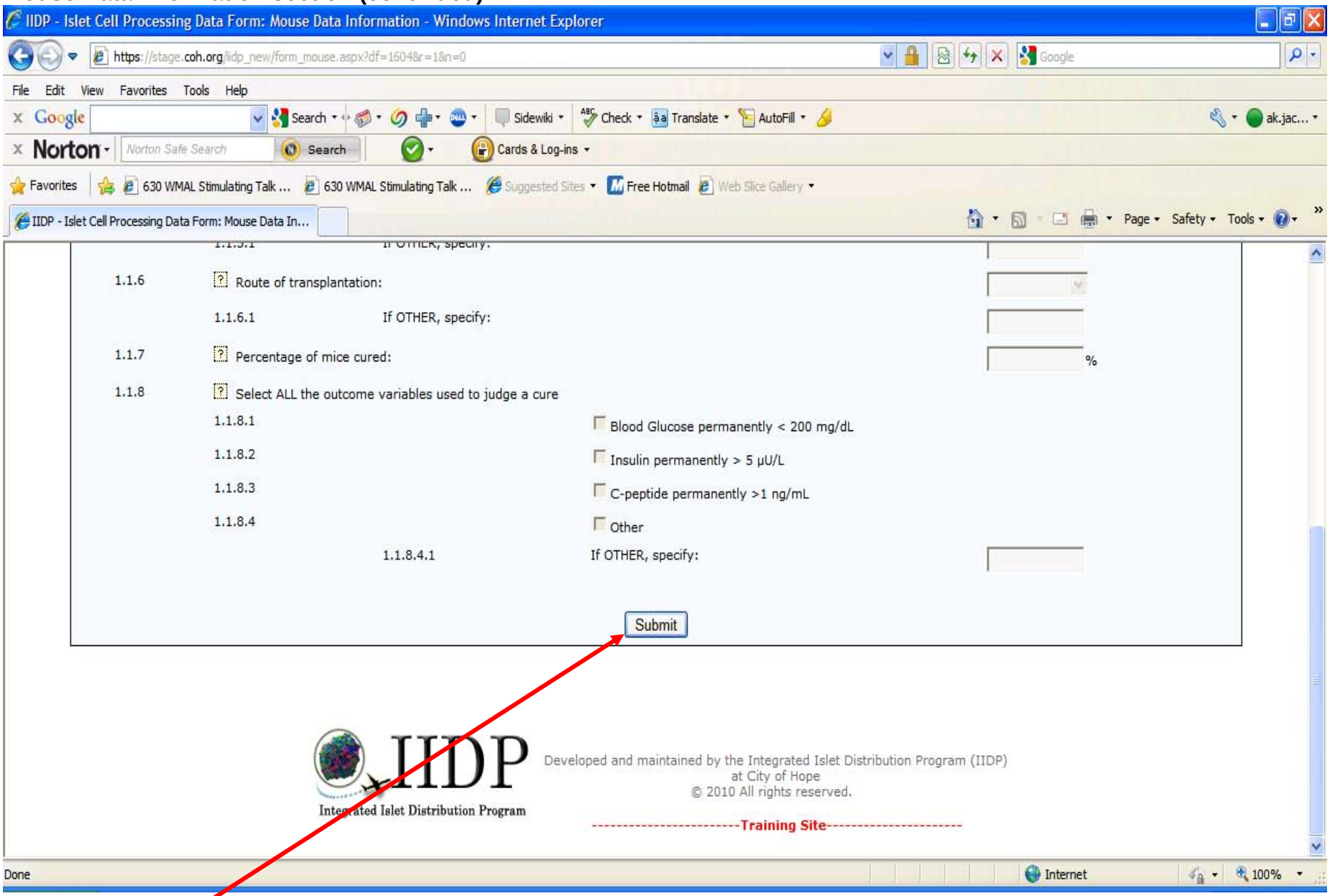
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	Complete	
[Edit]		Mouse Data Information	New	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Mouse Data Information section – Complete the questions in the Mouse Data Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.

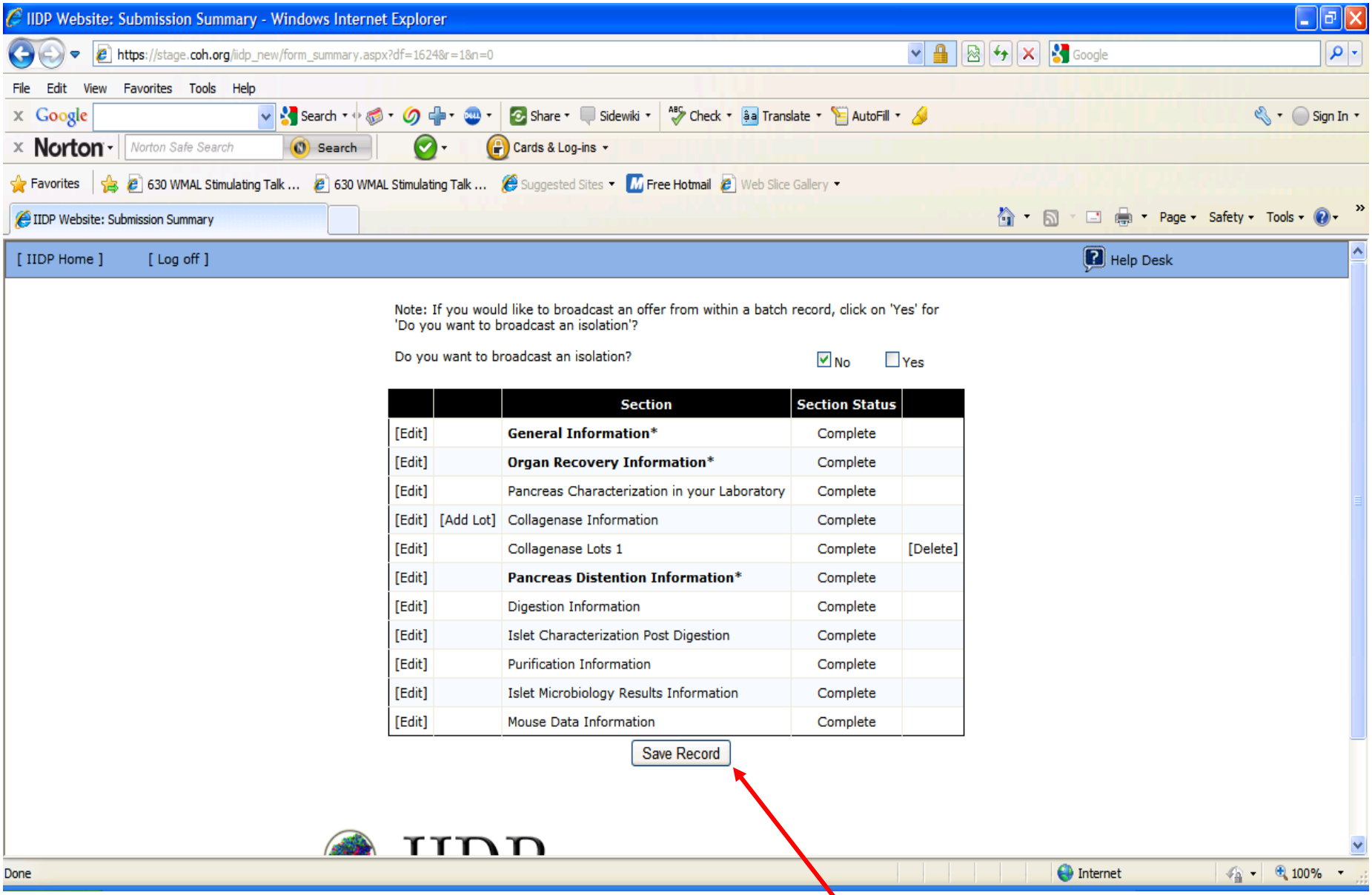


Mouse Data Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.



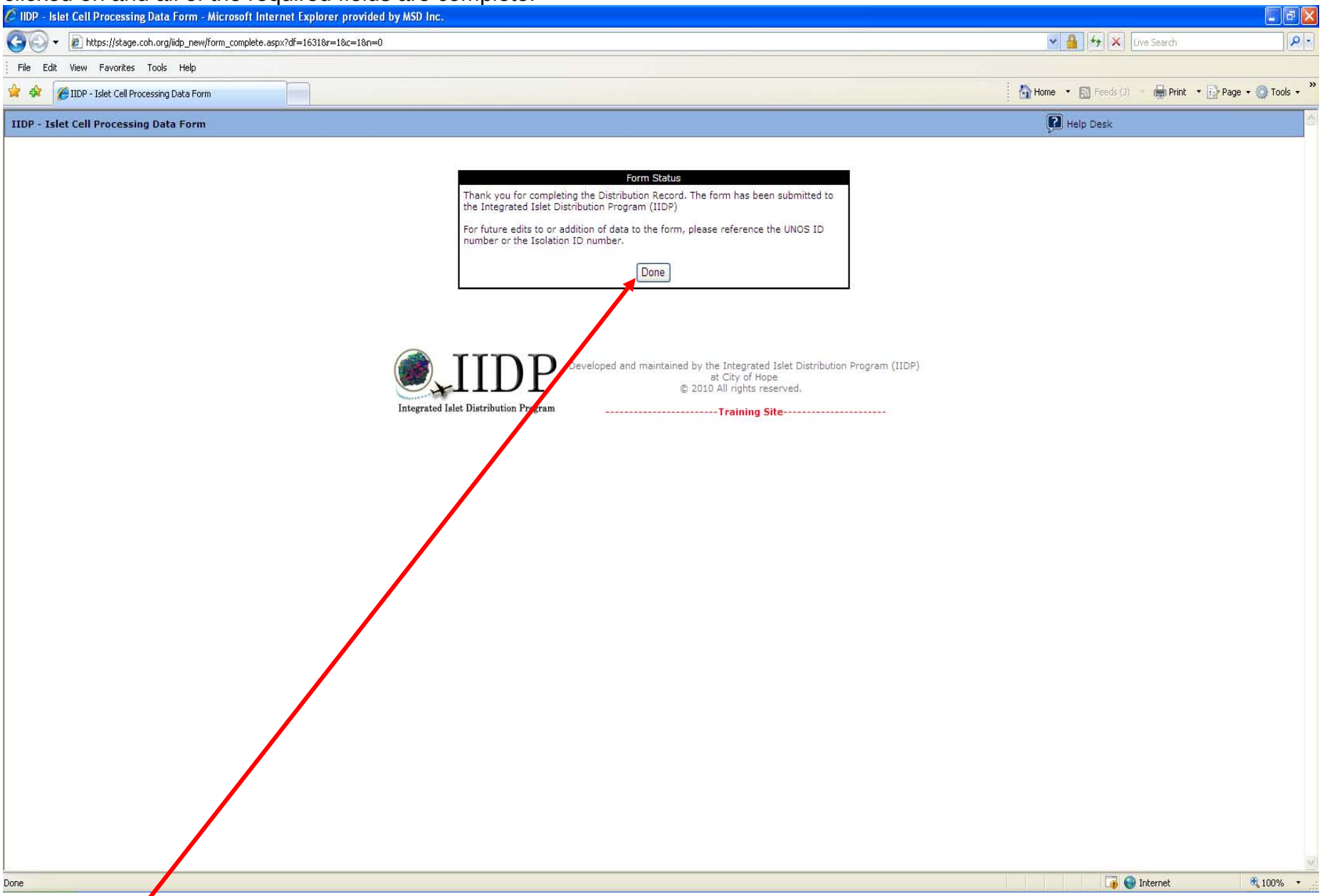
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	Complete	
[Edit]		Mouse Data Information	Complete	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Confirmation screen – Incomplete data fields - The system will display this confirmation message when **[Save Record]** is clicked on and there are required fields that are not complete. **Refer to 7.0 Edit/View an Existing Distribution Record for more detail on editing or adding data to an existing data form.**

Click on **[Done]** and the system will return the user to the Main Page.

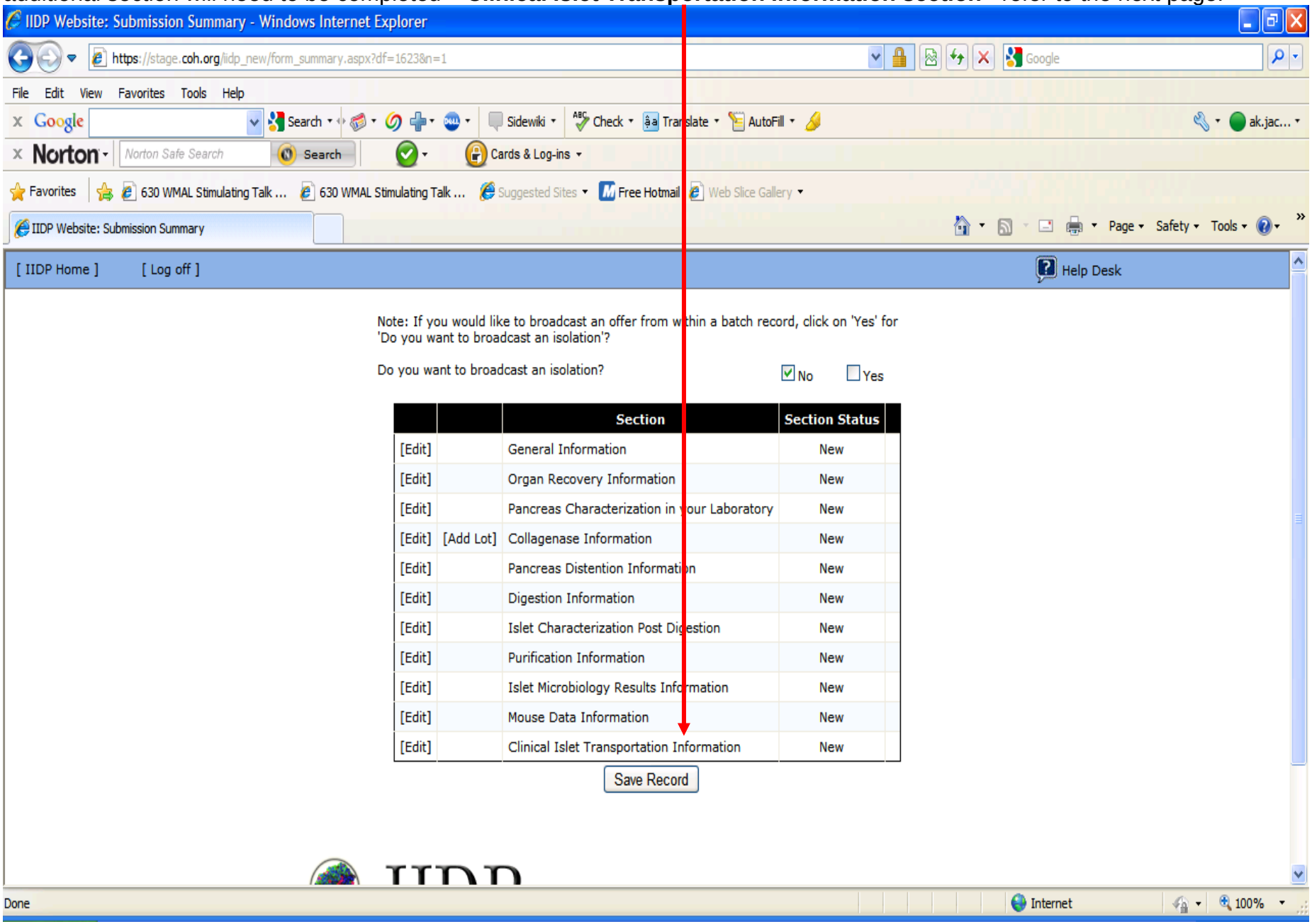
Confirmation screen – Complete Data Fields – The system will display this confirmation message when **[Save Record]** is clicked on and all of the required fields are complete.



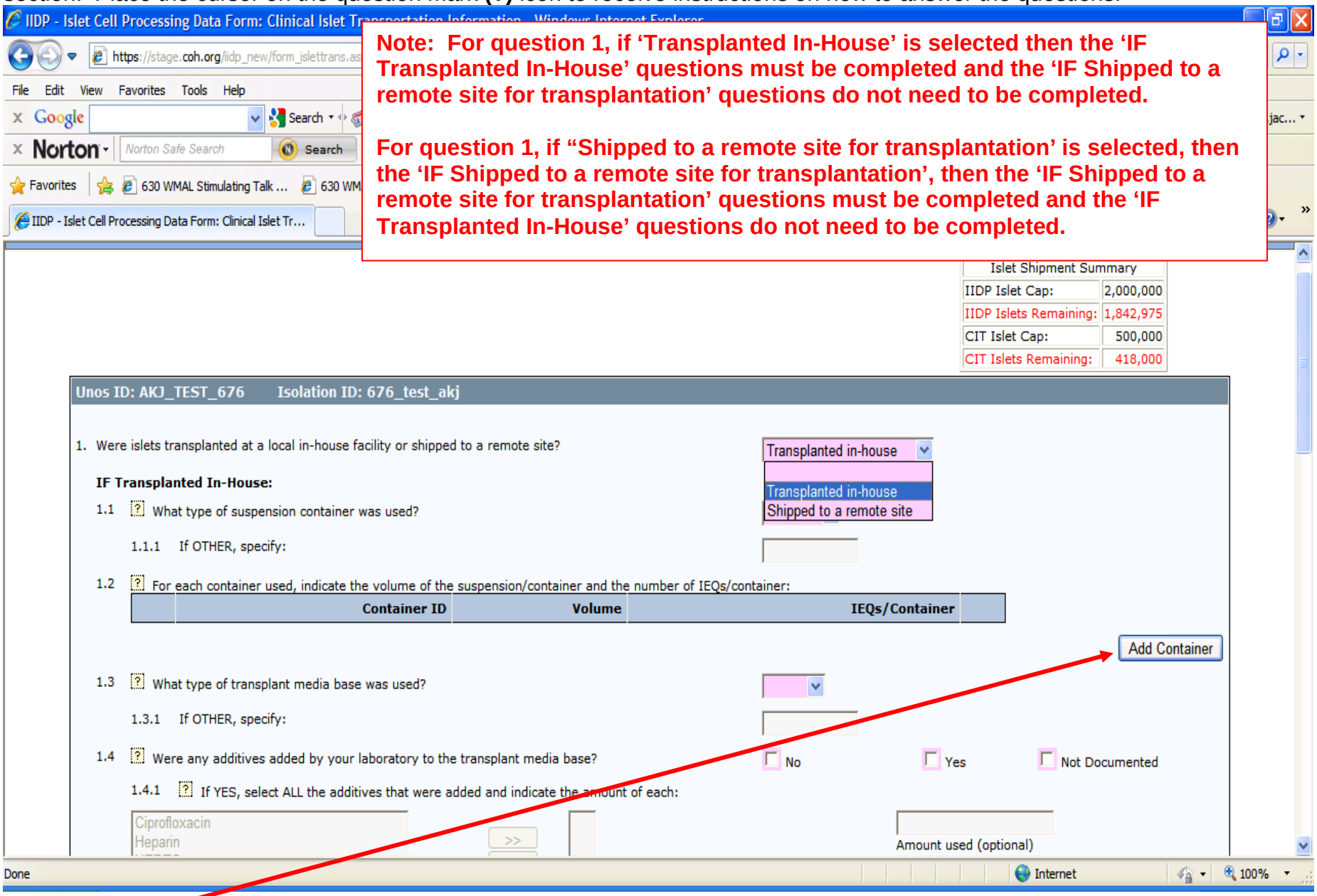
Click on **[Done]** and the system will return the user to the Main Page.

Main Page – Click on any menu option as needed OR click on **[Log off]** to log out of the system.

Addendum – If the Islets had been used for Clinical Transplant (Question 3.2 in the General Information section) then an additional section will need to be completed – **Clinical Islet Transportation Information section** - refer to the next page.

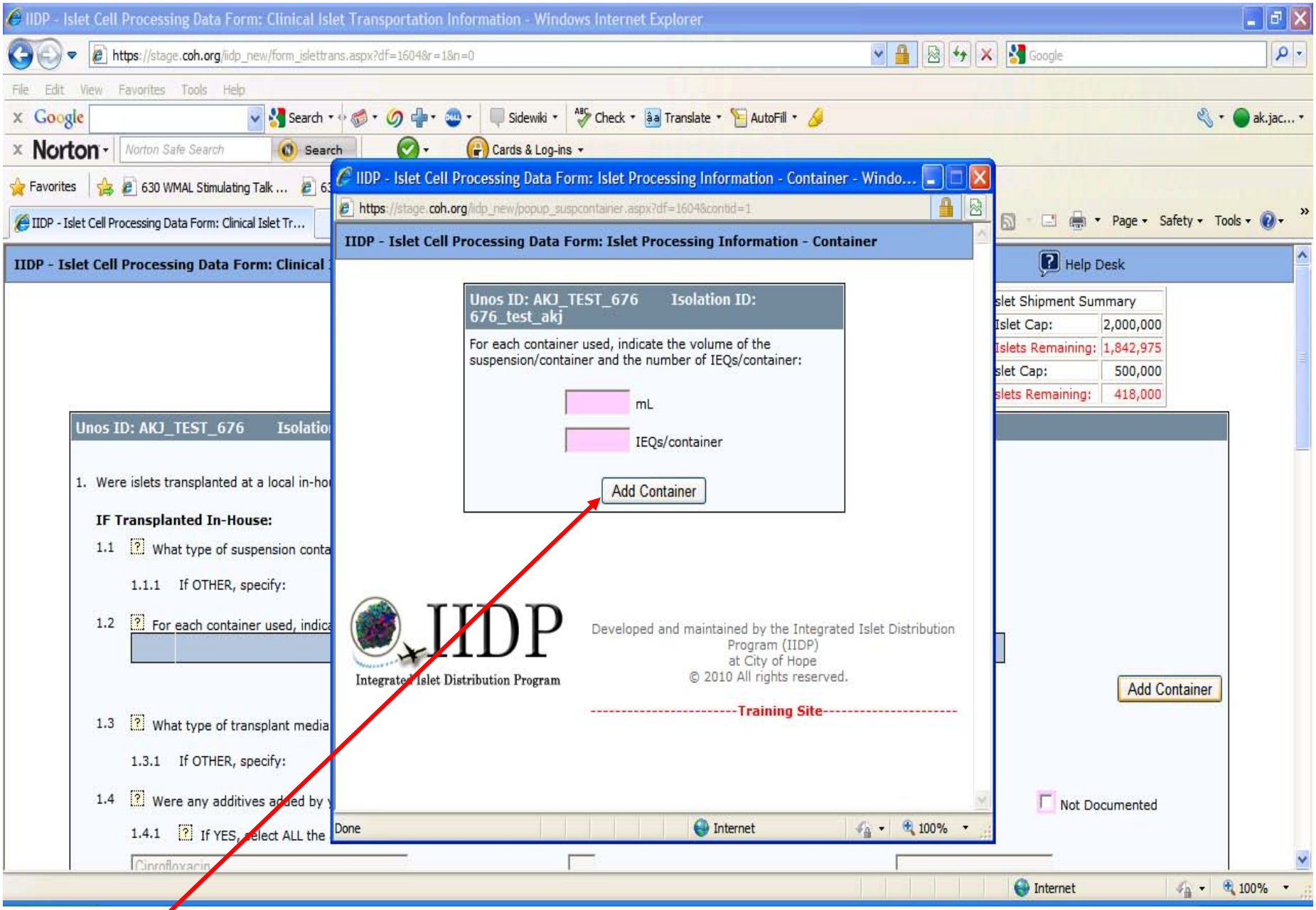


Clinical Islet Transportation Information section – Complete the questions in the Clinical Islet Transportation Information section. Place the cursor on the question mark **(?)** icon to receive instructions on how to answer the questions.



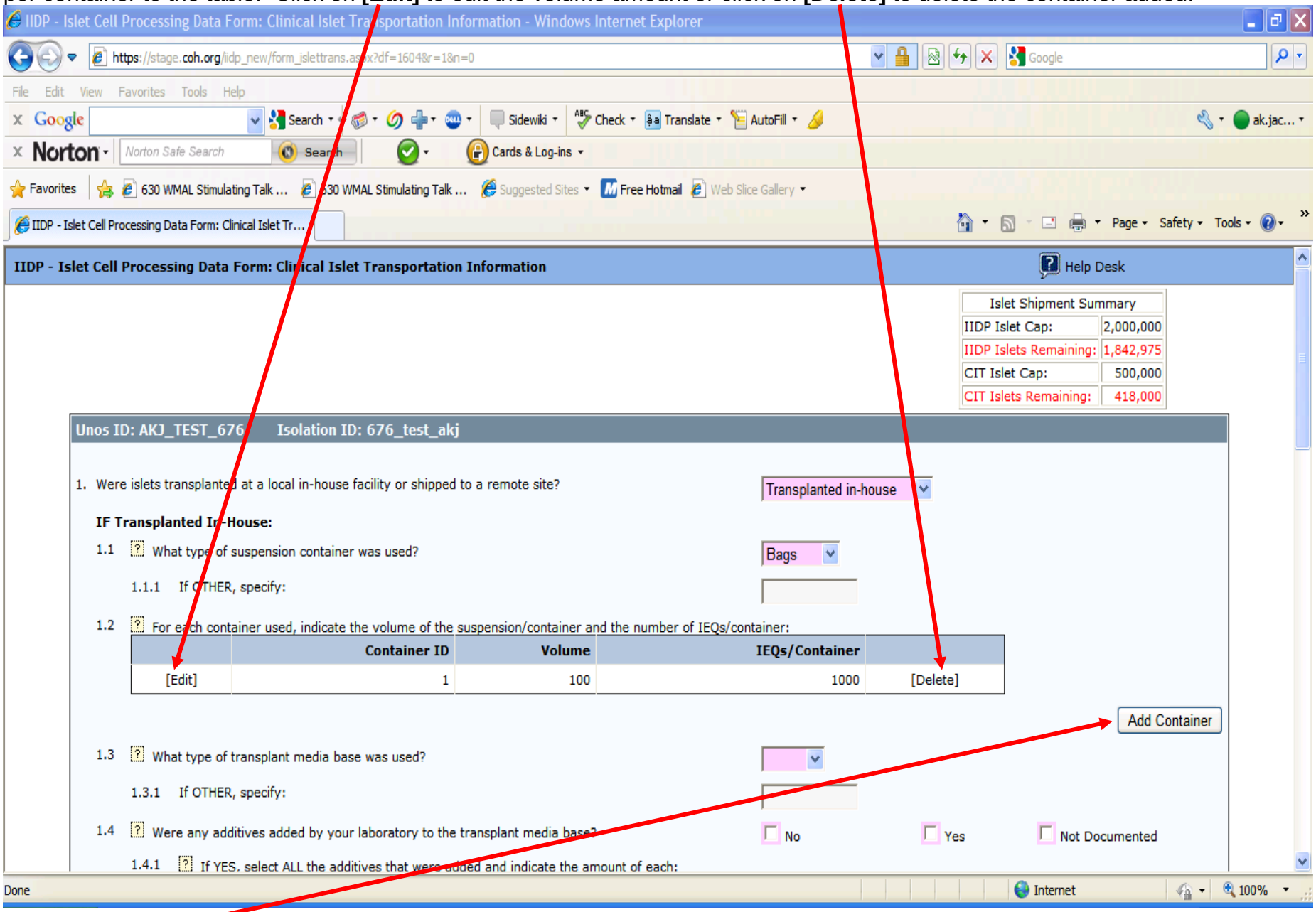
Click on **[Add Container]** to complete the volume information for each suspension container used. Refer to the next page.

Clinical Islet Transportation Information section (continued) - Enter the volume of the suspension container and the IEQs per container.



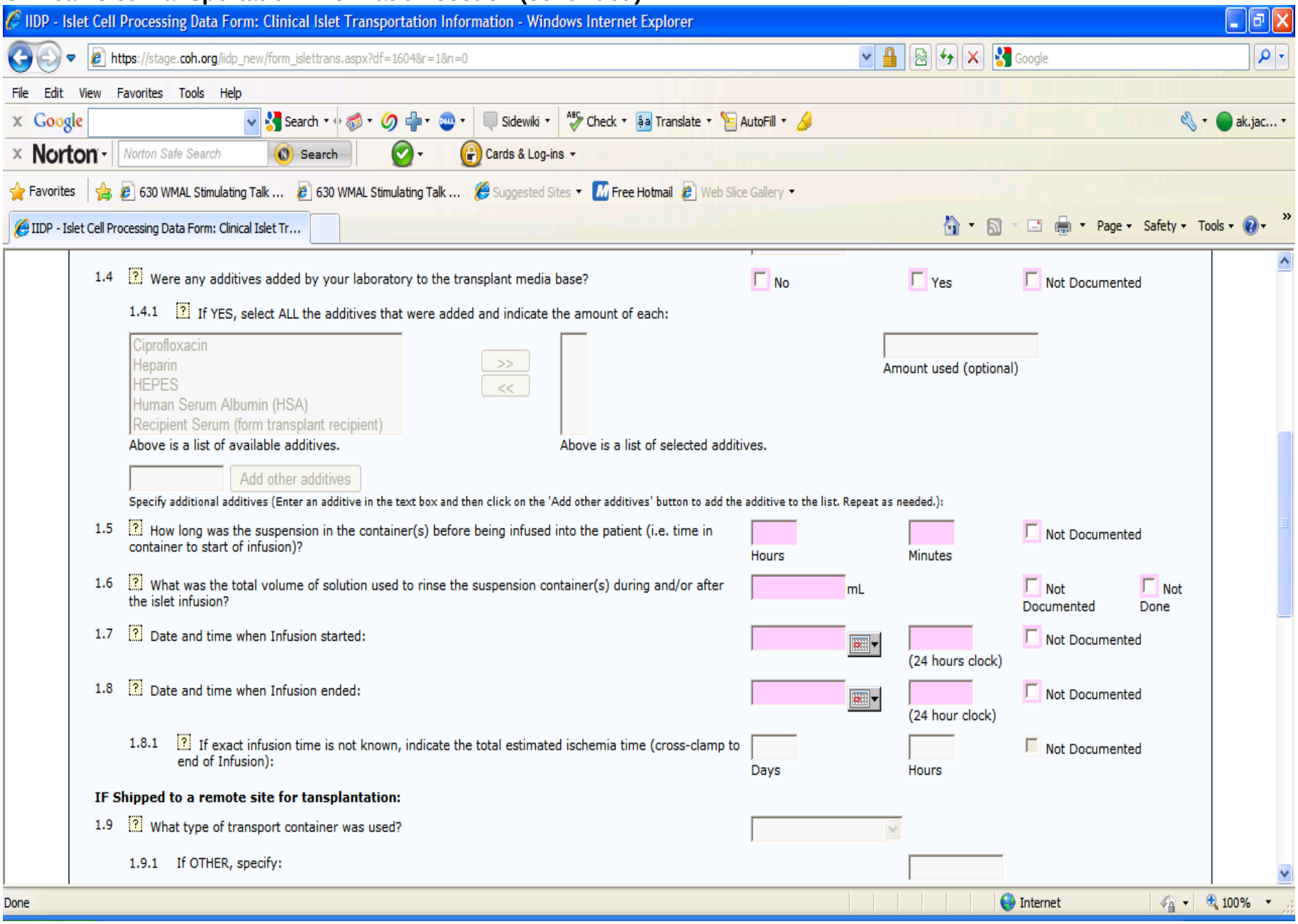
Click on **[Add Container] -** refer to the next page.

Clinical Islet Transportation Information section (continued) – The system adds the suspension container volume and IEQs per container to the table. Click on **[Edit]** to edit the volume amount or click on **[Delete]** to delete the container added.

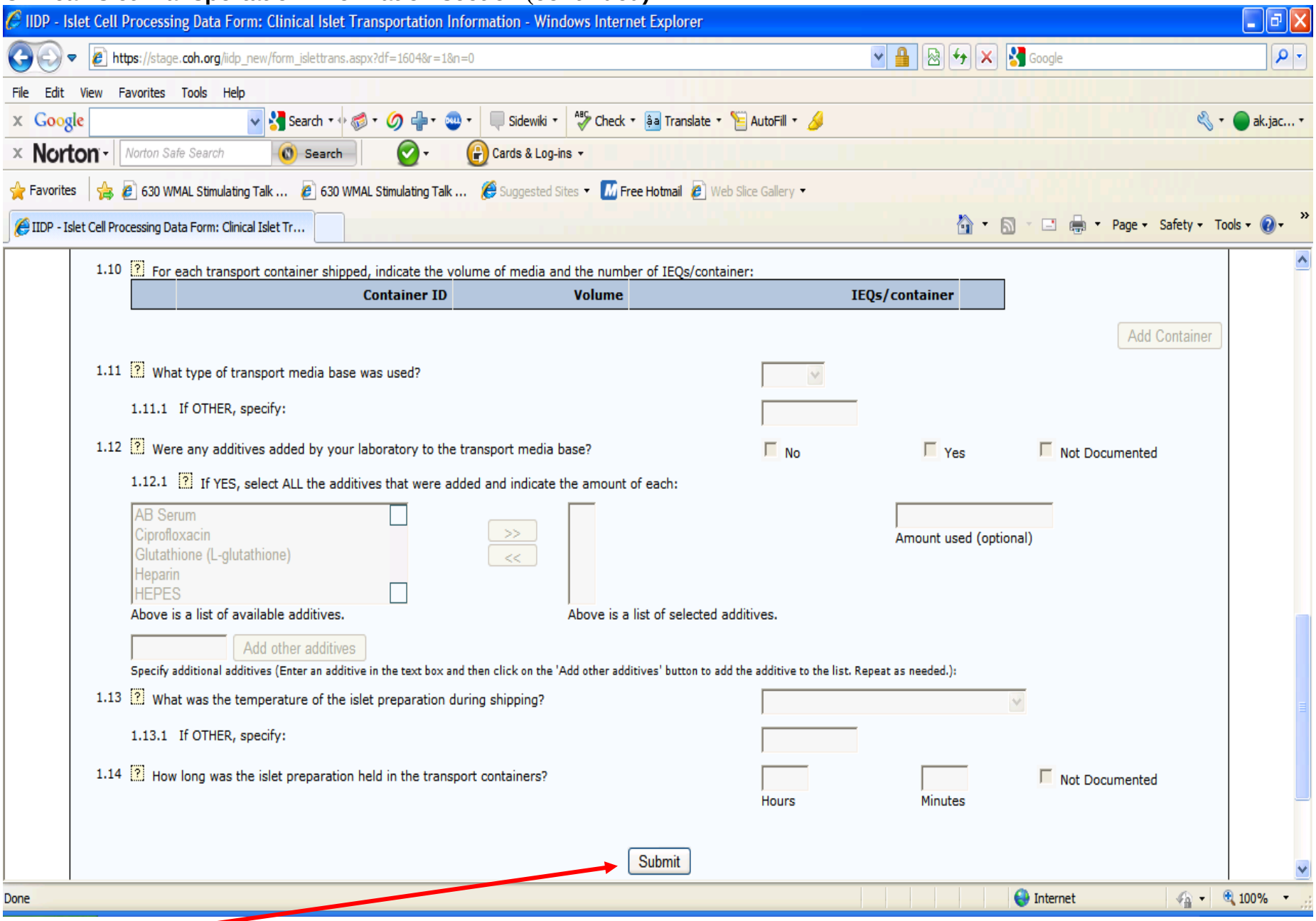


Click on **[Add Container]** to add additional container information as needed OR continue completing the rest of the form.

Clinical Islet Transportation Information section (continued)

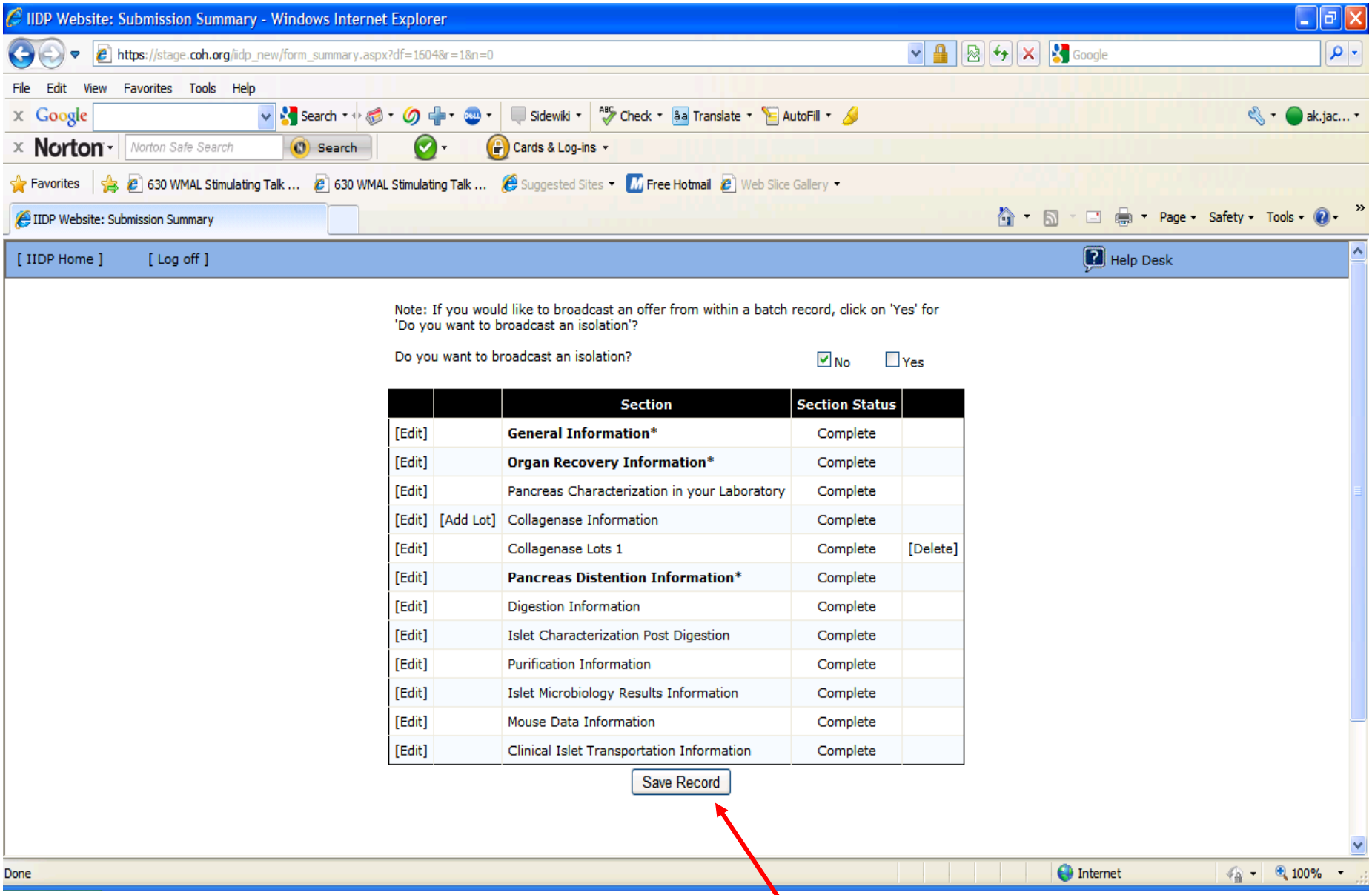


Clinical Islet Transportation Information section (continued)



Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of each section.

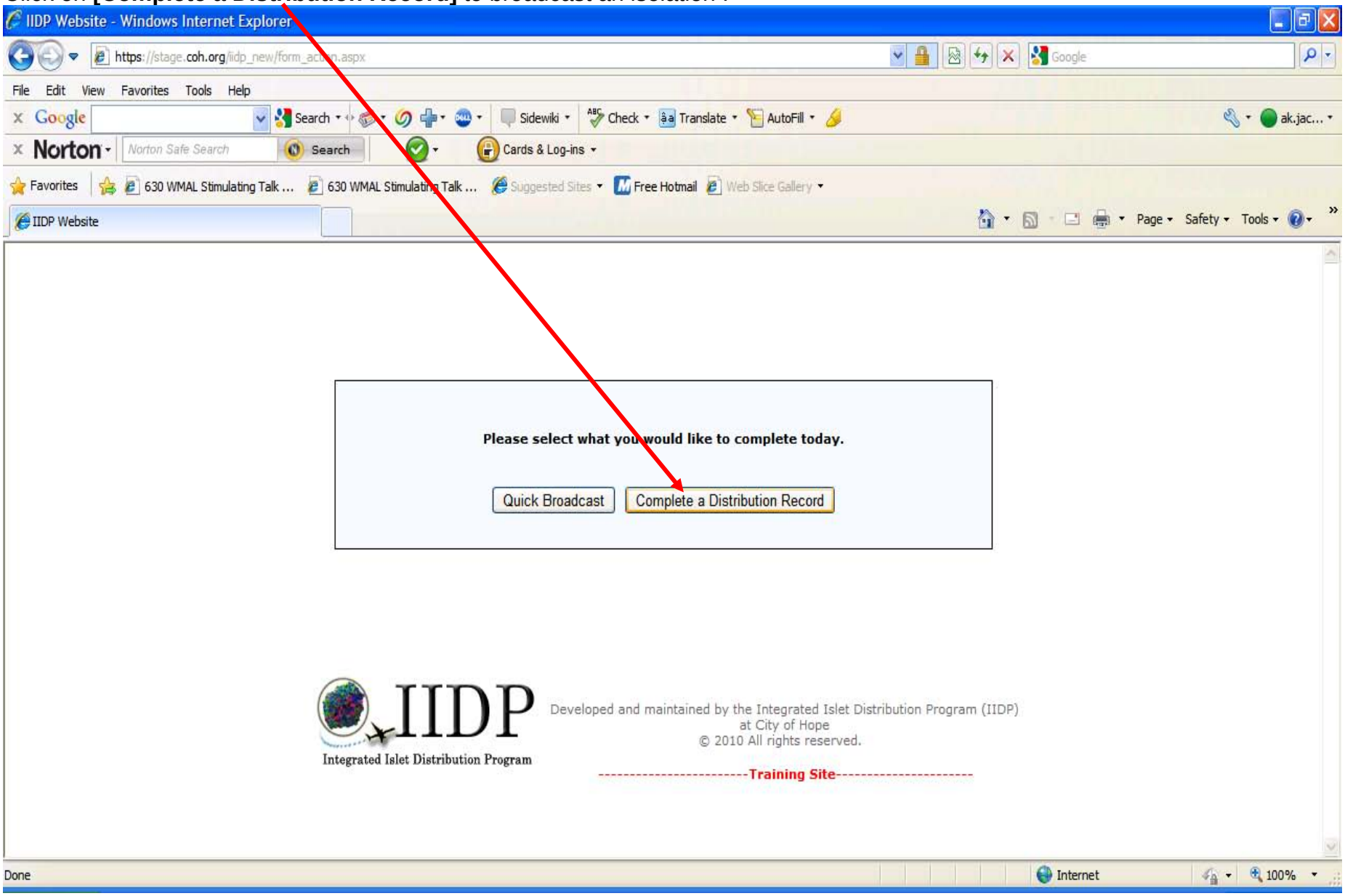


		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	Complete	
[Edit]		Mouse Data Information	Complete	
[Edit]		Clinical Islet Transportation Information	Complete	

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

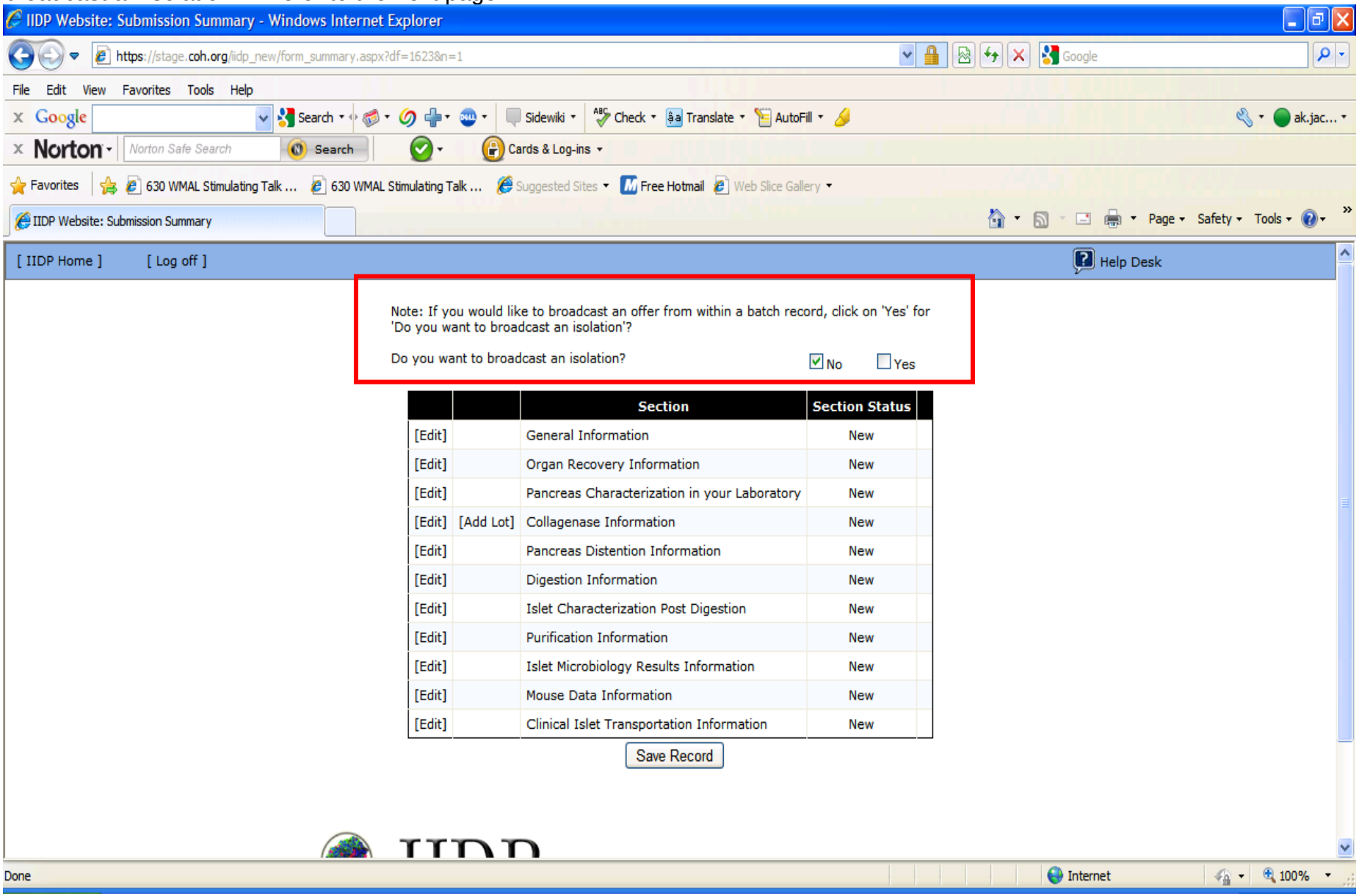
6.0 Broadcast an Isolation from the Distribution Record

Click on **[Complete a Distribution Record]** to broadcast an isolation .

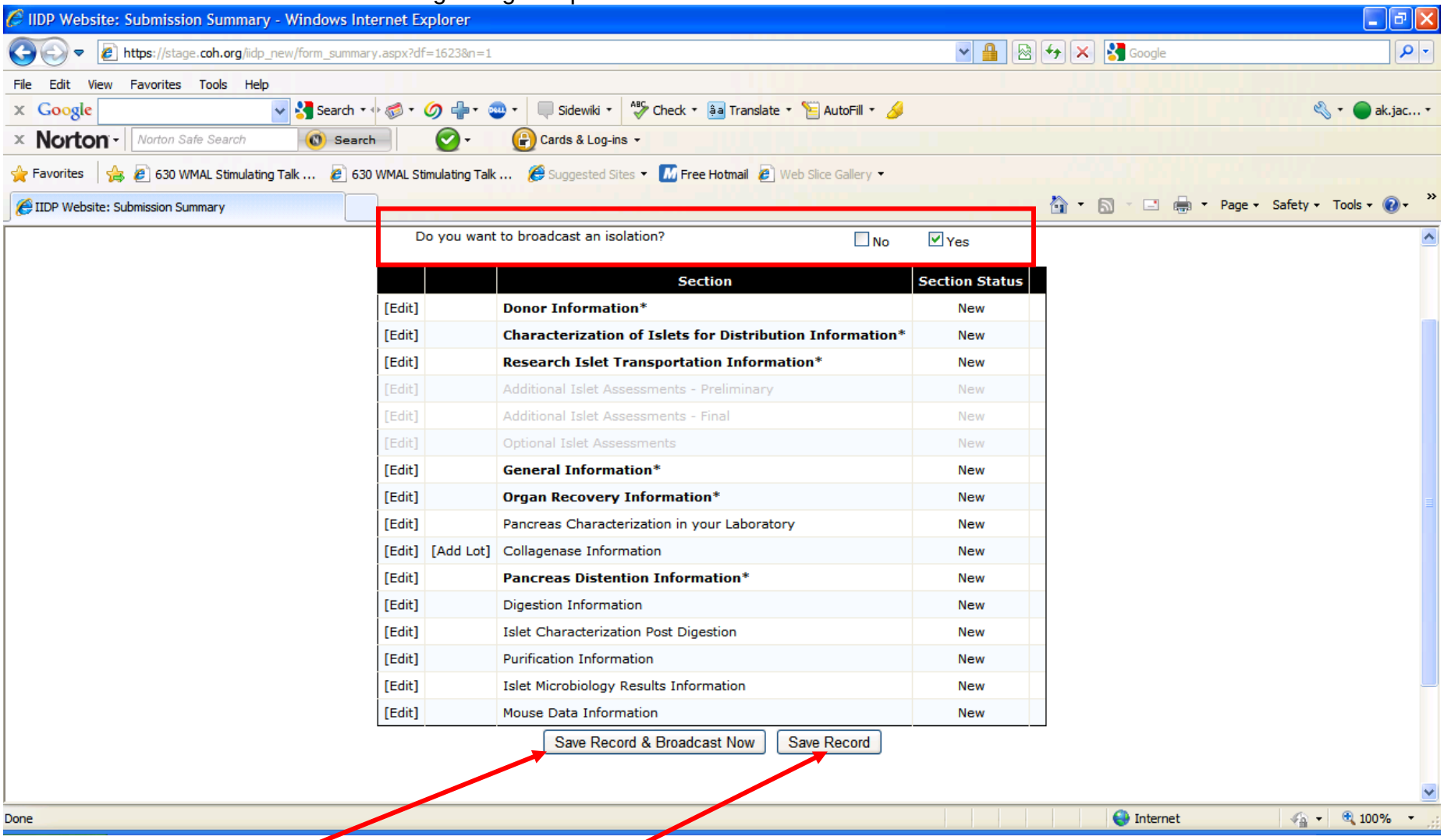


UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit].** Click on **[Cancel]** to return to the Main Page. Refer to pages 11 – 14 for information regarding if a duplicate UNOS ID and/or Isolation ID is entered

This is the default Distribution Record Form Summary Detail Screen that is displayed when **[Complete a Distribution Record]** is selected. In order to broadcast an isolation from within the Distribution Record, 'Yes' must be selected for "Do you want to broadcast an isolation?" - refer to the next page.



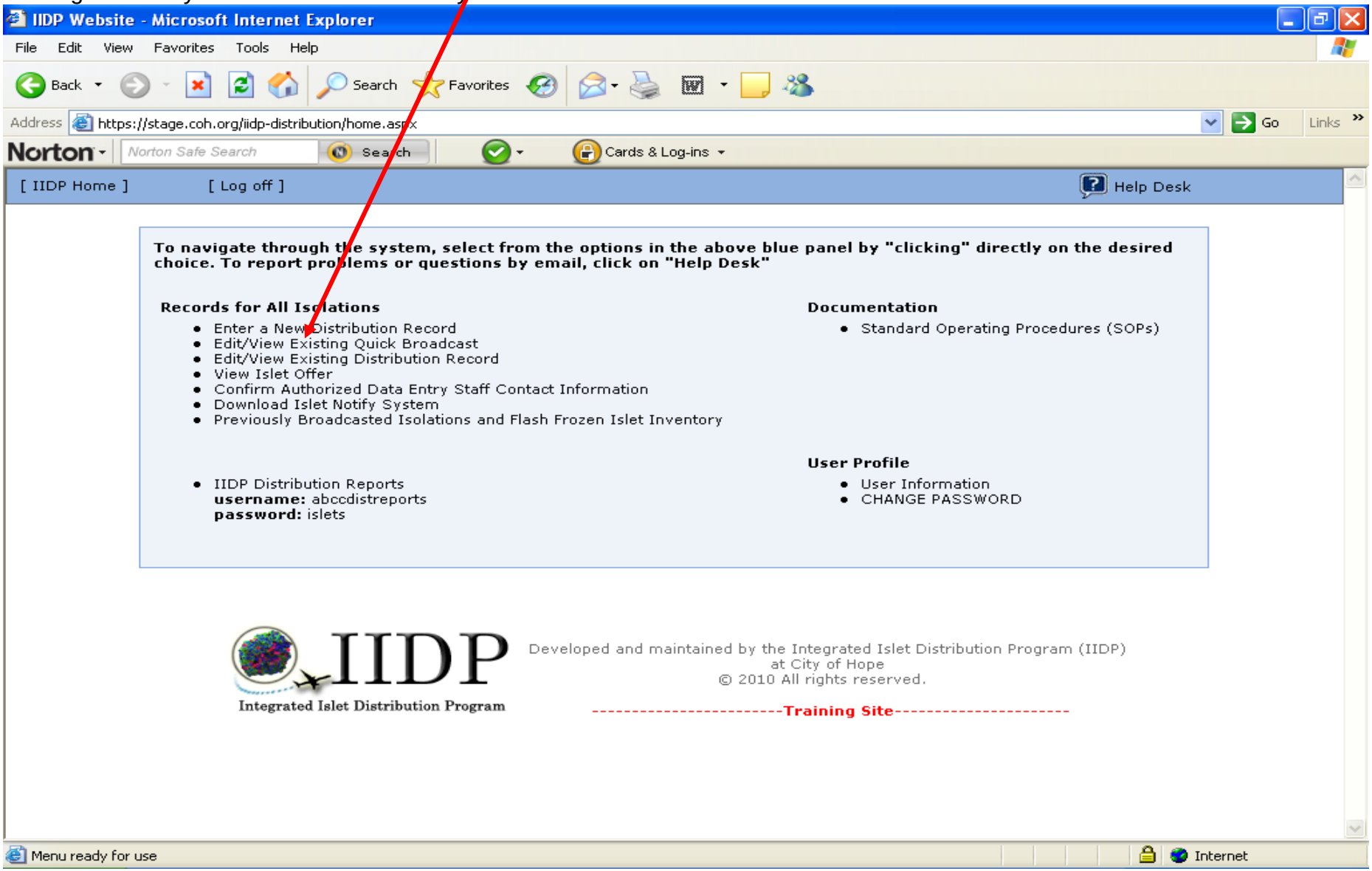
The three (3) required broadcast forms are now displayed in the Summary Detail screen. An isolation can be broadcast within the distribution record at any time as long as the three required broadcast forms have been completed. **Refer to 4.0 Broadcast an Isolation – Quick Broadcast** for information regarding completion of the broadcast forms and **refer to 5.0 Complete a Distribution Record** for information regarding completion of the Distribution Record.



Click on **[Save Record and Broadcast Now]** or **[Save Record]. [Save Record and Broadcast Now]** will save the Distribution Record in the system and will broadcast the isolation – **refer to pages 15 – 34 in 4.0 Broadcast an Isolation – Quick Broadcast. [Save Record]** will save the Distribution Record in the system and will be available to edit/view as needed – **refer to 7.0 Edit/View Existing Distribution Record.**

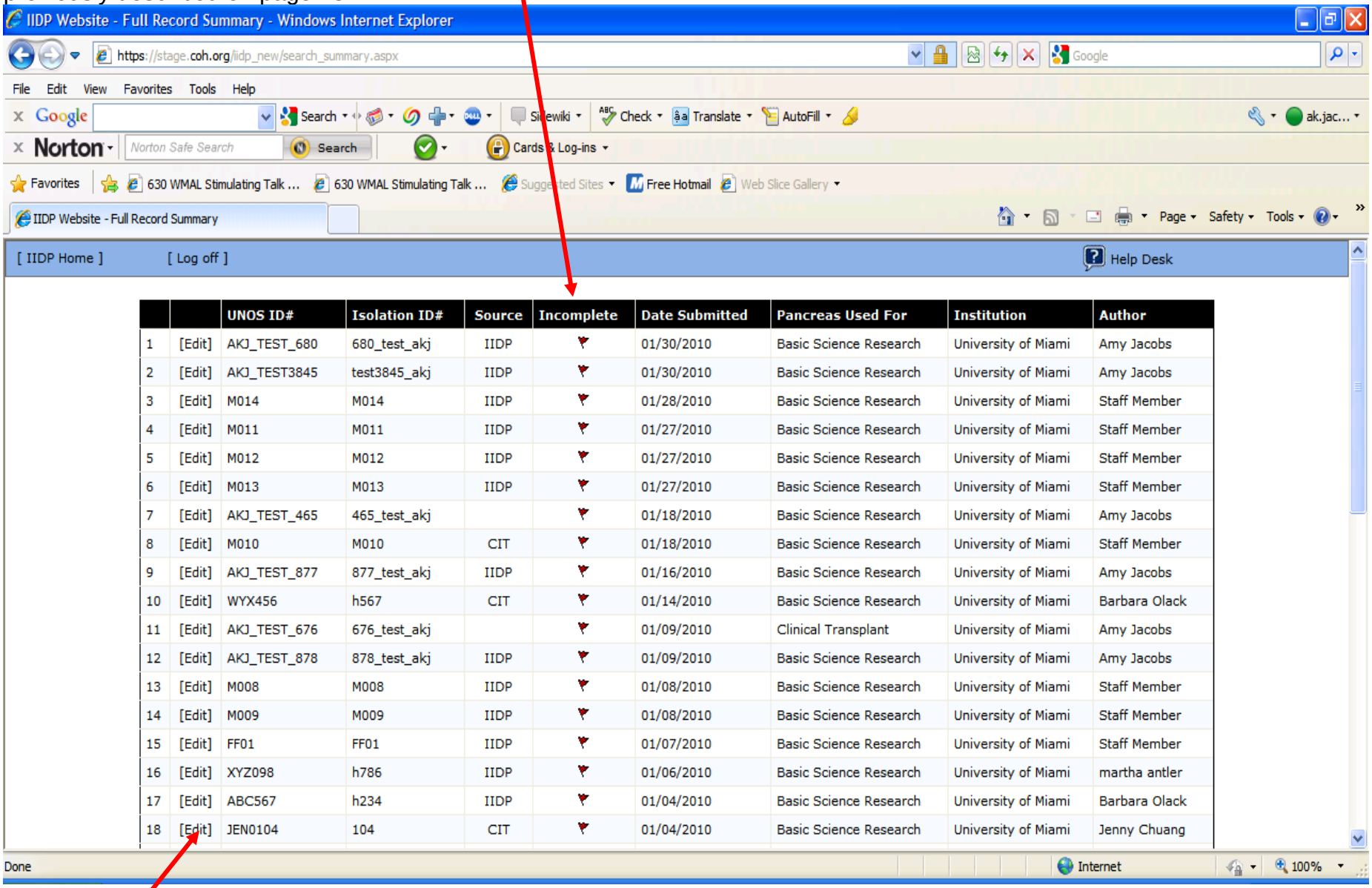
7.0 Edit/View Existing Distribution Record

Main Page - Click on the menu option **[Edit/View existing distribution record]** under **[Records for All Isolations]** to display the existing data entry forms entered in to the system for islet isolations.



The system will then display all of the distribution records entered for your specific institution.

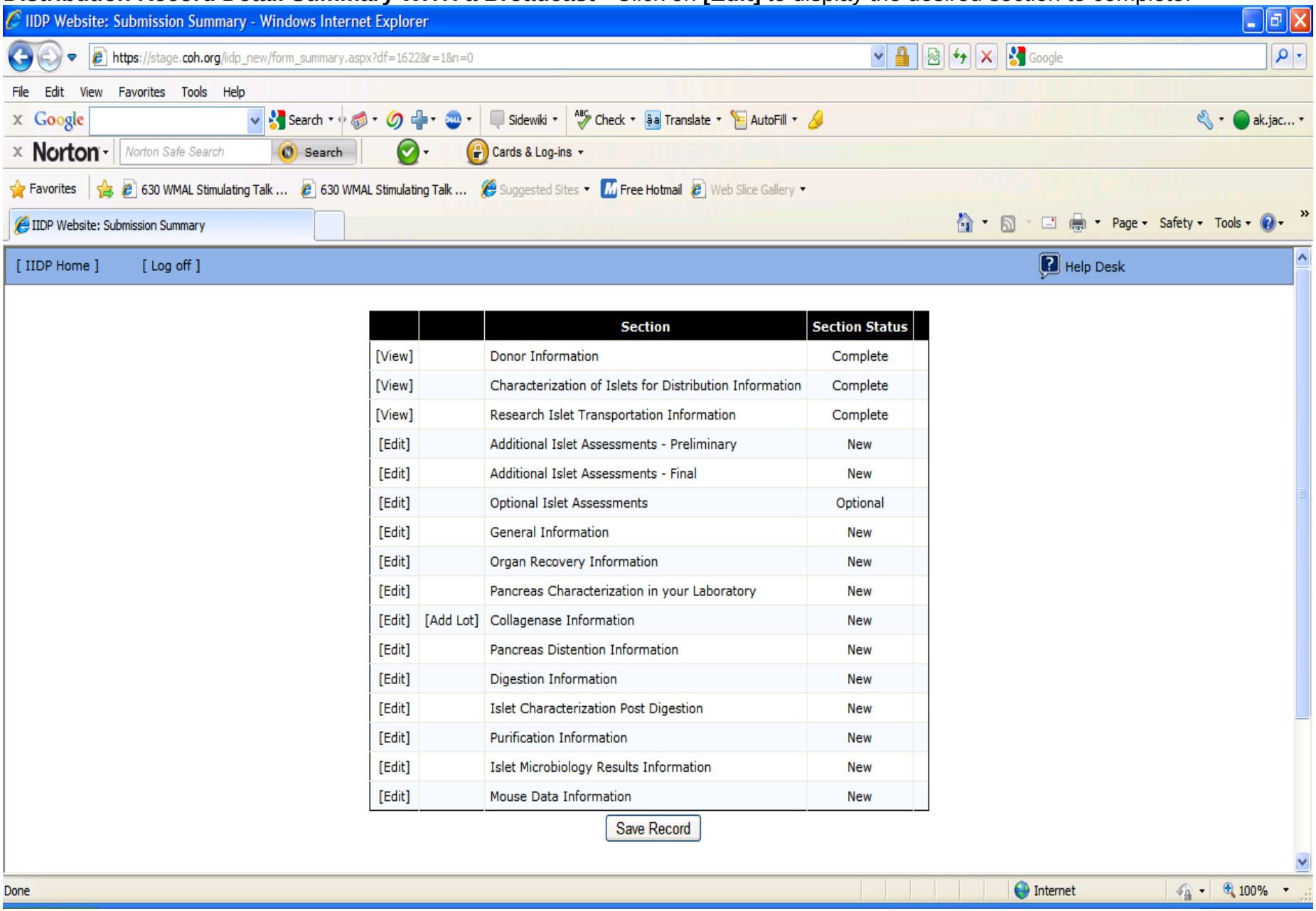
Existing Distribution Records - The system will display the list of Distribution Records that have been entered into the system for your institution. Incomplete forms will be 'flagged'. Click on any of the Headers to sort by - for example the UNOS ID # as previously described on page 13.



		UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author
1	[Edit]	AKJ_TEST_680	680_test_akj	IIDP		01/30/2010	Basic Science Research	University of Miami	Amy Jacobs
2	[Edit]	AKJ_TEST3845	test3845_akj	IIDP		01/30/2010	Basic Science Research	University of Miami	Amy Jacobs
3	[Edit]	M014	M014	IIDP		01/28/2010	Basic Science Research	University of Miami	Staff Member
4	[Edit]	M011	M011	IIDP		01/27/2010	Basic Science Research	University of Miami	Staff Member
5	[Edit]	M012	M012	IIDP		01/27/2010	Basic Science Research	University of Miami	Staff Member
6	[Edit]	M013	M013	IIDP		01/27/2010	Basic Science Research	University of Miami	Staff Member
7	[Edit]	AKJ_TEST_465	465_test_akj			01/18/2010	Basic Science Research	University of Miami	Amy Jacobs
8	[Edit]	M010	M010	CIT		01/18/2010	Basic Science Research	University of Miami	Staff Member
9	[Edit]	AKJ_TEST_877	877_test_akj	IIDP		01/16/2010	Basic Science Research	University of Miami	Amy Jacobs
10	[Edit]	WYX456	h567	CIT		01/14/2010	Basic Science Research	University of Miami	Barbara Olack
11	[Edit]	AKJ_TEST_676	676_test_akj			01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs
12	[Edit]	AKJ_TEST_878	878_test_akj	IIDP		01/09/2010	Basic Science Research	University of Miami	Amy Jacobs
13	[Edit]	M008	M008	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
14	[Edit]	M009	M009	IIDP		01/08/2010	Basic Science Research	University of Miami	Staff Member
15	[Edit]	FF01	FF01	IIDP		01/07/2010	Basic Science Research	University of Miami	Staff Member
16	[Edit]	XYZ098	h786	IIDP		01/06/2010	Basic Science Research	University of Miami	martha antler
17	[Edit]	ABC567	h234	IIDP		01/04/2010	Basic Science Research	University of Miami	Barbara Olack
18	[Edit]	JEN0104	104	CIT		01/04/2010	Basic Science Research	University of Miami	Jenny Chuang

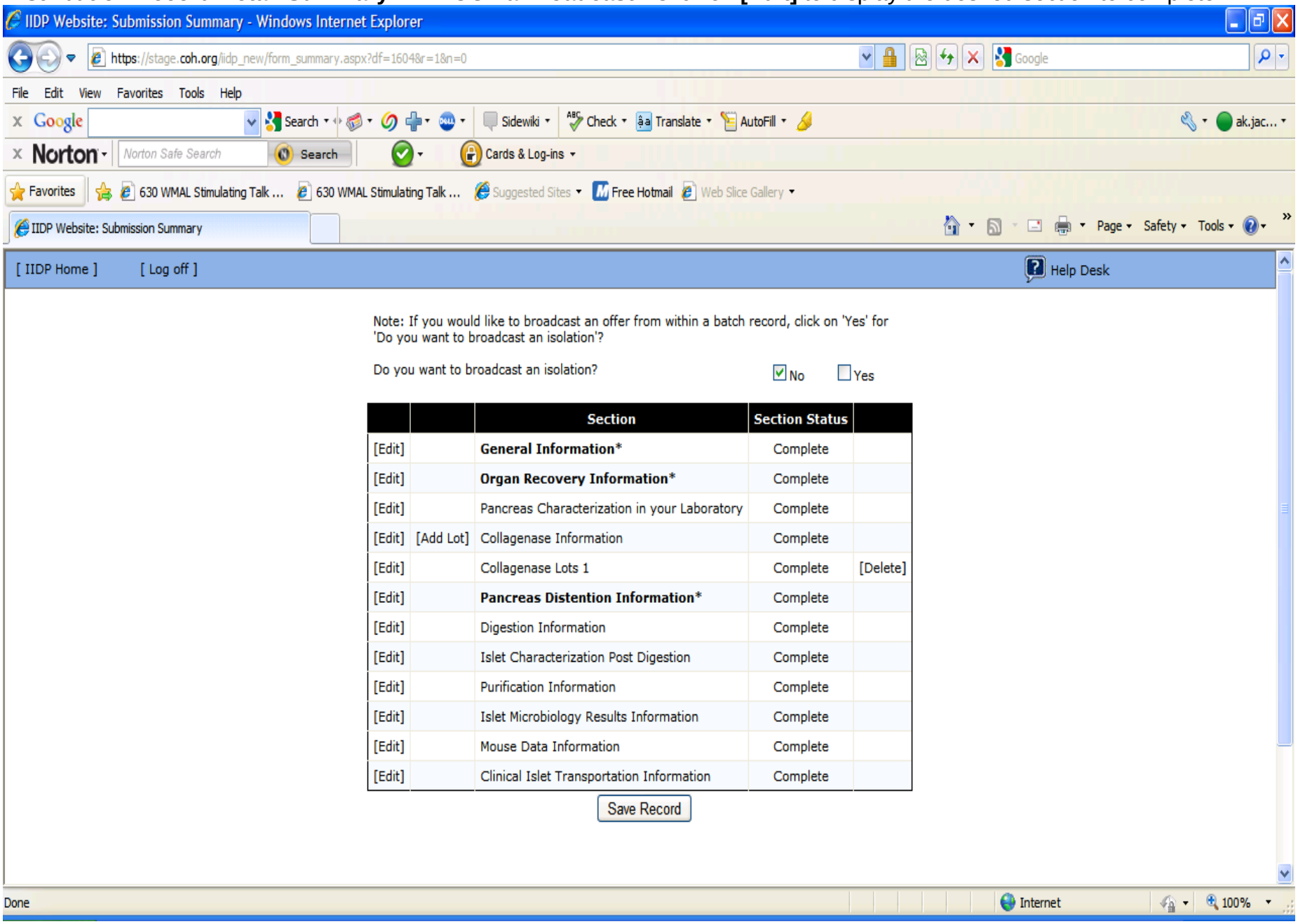
Click on **[Edit]** of the desired Distribution Record to edit and/or add data to the form. The system will display the Distribution Record Detail Summary screen for the user to select the section(s) to edit and/or add data.

Distribution Record Detail Summary WITH a Broadcast - Click on **[Edit]** to display the desired section to complete.



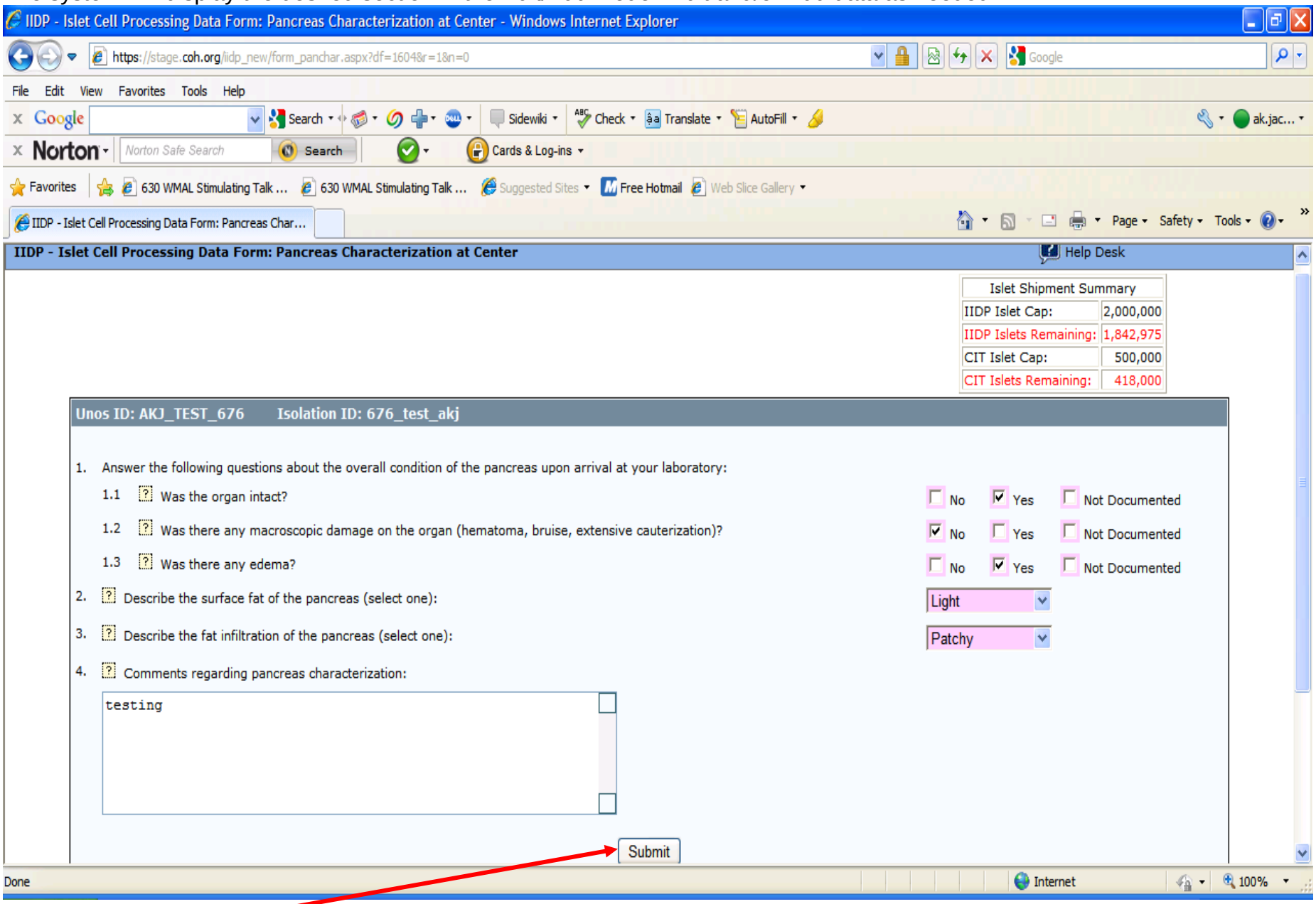
		Section	Section Status
[View]		Donor Information	Complete
[View]		Characterization of Islets for Distribution Information	Complete
[View]		Research Islet Transportation Information	Complete
[Edit]		Additional Islet Assessments - Preliminary	New
[Edit]		Additional Islet Assessments - Final	New
[Edit]		Optional Islet Assessments	Optional
[Edit]		General Information	New
[Edit]		Organ Recovery Information	New
[Edit]		Pancreas Characterization in your Laboratory	New
[Edit]	[Add Lot]	Collagenase Information	New
[Edit]		Pancreas Distention Information	New
[Edit]		Digestion Information	New
[Edit]		Islet Characterization Post Digestion	New
[Edit]		Purification Information	New
[Edit]		Islet Microbiology Results Information	New
[Edit]		Mouse Data Information	New

Distribution Record Detail Summary WITHOUT a Broadcast - Click on **[Edit]** to display the desired section to complete.



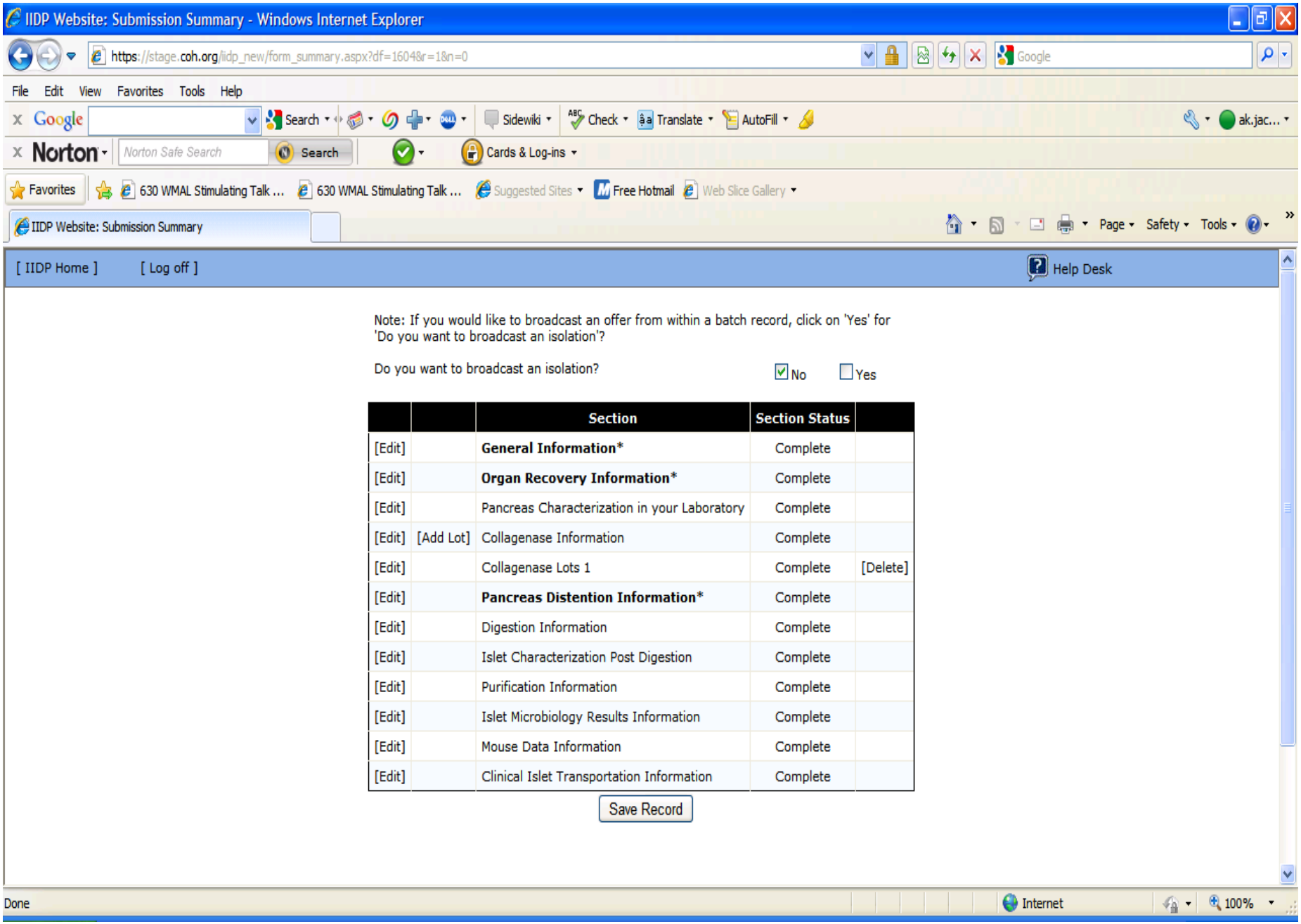
		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	Complete	
[Edit]		Mouse Data Information	Complete	
[Edit]		Clinical Islet Transportation Information	Complete	

The system will display the desired section in the Edit/Add Mode. Edit and/or Add data as needed.



Click on **[Submit]** to submit the edits and/or additions to the system. The system will return the user to the Distribution Record Detail Summary.

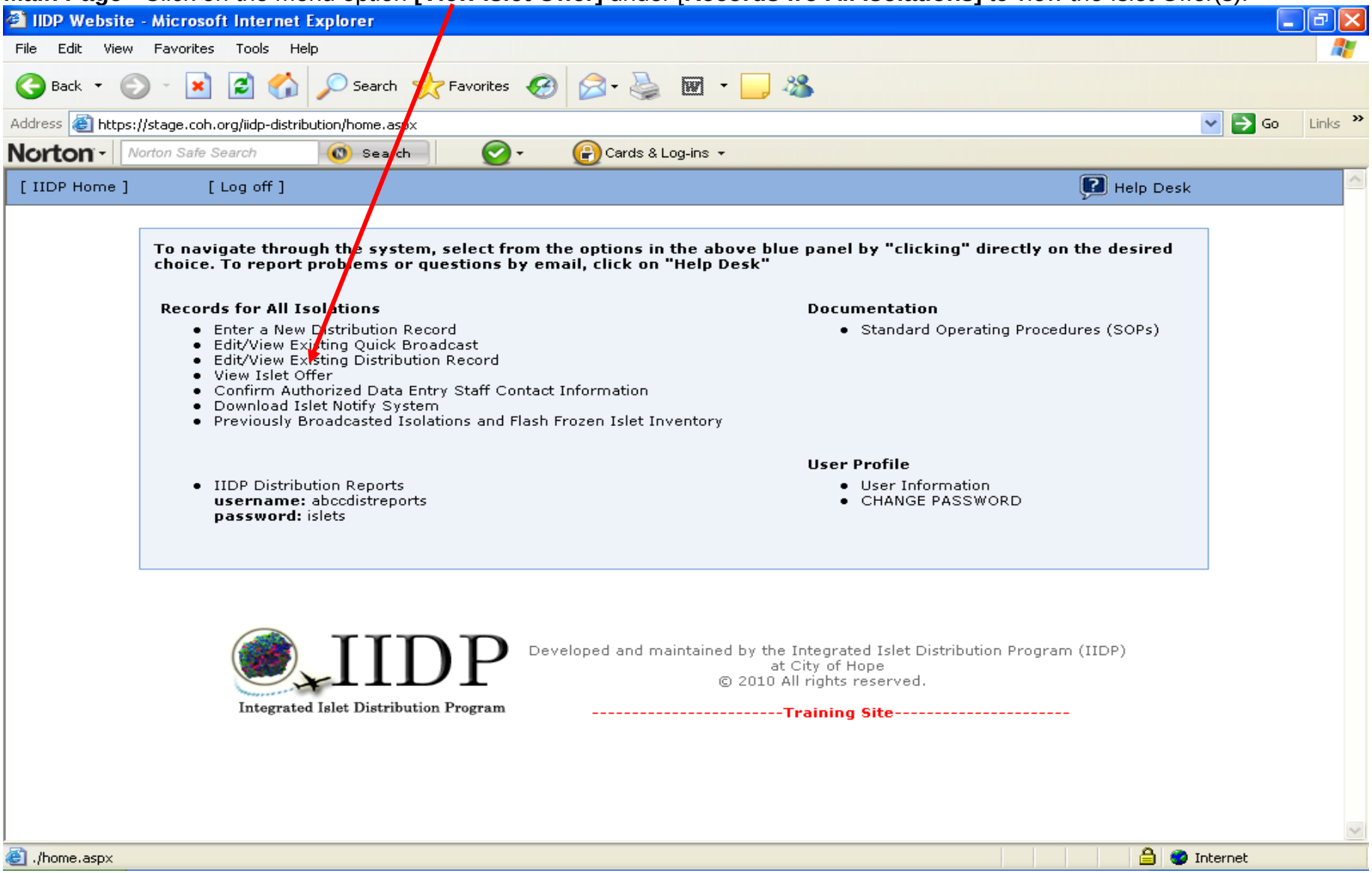
Distribution Record Detail Summary – Repeat the process as needed to edit and/or add data to the Distribution Record sections.



		Section	Section Status	
[Edit]		**General Information***	Complete	
[Edit]		**Organ Recovery Information***	Complete	
[Edit]		Pancreas Characterization in your Laboratory	Complete	
[Edit]	[Add Lot]	Collagenase Information	Complete	
[Edit]		Collagenase Lots 1	Complete	[Delete]
[Edit]		**Pancreas Distention Information***	Complete	
[Edit]		Digestion Information	Complete	
[Edit]		Islet Characterization Post Digestion	Complete	
[Edit]		Purification Information	Complete	
[Edit]		Islet Microbiology Results Information	Complete	
[Edit]		Mouse Data Information	Complete	
[Edit]		Clinical Islet Transportation Information	Complete	

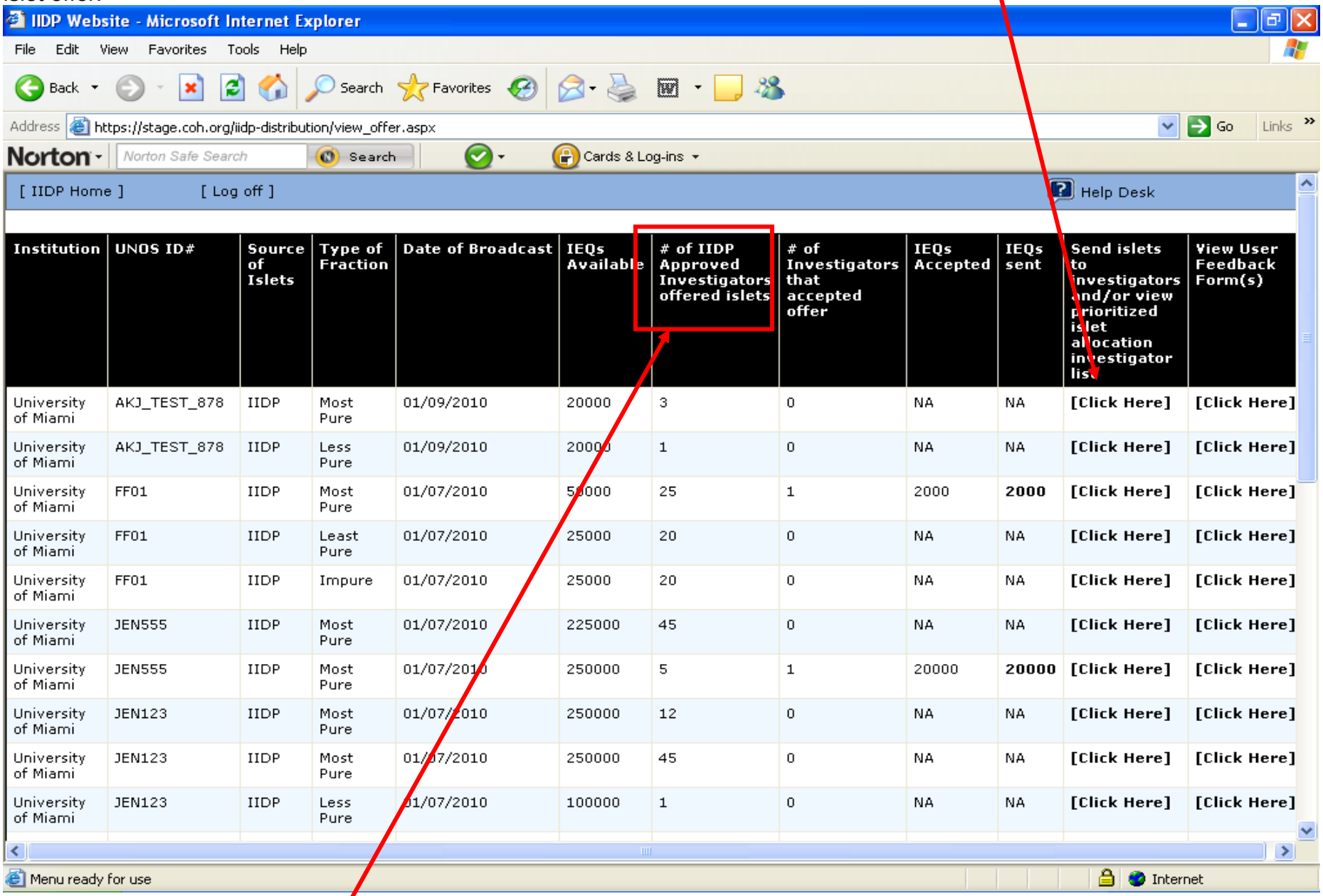
8.0 View Islet Offer

Main Page - Click on the menu option **[View Islet Offer]** under [**Records fro All Isolations]** to view the Islet Offer(s).



The system will then display the Islet Offer(s) – refer to the next page.

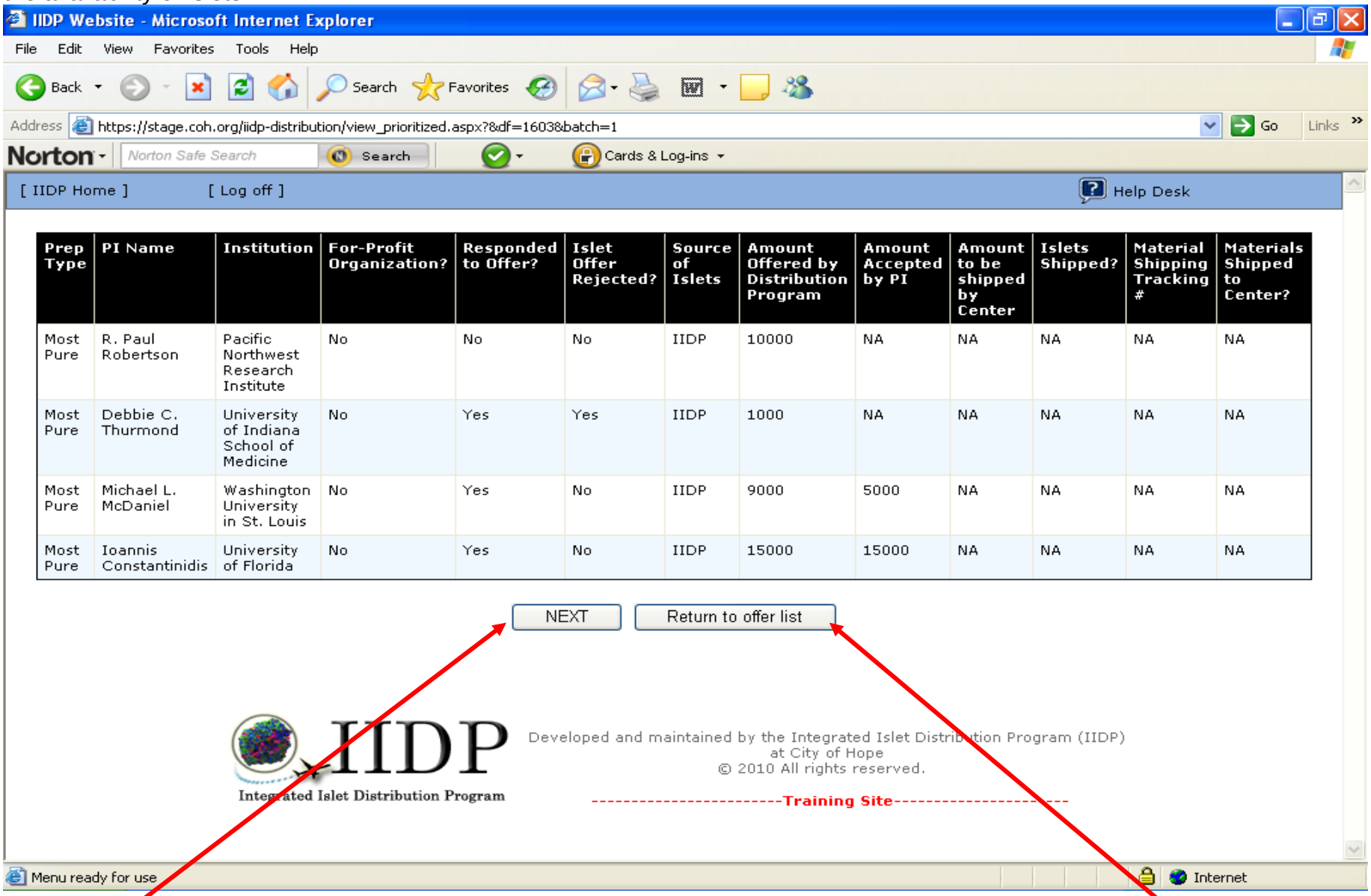
View Islet Offer – The system displays all of the islet offers that are in the system. Click on **[Click Here]** to display the designated islet offer.



Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	View User Feedback Form(s)
University of Miami	AKJ_TEST_878	IIDP	Most Pure	01/09/2010	20000	3	0	NA	NA	[Click Here]	[Click Here]
University of Miami	AKJ_TEST_878	IIDP	Less Pure	01/09/2010	20000	1	0	NA	NA	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Most Pure	01/07/2010	50000	25	1	2000	**2000**	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Least Pure	01/07/2010	25000	20	0	NA	NA	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Impure	01/07/2010	25000	20	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN555	IIDP	Most Pure	01/07/2010	225000	45	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN555	IIDP	Most Pure	01/07/2010	250000	5	1	20000	**20000**	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Most Pure	01/07/2010	250000	12	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Most Pure	01/07/2010	250000	45	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Less Pure	01/07/2010	100000	1	0	NA	NA	[Click Here]	[Click Here]

[# of IIDP Approved Basic Science Investigators offered islets] indicates the number of PIs who received the offer – whether the offer was sent to a predetermined number (e.g., seven (7) PIs) or if the offer was sent to all of the PIs (e.g., Mass Offer).

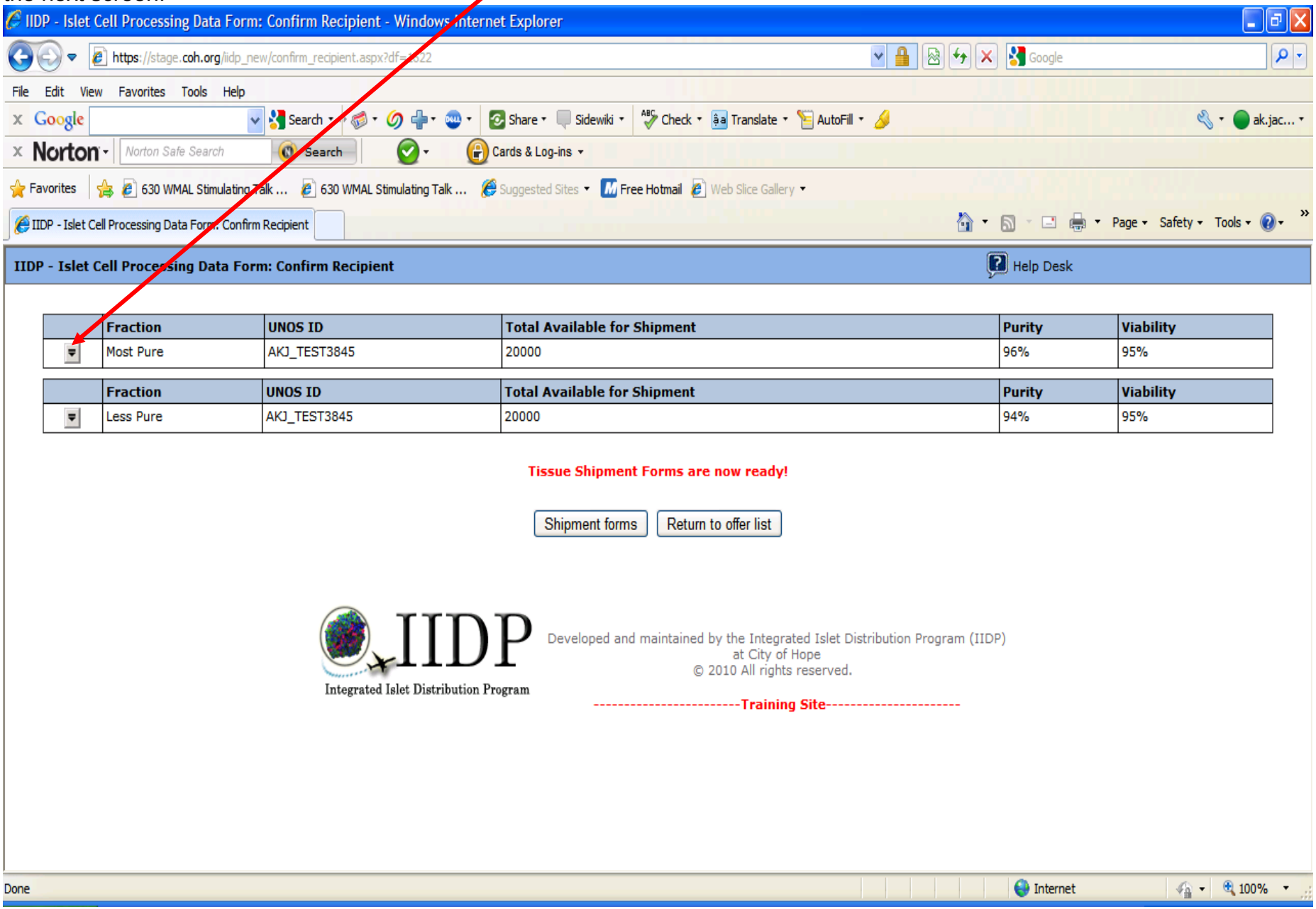
Islet Offer screen - The system will display the islet offer of the designated UNOS ID and Type of Fraction. The system will display the names and associated information of the Principal Investigators who have been sent the broadcast message regarding the availability of islets.



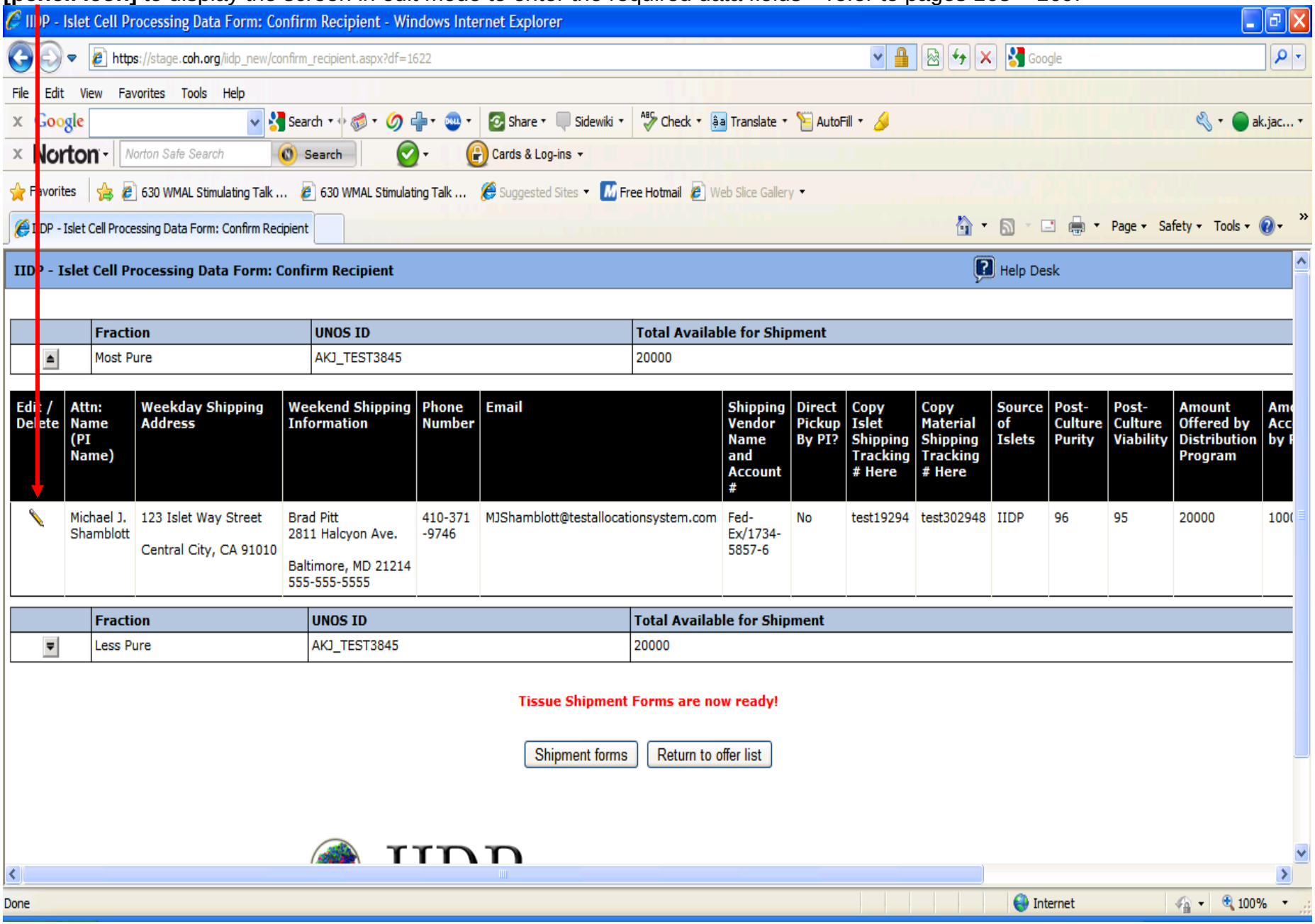
Prep Type	PI Name	Institution	For-Profit Organization?	Responded to Offer?	Islet Offer Rejected?	Source of Islets	Amount Offered by Distribution Program	Amount Accepted by PI	Amount to be shipped by Center	Islets Shipped?	Material Shipping Tracking #	Materials Shipped to Center?
Most Pure	R. Paul Robertson	Pacific Northwest Research Institute	No	No	No	IIDP	10000	NA	NA	NA	NA	NA
Most Pure	Debbie C. Thurmond	University of Indiana School of Medicine	No	Yes	Yes	IIDP	1000	NA	NA	NA	NA	NA
Most Pure	Michael L. McDaniel	Washington University in St. Louis	No	Yes	No	IIDP	9000	5000	NA	NA	NA	NA
Most Pure	Ioannis Constantinidis	University of Florida	No	Yes	No	IIDP	15000	15000	NA	NA	NA	NA

Click on **[Next]** to proceed to the shipping information screen – refer to the next page. Click on **[Return to offer list]** to view the list of all of the islet offers in the system – refer to page 163.

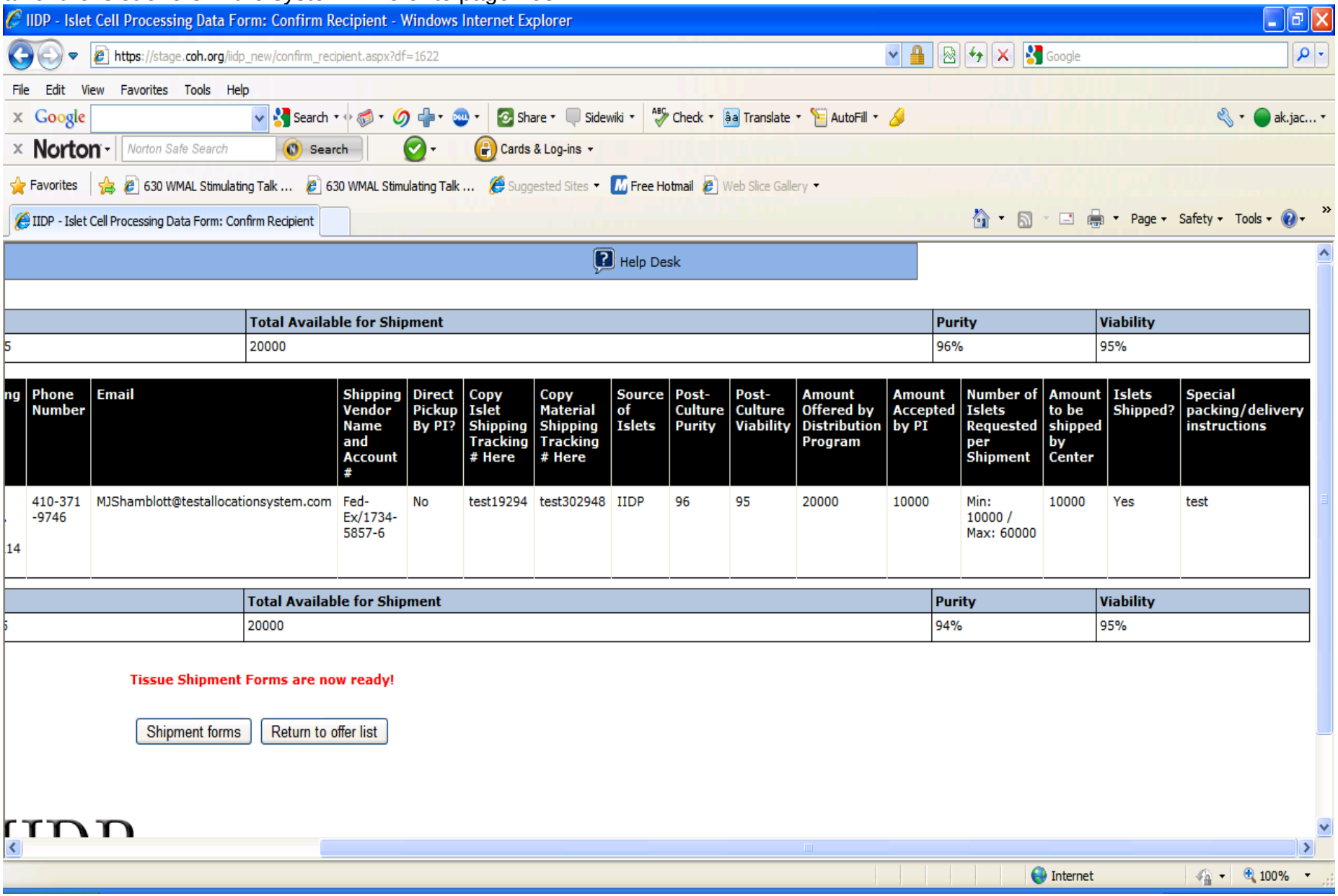
Islet Offer Shipping Information – Click on the **icon** to display the PI(s) shipping information regarding the islet offer – refer to the next screen.



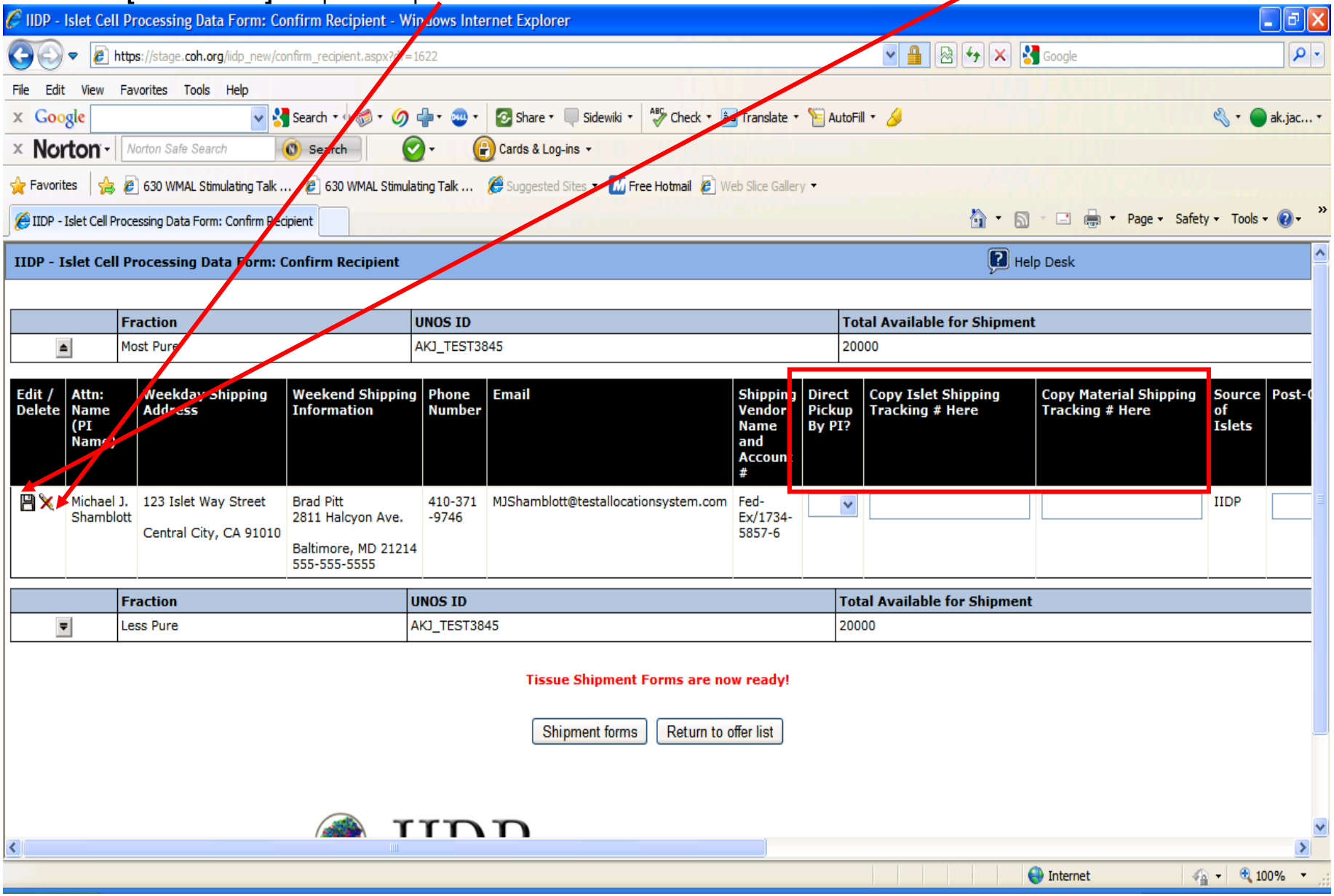
Predetermined PI Shipping List – The system displays the PI name(s) and associated shipping information. Click on the **[pencil icon]** to display the screen in edit mode to enter the required data fields – refer to pages 168 – 169.



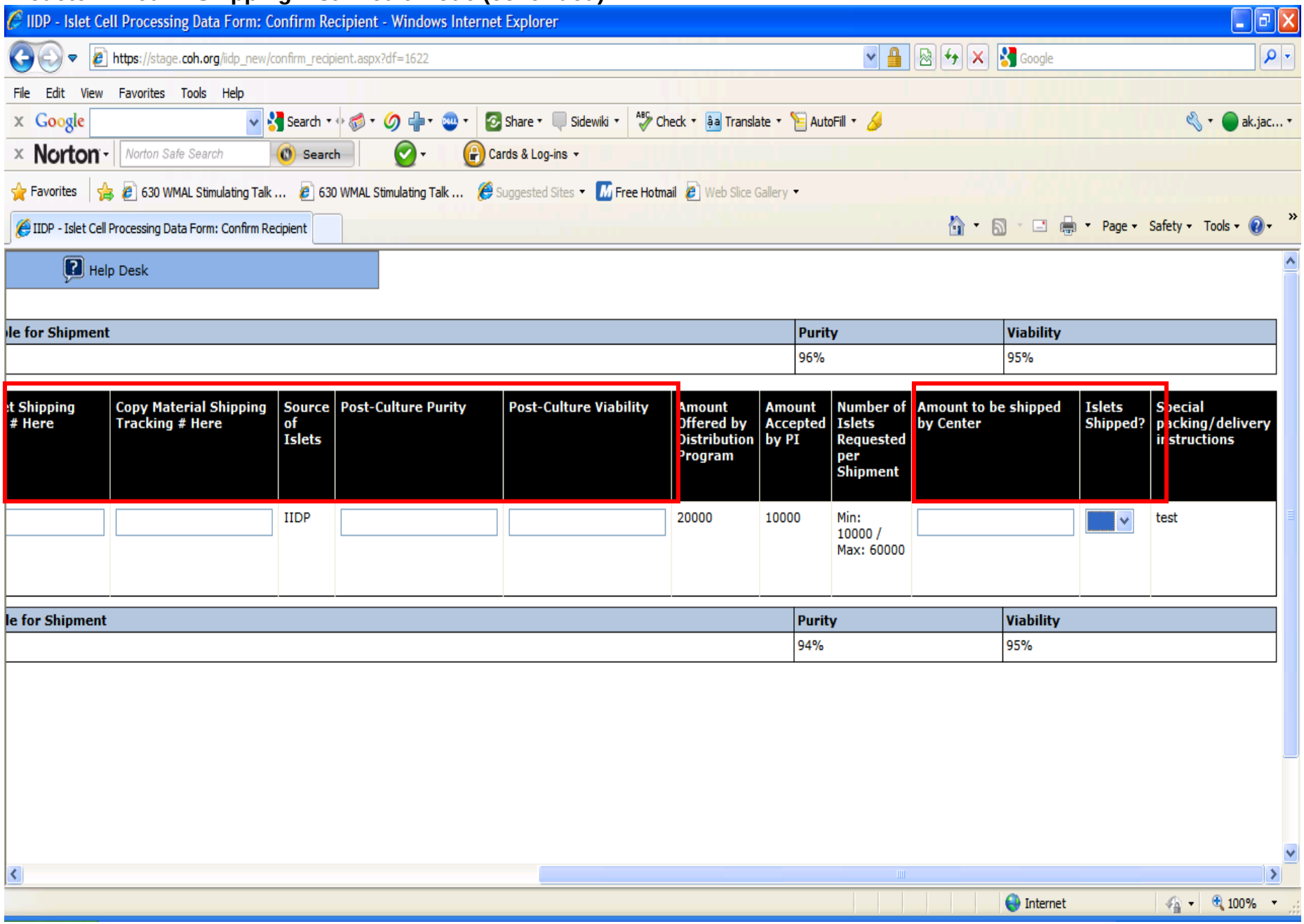
[Print Shipment forms for all confirmed users] will remain non-functional until all the appropriate fields are edited/updated and the islet offer time has expired. Click on **[Print this page]** to print the page. Click on **[Return to offer list]** to return to the list of all of the islet offers in the system – Refer to page 163.



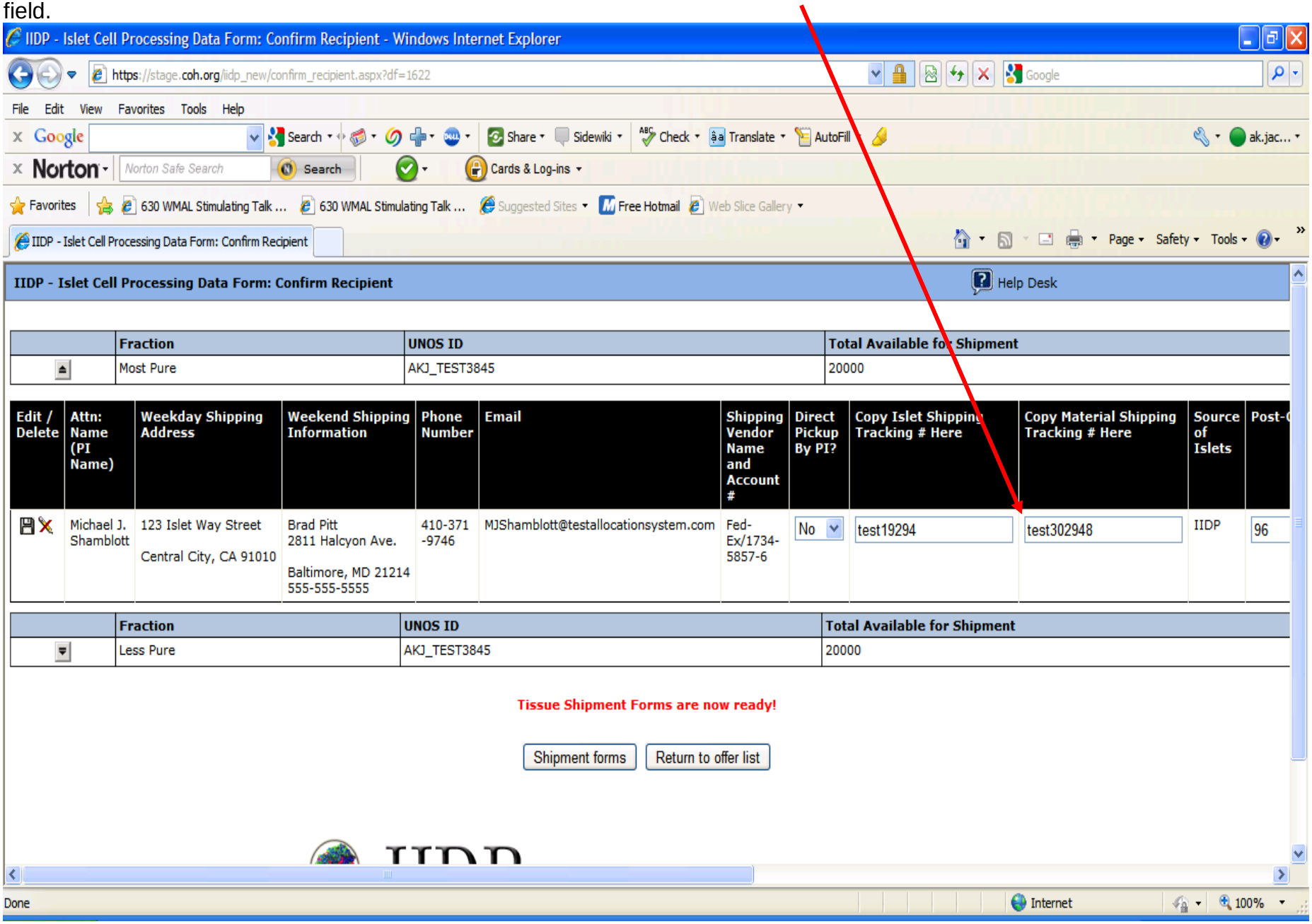
Predetermined PI Shipping List in edit mode – the system will display the shipping in the edit mode. Enter the **[Direct Pickup by PI], [Copy Islet Shipping Tracking # Here], [Copy Materials Shipping Tracking # Here], [Post Culture Purity], [Post Culture Viability], [Amount to be shipped by Center] and [Islets Shipped].** Click on the **[Save icon]** to save the information or click on the **[Cancel icon].** Repeat the process as needed for each PI to receive islets.



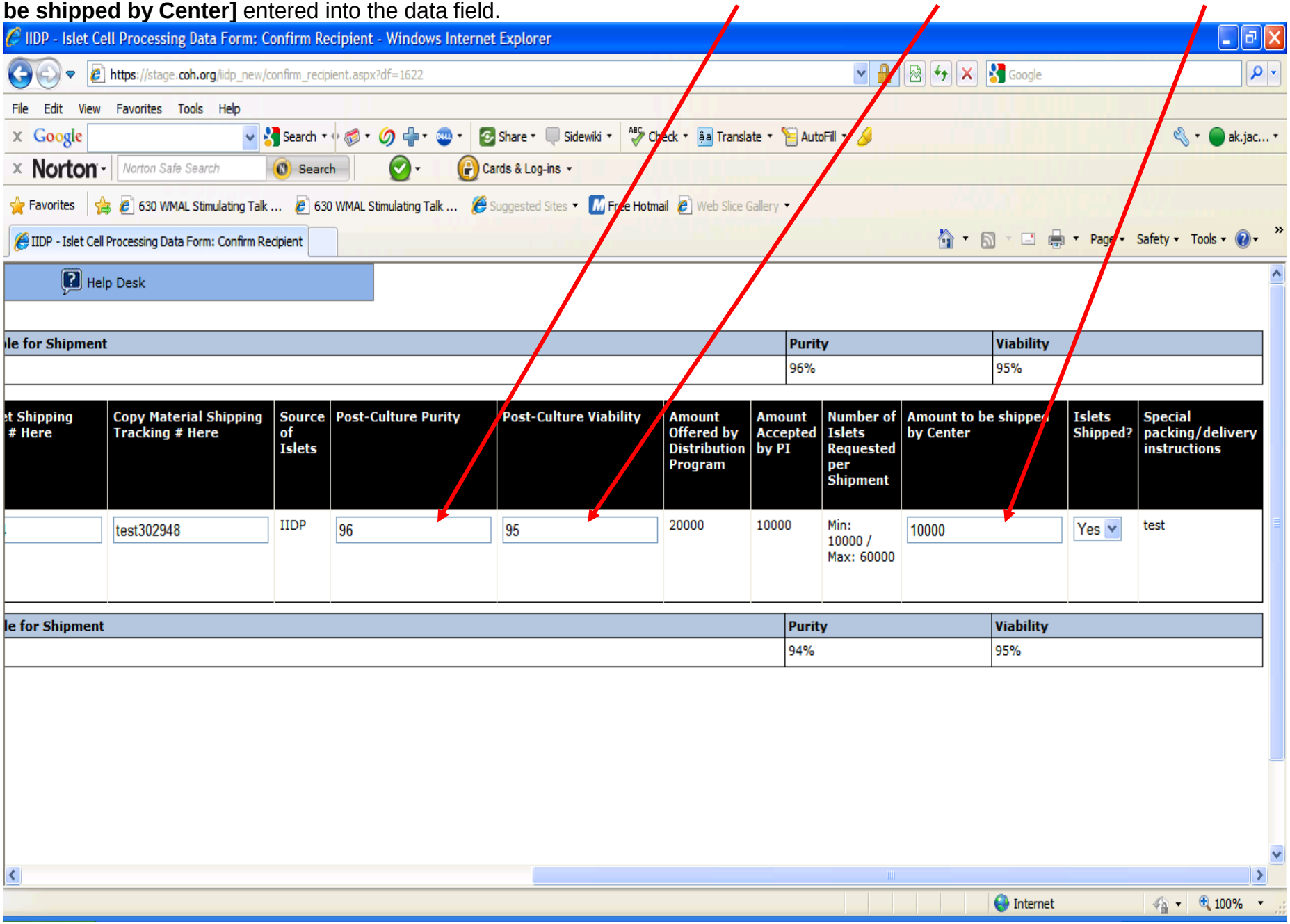
Predetermined PI Shipping List in edit mode (continued)



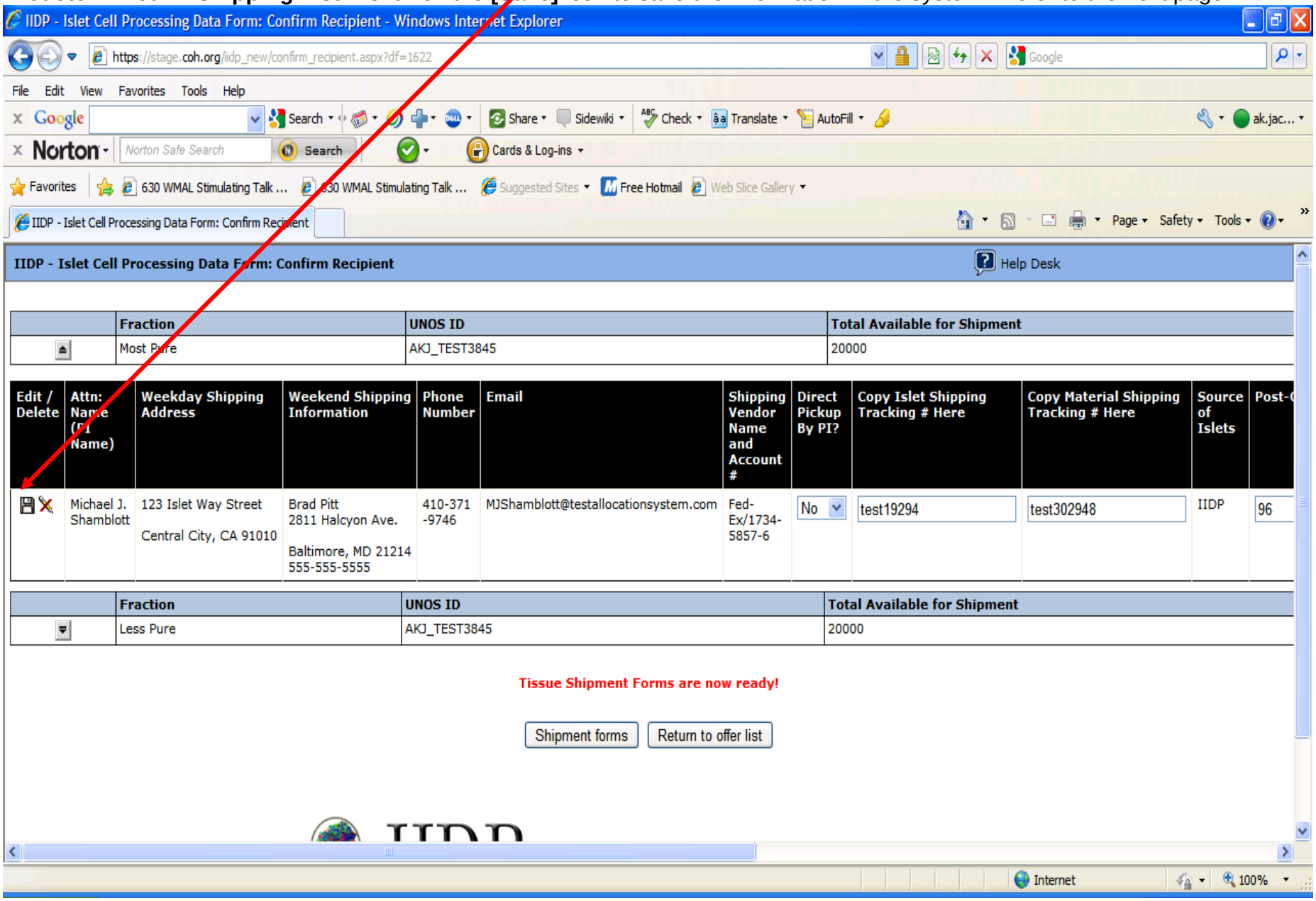
Predetermined PI Shipping List in edit mode - Example of an **[Copy Islet Shipping Tracking # Here]** entered into the data field.



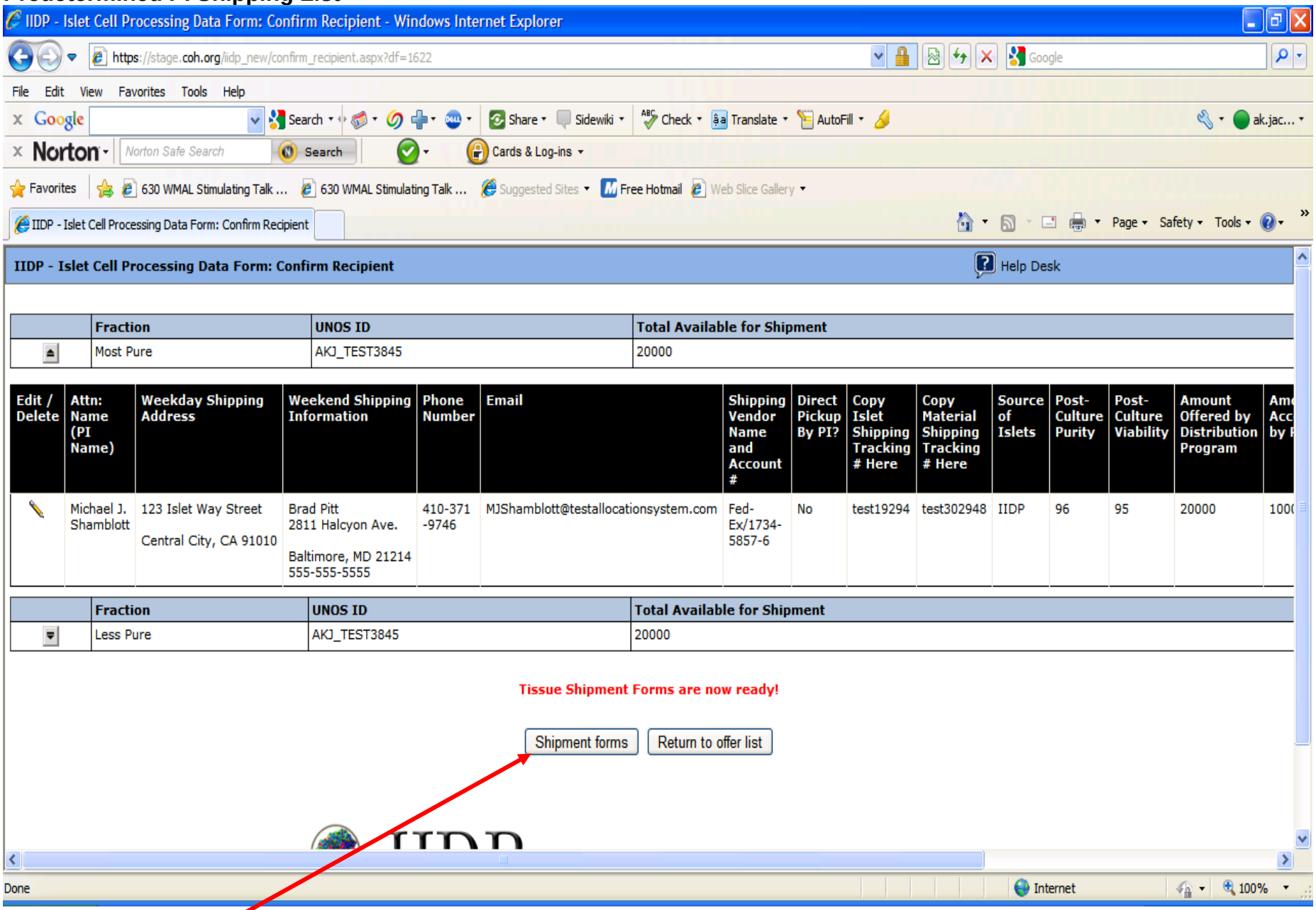
Predetermined PI Shipping List in edit mode – Examples of **[Post-Culture Purity], [Post-Culture Viability],** and **[Amount to be shipped by Center]** entered into the data field.



Predetermined PI Shipping List – Click on the **[Save]** icon to save the information in the system – refer to the next page.

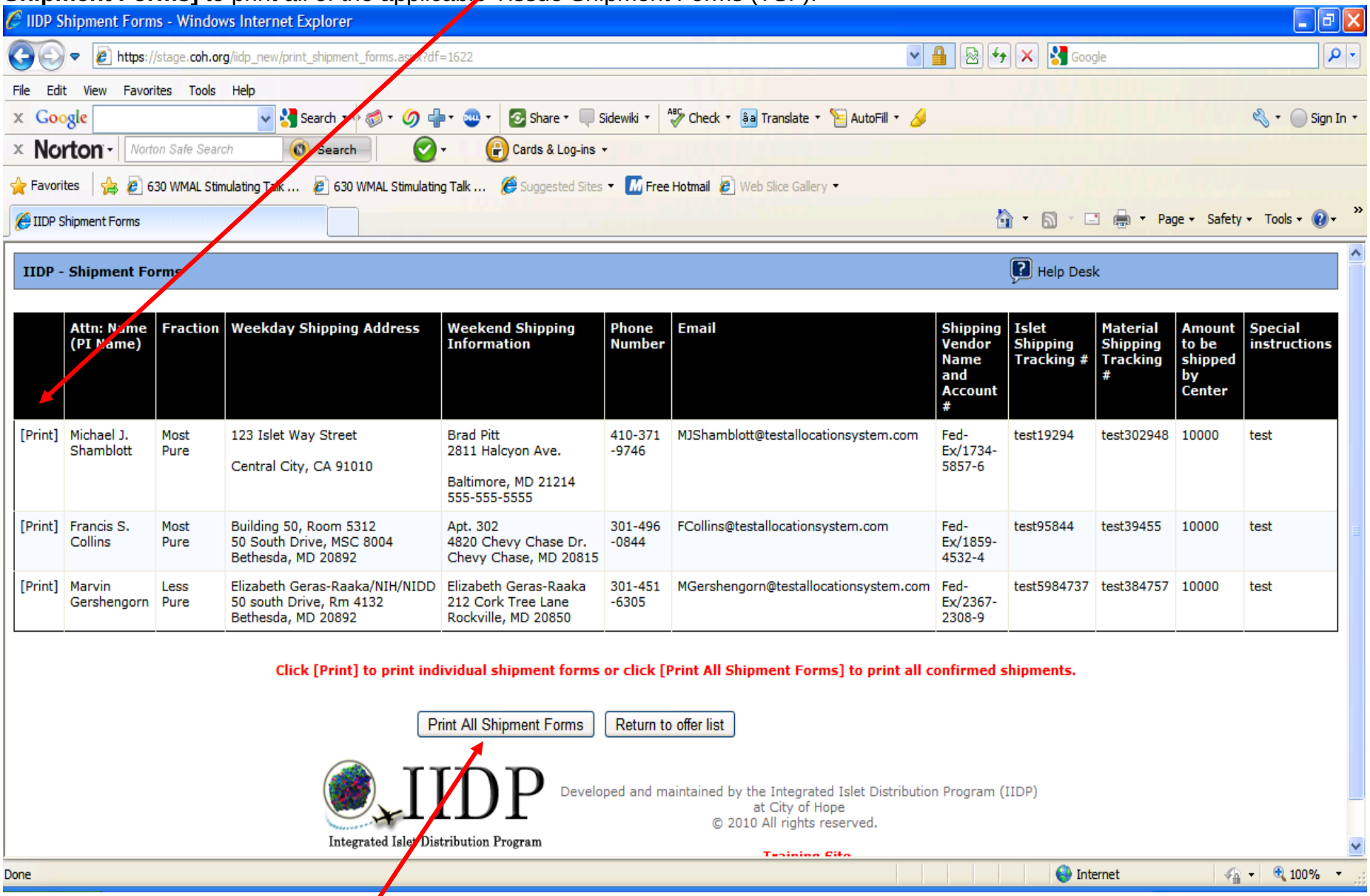


Predetermined PI Shipping List



Click on **[Shipment forms]** - refer to the next page.

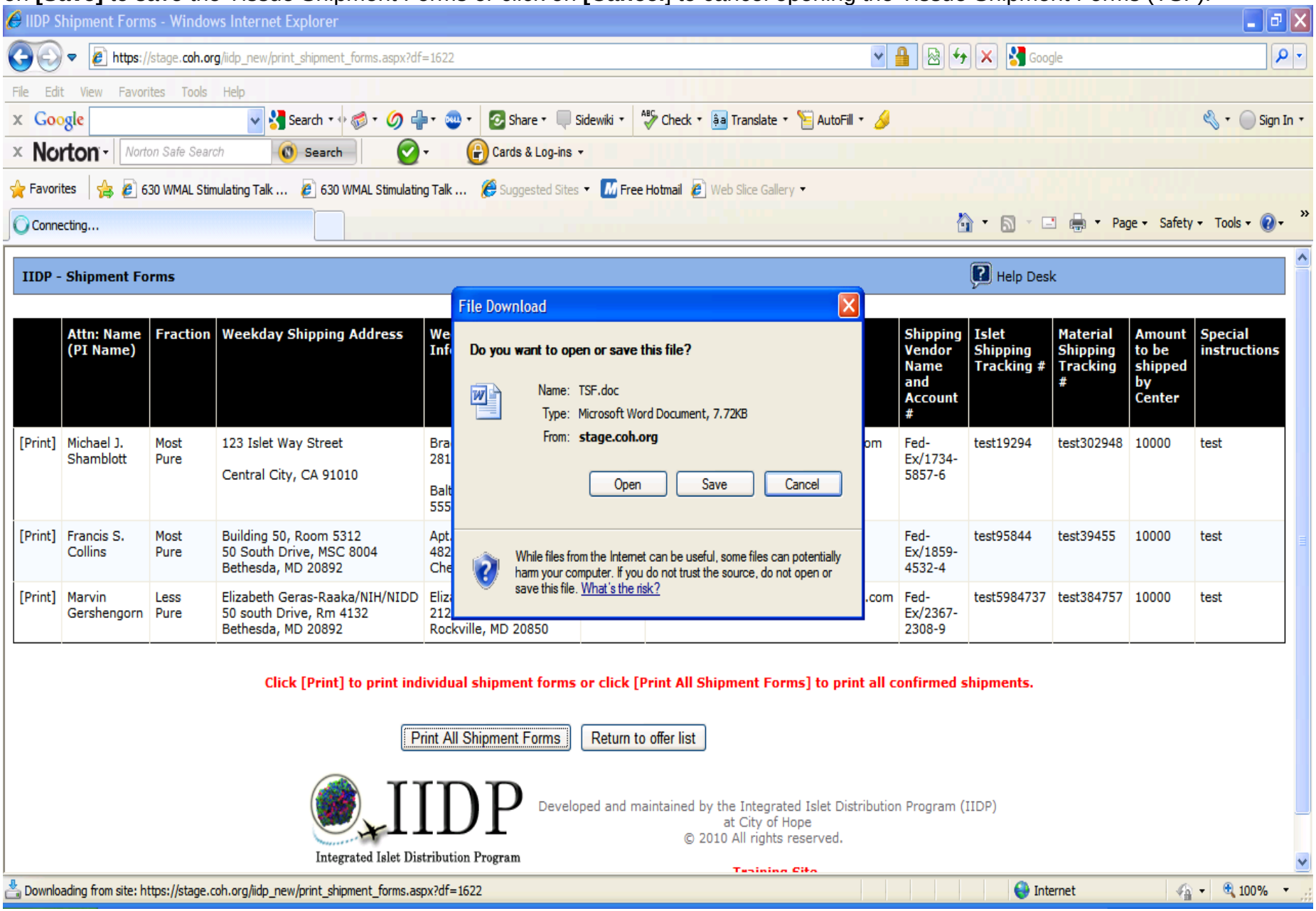
Predetermined PI Shipping List –Click on **[Print]** to print an individual Tissue Shipment Form (TSF) or click on **[Print ALL Shipment Forms]** to print all of the applicable Tissue Shipment Forms (TSF).



	Attn: Name (PI Name)	Fraction	Weekday Shipping Address	Weekend Shipping Information	Phone Number	Email	Shipping Vendor Name and Account #	Islet Shipping Tracking #	Material Shipping Tracking #	Amount to be shipped by Center	Special instructions
[Print]	Michael J. Shamblott	Most Pure	123 Islet Way Street Central City, CA 91010	Brad Pitt 2811 Halcyon Ave. Baltimore, MD 21214 555-555-5555	410-371-9746	MJShamblott@testallocationsystem.com	Fed-Ex/1734-5857-6	test19294	test302948	10000	test
[Print]	Francis S. Collins	Most Pure	Building 50, Room 5312 50 South Drive, MSC 8004 Bethesda, MD 20892	Apt. 302 4820 Chevy Chase Dr. Chevy Chase, MD 20815	301-496-0844	FCollins@testallocationsystem.com	Fed-Ex/1859-4532-4	test95844	test39455	10000	test
[Print]	Marvin Gershengorn	Less Pure	Elizabeth Geras-Raaka/NIH/NIDD 50 south Drive, Rm 4132 Bethesda, MD 20892	Elizabeth Geras-Raaka 212 Cork Tree Lane Rockville, MD 20850	301-451-6305	MGershengorn@testallocationsystem.com	Fed-Ex/2367-2308-9	test5984737	test384757	10000	test

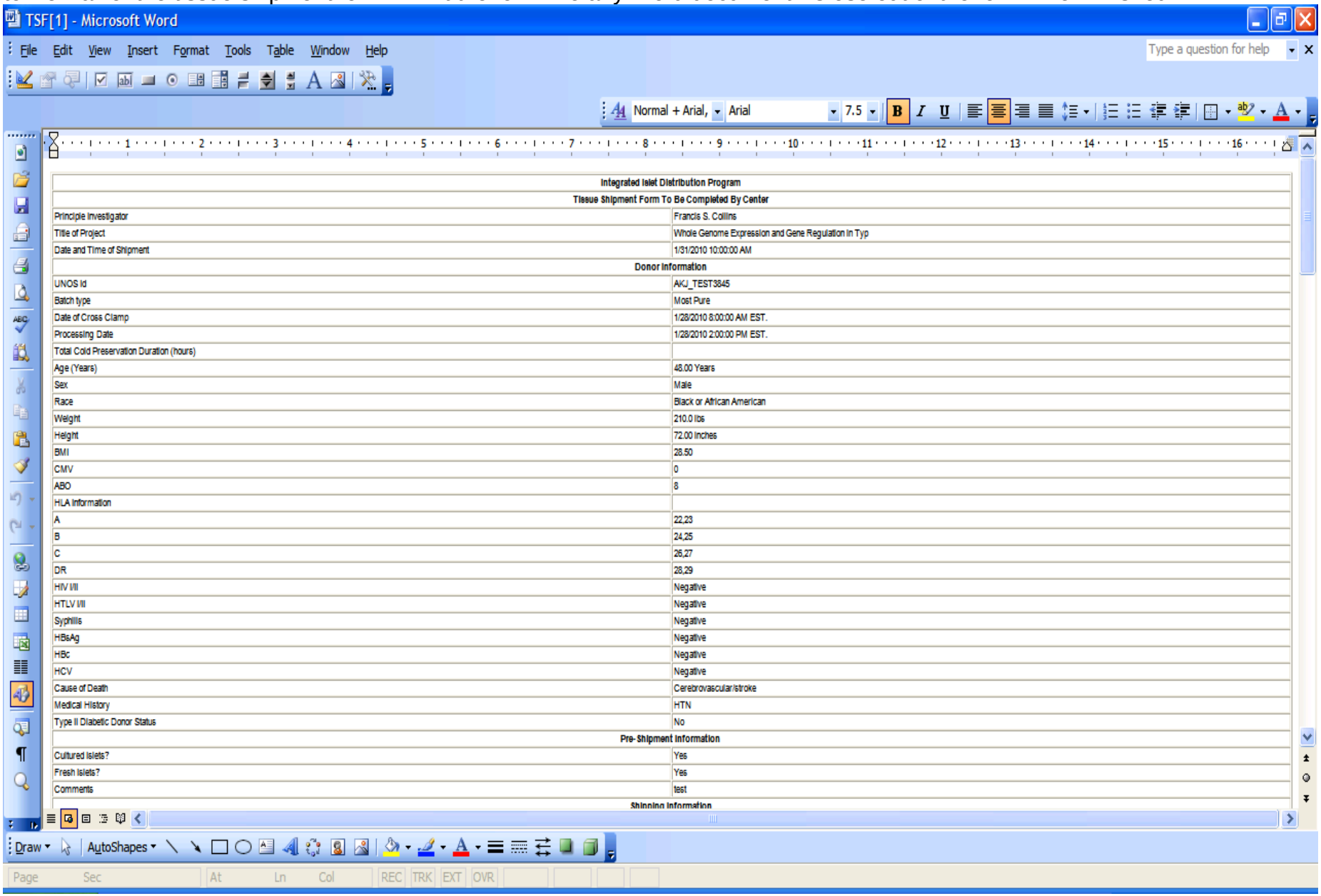
Click on **[Print ALL Shipment Forms]** when ready to print the shipment forms – refer to the next page. Click on **[Return to offer list]** to return to the list of all of the islet offers in the system – refer to page 163.

Print Shipment Forms – Click on **[Open]** to view and then print the Tissue Shipment Forms (TSF) – refer to the next page. Click on **[Save]** to save the Tissue Shipment Forms or click on **[Cancel]** to cancel opening the Tissue Shipment Forms (TSF).



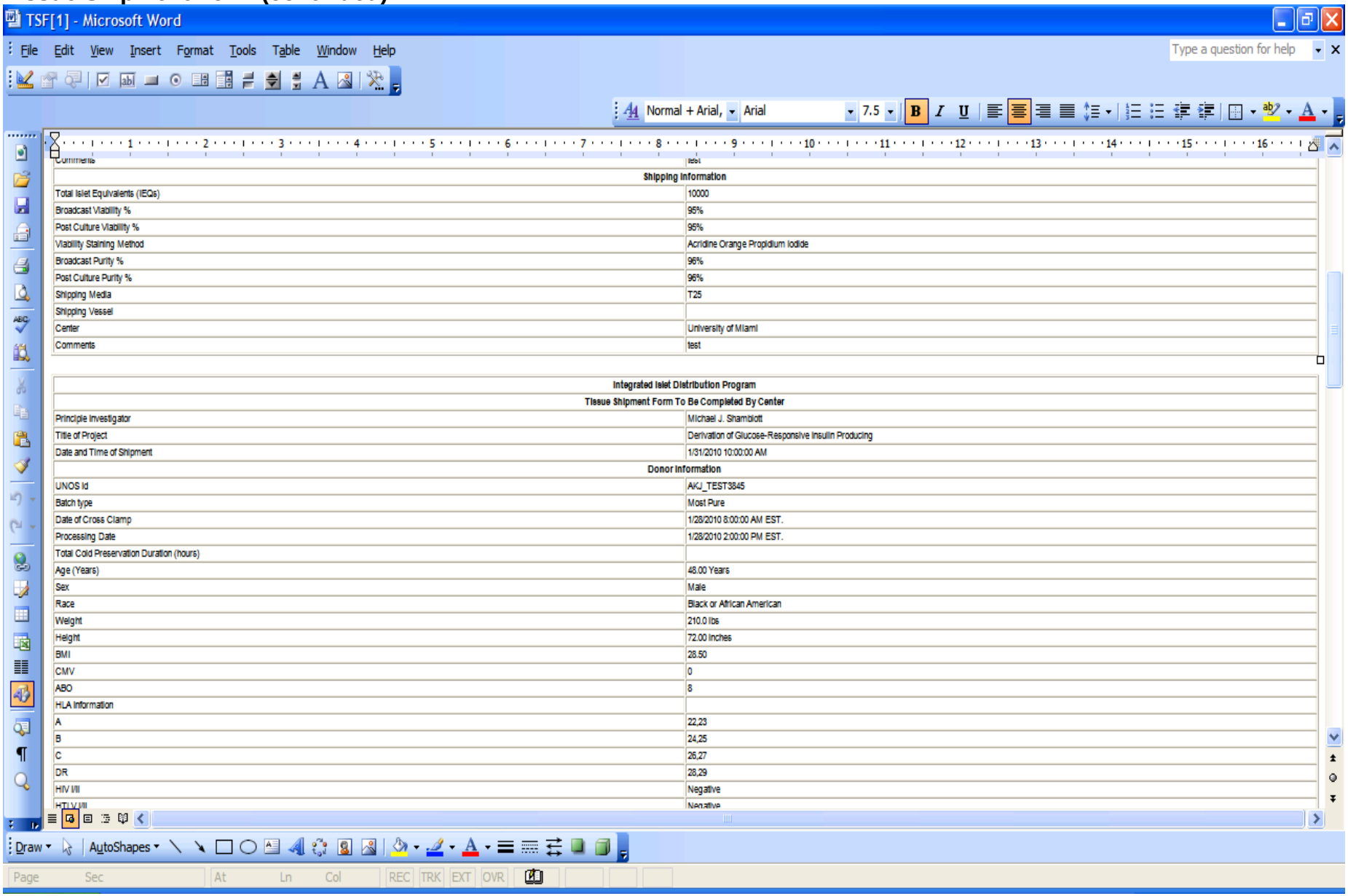
	Attn: Name (PI Name)	Fraction	Weekday Shipping Address	Shipping Vendor Name and Account #	Islet Shipping Tracking #	Material Shipping Tracking #	Amount to be shipped by Center	Special instructions
[Print]	Michael J. Shamblott	Most Pure	123 Islet Way Street Central City, CA 91010	Fed-Ex/1734-5857-6	test19294	test302948	10000	test
[Print]	Francis S. Collins	Most Pure	Building 50, Room 5312 50 South Drive, MSC 8004 Bethesda, MD 20892	Fed-Ex/1859-4532-4	test95844	test39455	10000	test
[Print]	Marvin Gershengorn	Less Pure	Elizabeth Geras-Raaka/NIH/NIDD 50 south Drive, Rm 4132 Bethesda, MD 20892	Fed-Ex/2367-2308-9	test5984737	test384757	10000	test

Tissue Shipment Form - The system displays the tissue shipment form(s) to be printed. Use the scroll bar on the right hand side to view all of the tissue shipment form. Print the form like any Word document. Close out of the form when finished.



Integrated Islet Distribution Program	
Tissue Shipment Form To Be Completed By Center	
Principle Investigator	Francis S. Collins
Title of Project	Whole Genome Expression and Gene Regulation in Typ
Date and Time of Shipment	1/31/2010 10:00:00 AM
Donor Information	
UNOS Id	AKJ_TEST3845
Batch type	Most Pure
Date of Cross Clamp	1/28/2010 8:00:00 AM EST.
Processing Date	1/28/2010 2:00:00 PM EST.
Total Cold Preservation Duration (hours)	
Age (Years)	48.00 Years
Sex	Male
Race	Black or African American
Weight	210.0 lbs
Height	72.00 Inches
BMI	28.50
CMV	0
ABO	8
HLA Information	
A	22,23
B	24,25
C	26,27
DR	28,29
HIV I/II	Negative
HTLV I/II	Negative
Syphilis	Negative
HBsAg	Negative
HBc	Negative
HCV	Negative
Cause of Death	Cerebrovascular/stroke
Medical History	HTN
Type II Diabetic Donor Status	No
Pre-Shipment Information	
Cultured Islets?	Yes
Fresh Islets?	Yes
Comments	test
Shipping Information	

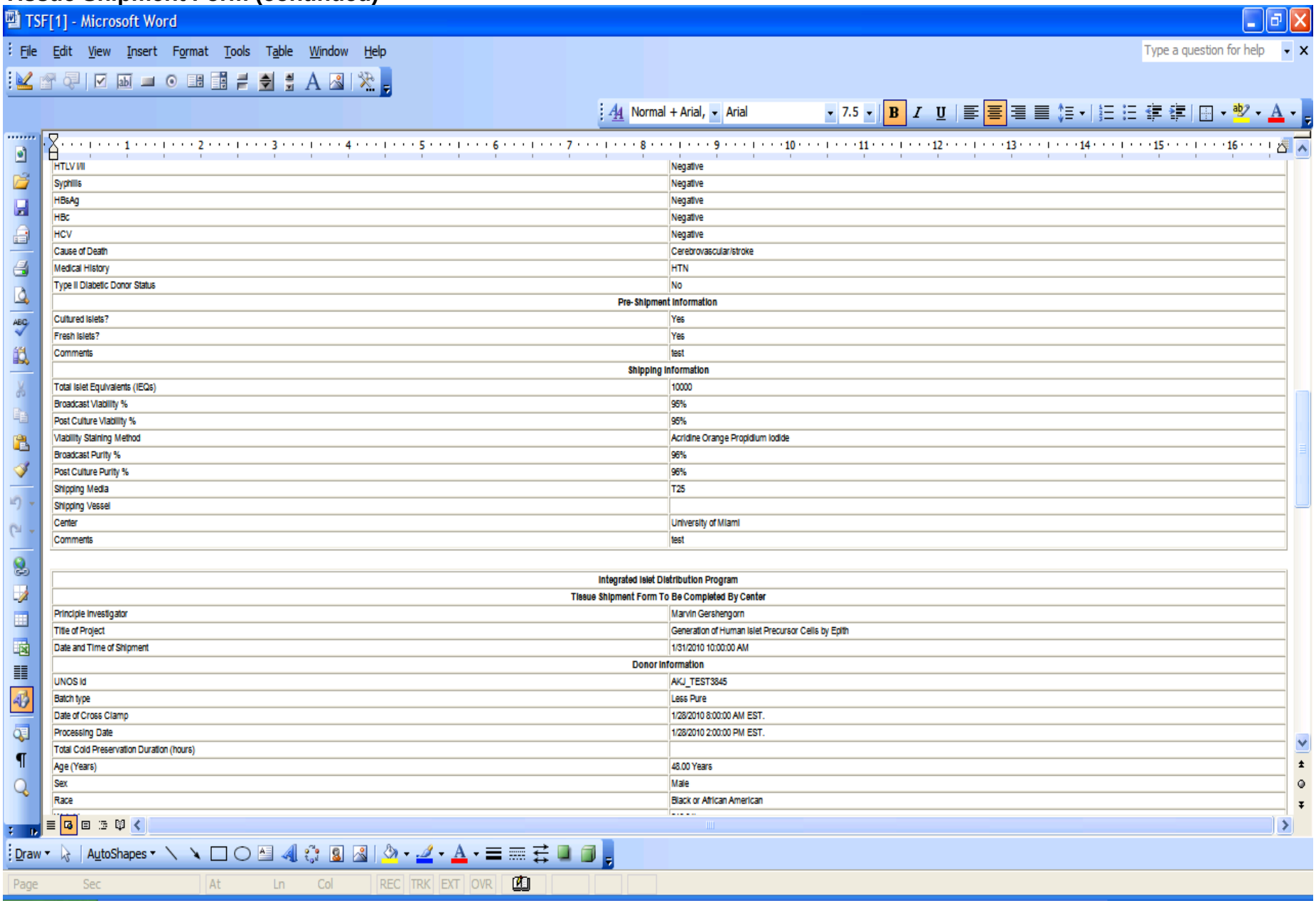
Tissue Shipment Form (continued)



Shipping Information	
Total Islet Equivalents (IEQs)	10000
Broadcast Viability %	95%
Post Culture Viability %	95%
Viability Staining Method	Acridine Orange Propidium Iodide
Broadcast Purity %	96%
Post Culture Purity %	96%
Shipping Media	T25
Shipping Vessel	
Center	University of Miami
Comments	test

Integrated Islet Distribution Program	
Tissue Shipment Form To Be Completed By Center	
Principle Investigator	Michael J. Shamblott
Title of Project	Derivation of Glucose-Responsive Insulin Producing
Date and Time of Shipment	1/31/2010 10:00:00 AM
Donor Information	
UNOS Id	AKJ_TEST3845
Batch type	Most Pure
Date of Cross Clamp	1/28/2010 8:00:00 AM EST.
Processing Date	1/28/2010 2:00:00 PM EST.
Total Cold Preservation Duration (hours)	
Age (Years)	48.00 Years
Sex	Male
Race	Black or African American
Weight	210.0 lbs
Height	72.00 Inches
BMI	28.50
CMV	0
ABO	8
HLA Information	
A	22,23
B	24,25
C	26,27
DR	28,29
HIV I/II	Negative
HTLV I/II	Negative

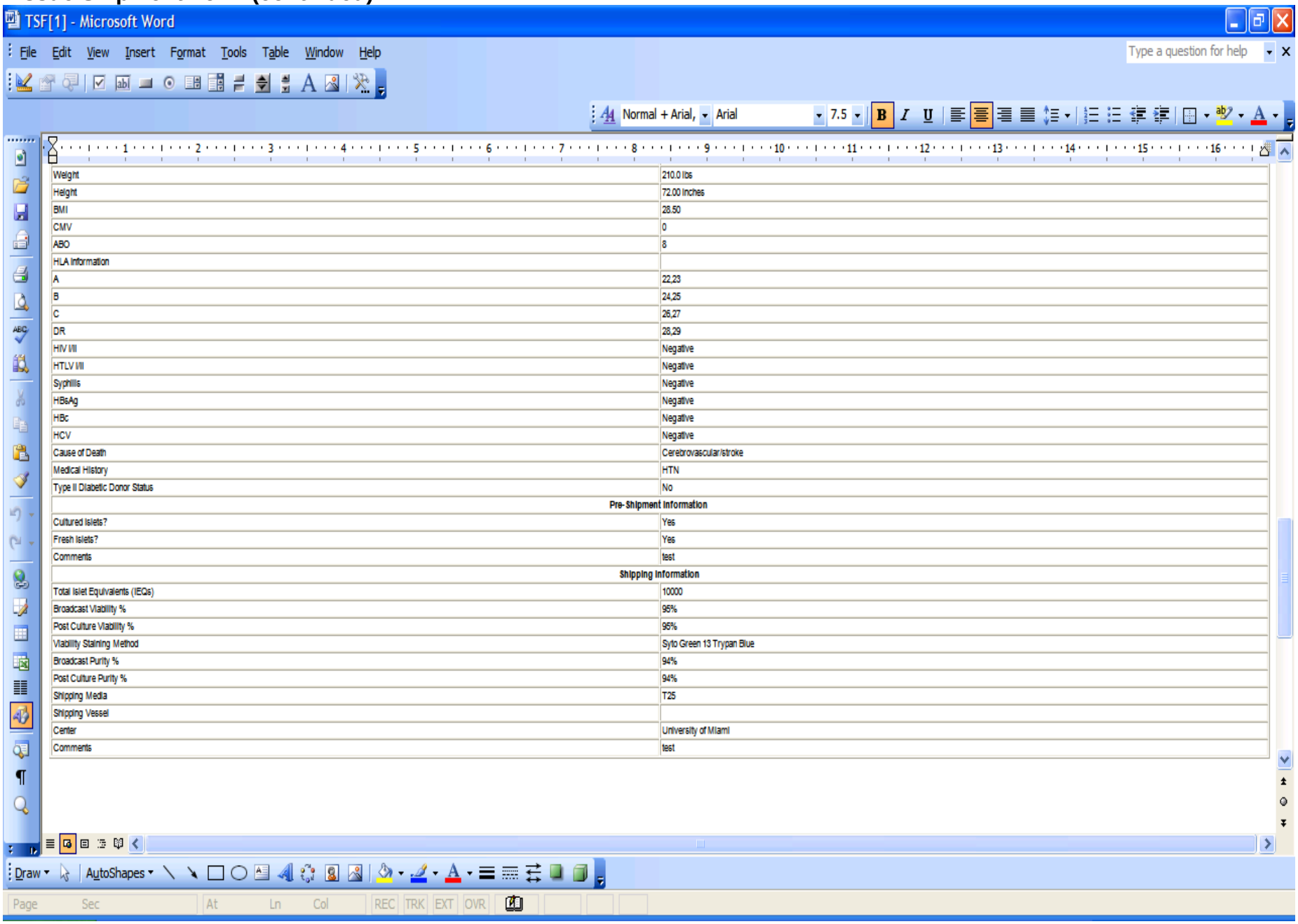
Tissue Shipment Form (continued)



HTLV III	Negative
Syphilis	Negative
HBsAg	Negative
HBc	Negative
HCV	Negative
Cause of Death	Cerebrovascular/stroke
Medical History	HTN
Type II Diabetic Donor Status	No
Pre-Shipment Information	
Cultured Islets?	Yes
Fresh Islets?	Yes
Comments	test
Shipping Information	
Total Islet Equivalents (IEQs)	10000
Broadcast Viability %	95%
Post Culture Viability %	95%
Viability Staining Method	Acridine Orange Propidium Iodide
Broadcast Purity %	96%
Post Culture Purity %	96%
Shipping Media	T25
Shipping Vessel	
Center	University of Miami
Comments	test

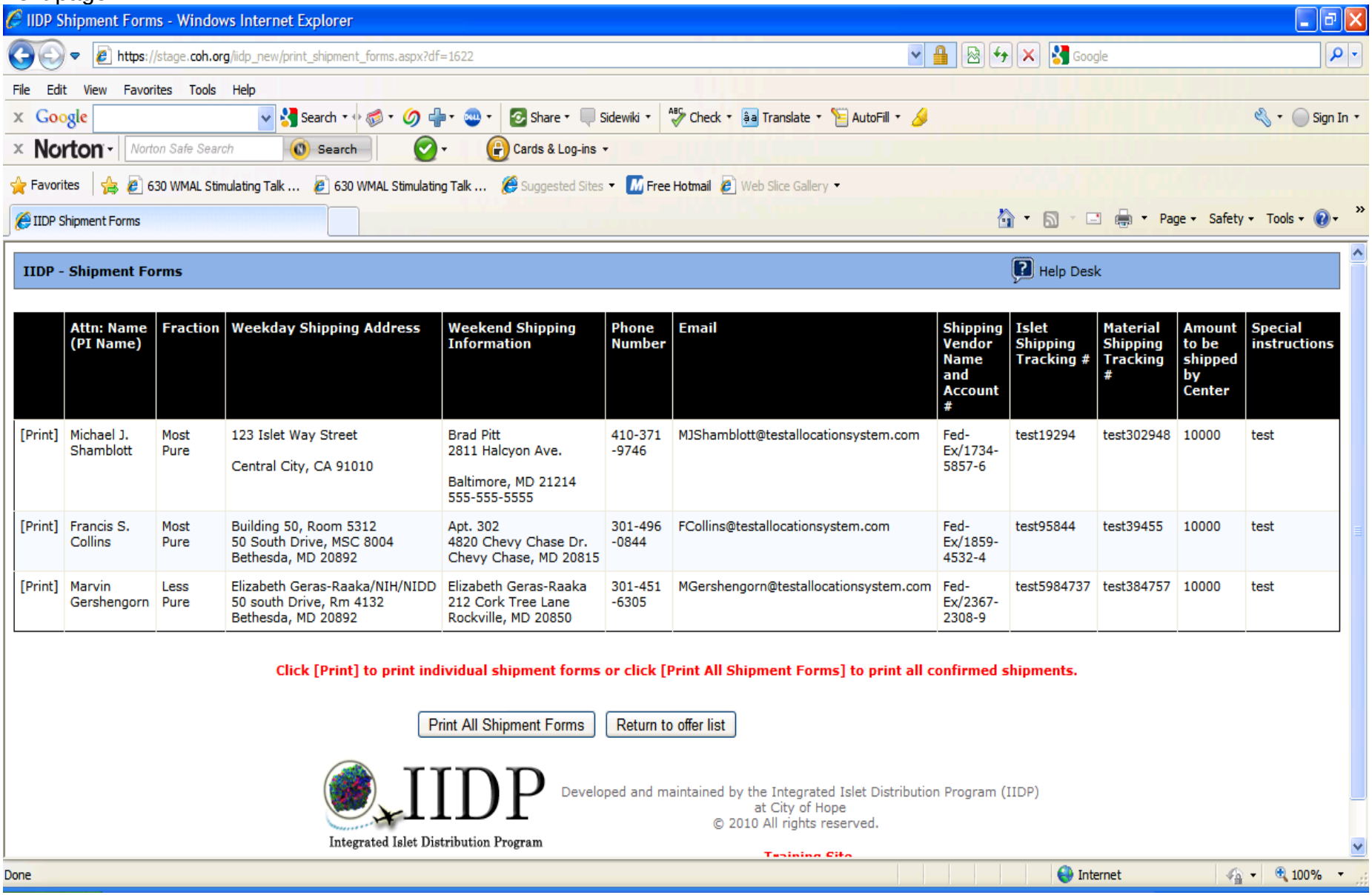
Integrated Islet Distribution Program	
Tissue Shipment Form To Be Completed By Center	
Principle Investigator	Marvin Gershengorn
Title of Project	Generation of Human Islet Precursor Cells by Epith
Date and Time of Shipment	1/31/2010 10:00:00 AM
Donor Information	
UNOS Id	AKJ_TEST3845
Batch type	Less Pure
Date of Cross Clamp	1/28/2010 8:00:00 AM EST.
Processing Date	1/28/2010 2:00:00 PM EST.
Total Cold Preservation Duration (hours)	
Age (Years)	48.00 Years
Sex	Male
Race	Black or African American

Tissue Shipment Form (continued)



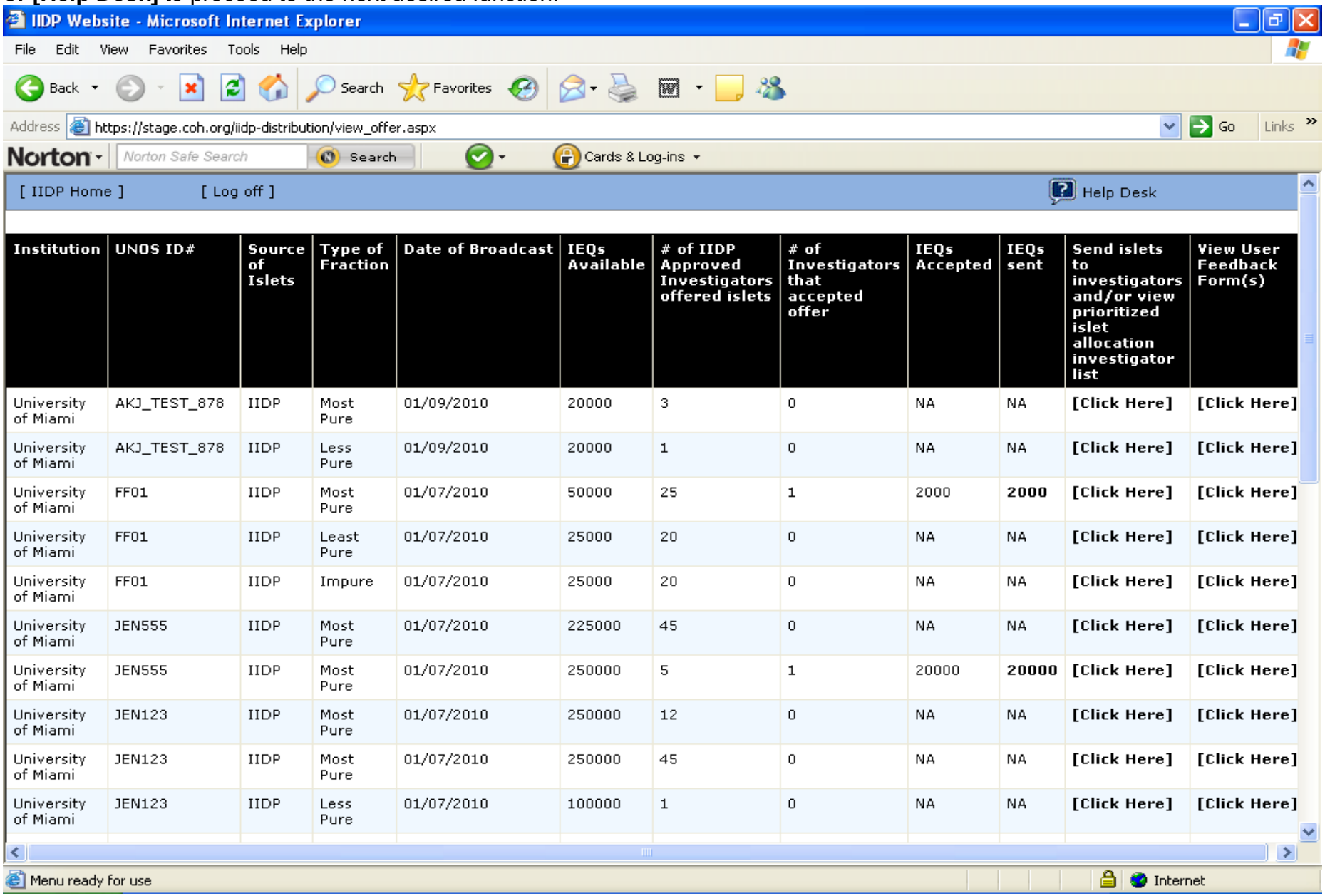
Weight	210.0 lbs
Height	72.00 inches
BMI	28.50
CMV	0
ABO	8
HLA Information	
A	22,23
B	24,25
C	26,27
DR	28,29
HIV I/II	Negative
HTLV I/II	Negative
Syphilis	Negative
HBsAg	Negative
HBc	Negative
HCV	Negative
Cause of Death	Cerebrovascular/stroke
Medical History	HTN
Type II Diabetic Donor Status	No
Pre-Shipment Information	
Cultured Islets?	Yes
Fresh Islets?	Yes
Comments	test
Shipping Information	
Total Islet Equivalents (IEQs)	10000
Broadcast Viability %	95%
Post Culture Viability %	95%
Viability Staining Method	Syto Green 13 Trypan Blue
Broadcast Purity %	94%
Post Culture Purity %	94%
Shipping Media	T25
Shipping Vessel	
Center	University of Miami
Comments	test

Islet Shipping Information screen – The system returns the user to the screen for the islet shipping information. Repeat the process as needed to print the shipment forms. Click on [**Return to offer list]** to return to the Islet Offers screen – refer to the next page.



	Attn: Name (PI Name)	Fraction	Weekday Shipping Address	Weekend Shipping Information	Phone Number	Email	Shipping Vendor Name and Account #	Islet Shipping Tracking #	Material Shipping Tracking #	Amount to be shipped by Center	Special instructions
[Print]	Michael J. Shamblott	Most Pure	123 Islet Way Street Central City, CA 91010	Brad Pitt 2811 Halcyon Ave. Baltimore, MD 21214 555-555-5555	410-371-9746	MJShamblott@testallocationsystem.com	Fed-Ex/1734-5857-6	test19294	test302948	10000	test
[Print]	Francis S. Collins	Most Pure	Building 50, Room 5312 50 South Drive, MSC 8004 Bethesda, MD 20892	Apt. 302 4820 Chevy Chase Dr. Chevy Chase, MD 20815	301-496-0844	FCollins@testallocationsystem.com	Fed-Ex/1859-4532-4	test95844	test39455	10000	test
[Print]	Marvin Gershengorn	Less Pure	Elizabeth Geras-Raaka/NIH/NIDD 50 south Drive, Rm 4132 Bethesda, MD 20892	Elizabeth Geras-Raaka 212 Cork Tree Lane Rockville, MD 20850	301-451-6305	MGershengorn@testallocationsystem.com	Fed-Ex/2367-2308-9	test5984737	test384757	10000	test

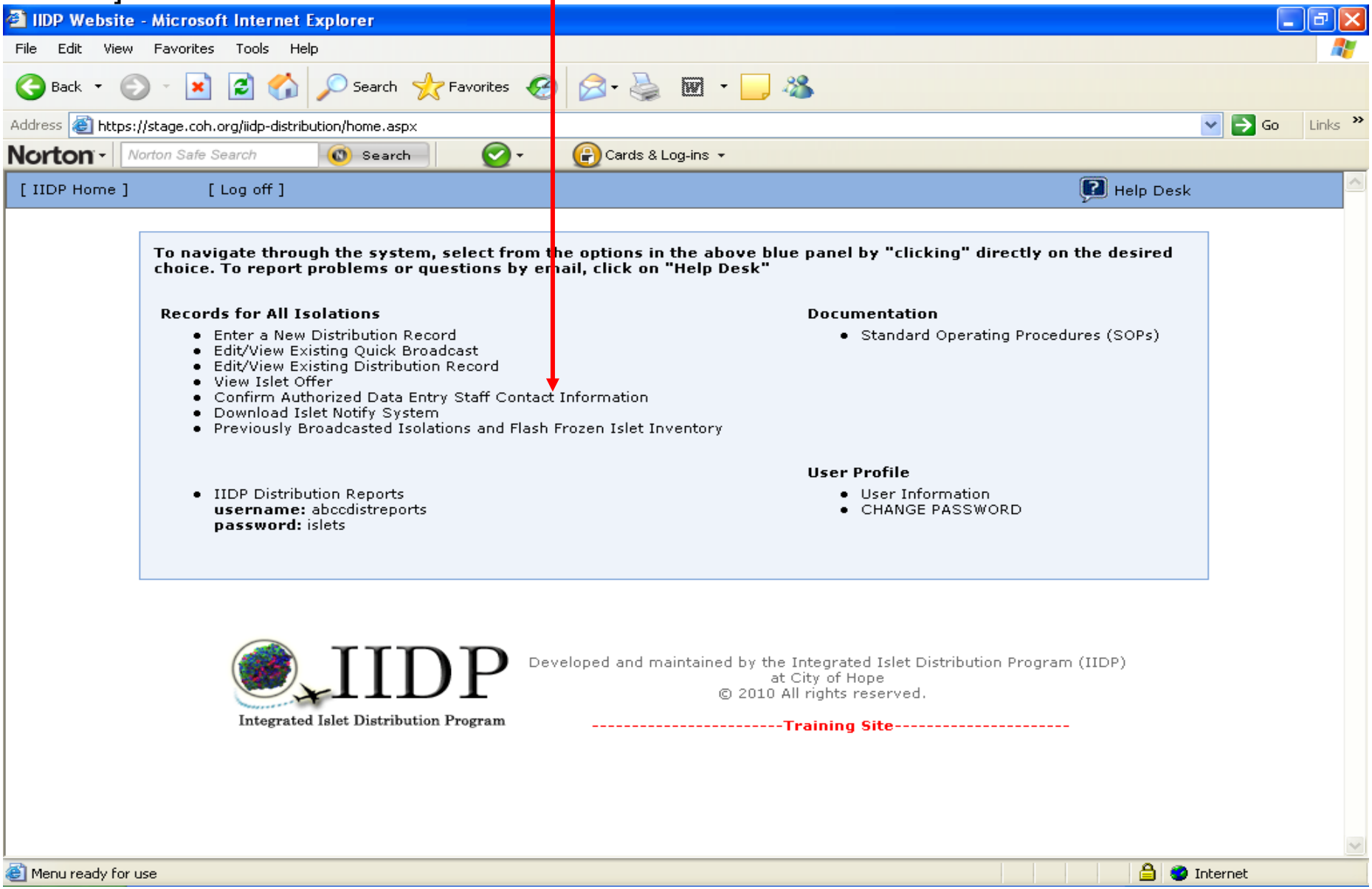
View Islet Offer – Repeat the process as just described above as needed. Select from a menu option **– [IIDP Home], [Log off], or [Help Desk]** to proceed to the next desired function.



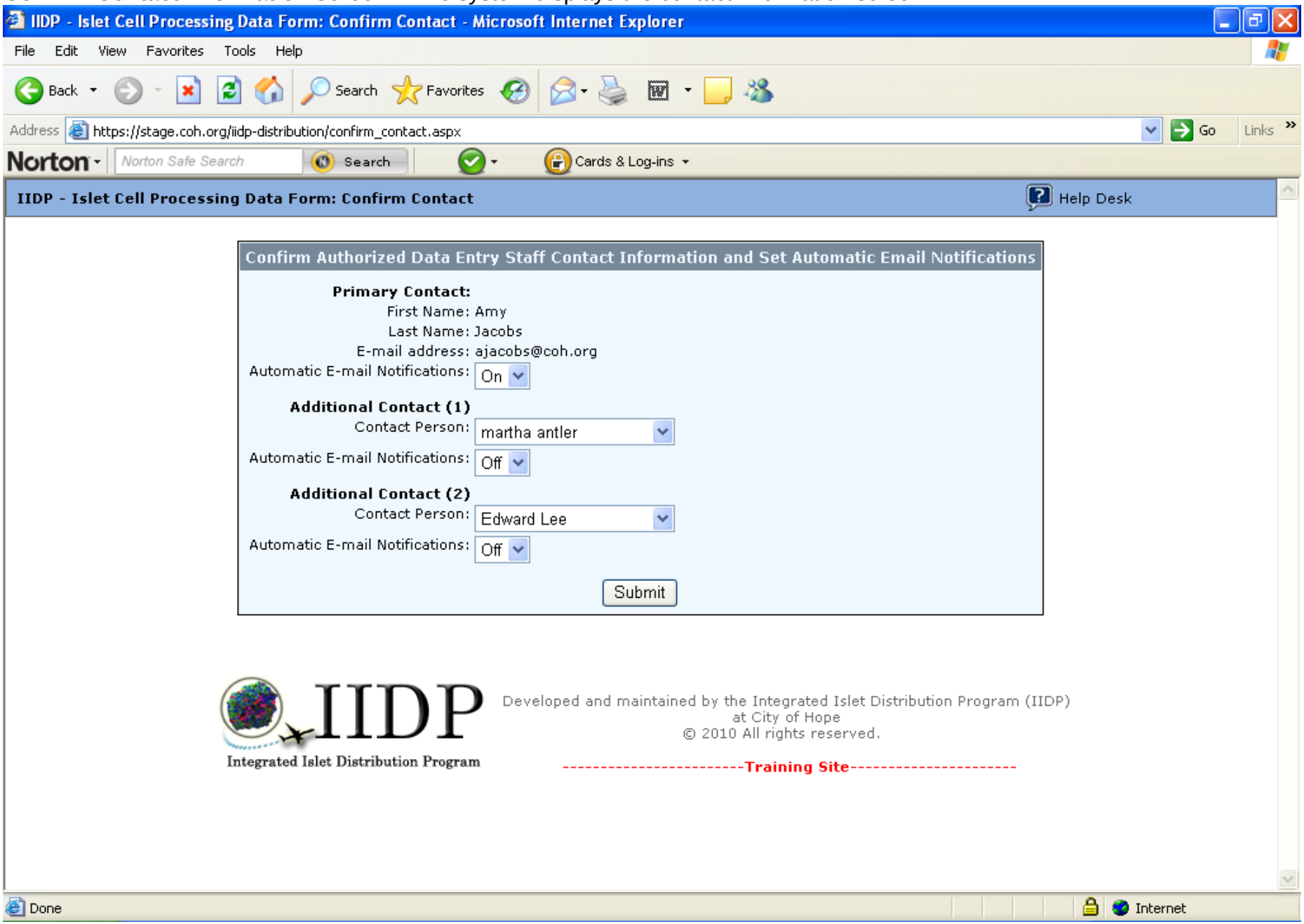
Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	View User Feedback Form(s)
University of Miami	AKJ_TEST_878	IIDP	Most Pure	01/09/2010	20000	3	0	NA	NA	[Click Here]	[Click Here]
University of Miami	AKJ_TEST_878	IIDP	Less Pure	01/09/2010	20000	1	0	NA	NA	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Most Pure	01/07/2010	50000	25	1	2000	**2000**	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Least Pure	01/07/2010	25000	20	0	NA	NA	[Click Here]	[Click Here]
University of Miami	FF01	IIDP	Impure	01/07/2010	25000	20	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN555	IIDP	Most Pure	01/07/2010	225000	45	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN555	IIDP	Most Pure	01/07/2010	250000	5	1	20000	**20000**	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Most Pure	01/07/2010	250000	12	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Most Pure	01/07/2010	250000	45	0	NA	NA	[Click Here]	[Click Here]
University of Miami	JEN123	IIDP	Less Pure	01/07/2010	100000	1	0	NA	NA	[Click Here]	[Click Here]

9.0 Confirm Authorized Broadcast Staff Contact Information

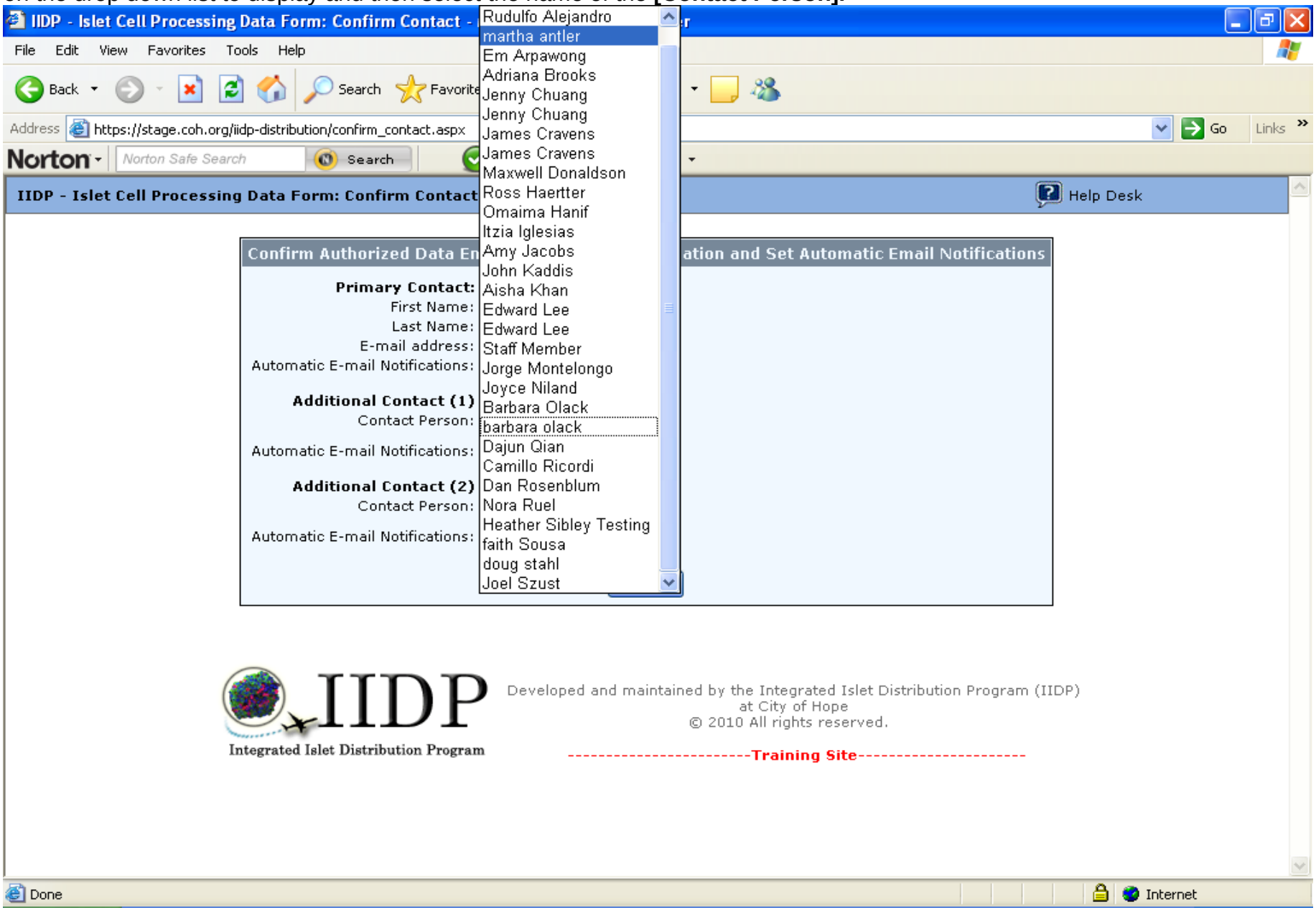
Main Page - Click on the menu option **[Confirm Authorized Data Entry Staff Contact Information]** under **[Records for All Isolations]** to confirm the contact information.



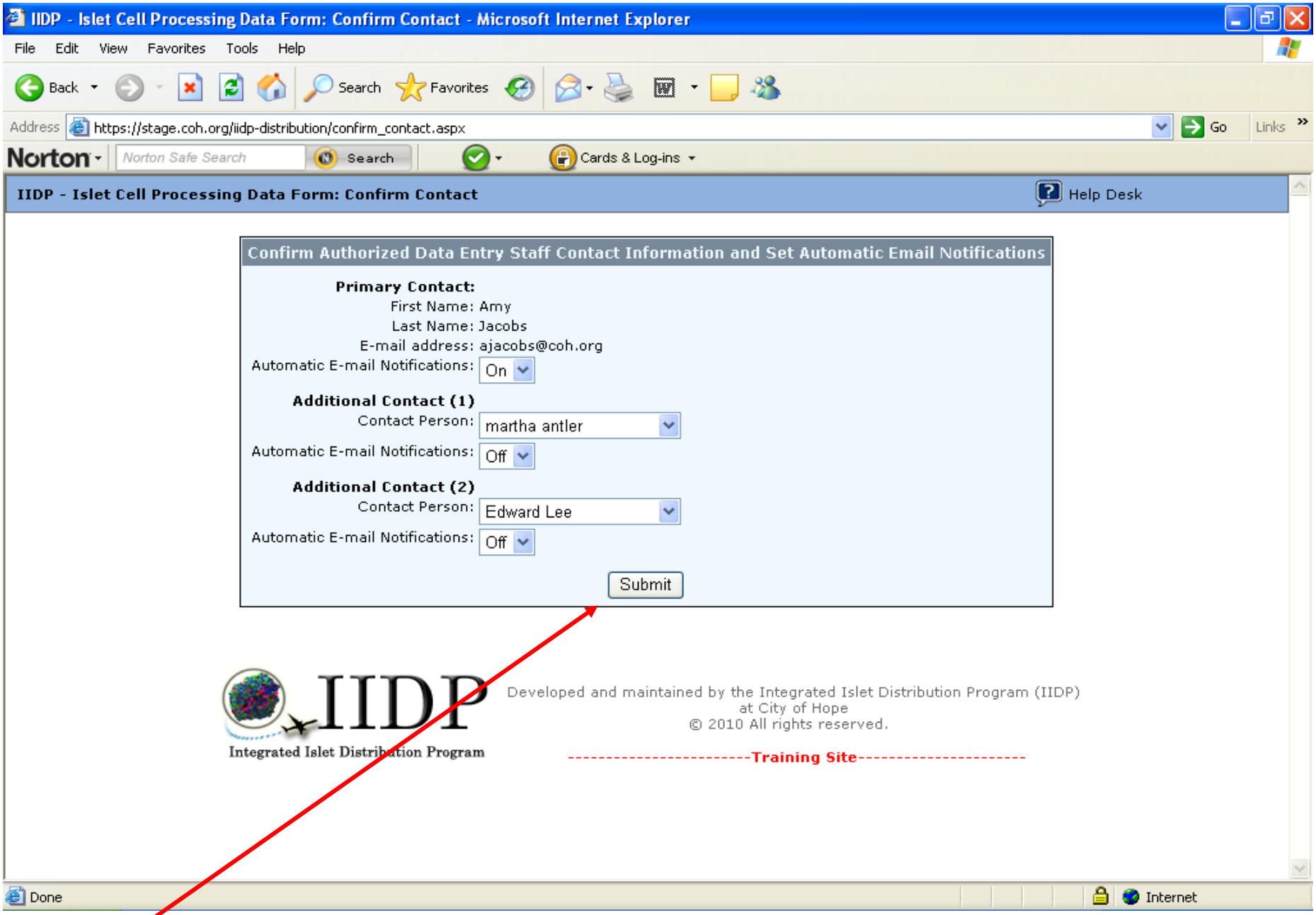
Confirm Contact Information screen – The system displays the contact information screen.



Confirm Contact Information screen – Click on the drop down list to change the **[Automatic E-mail Notification]** and/or click on the drop down list to display and then select the name of the **[Contact Person].**



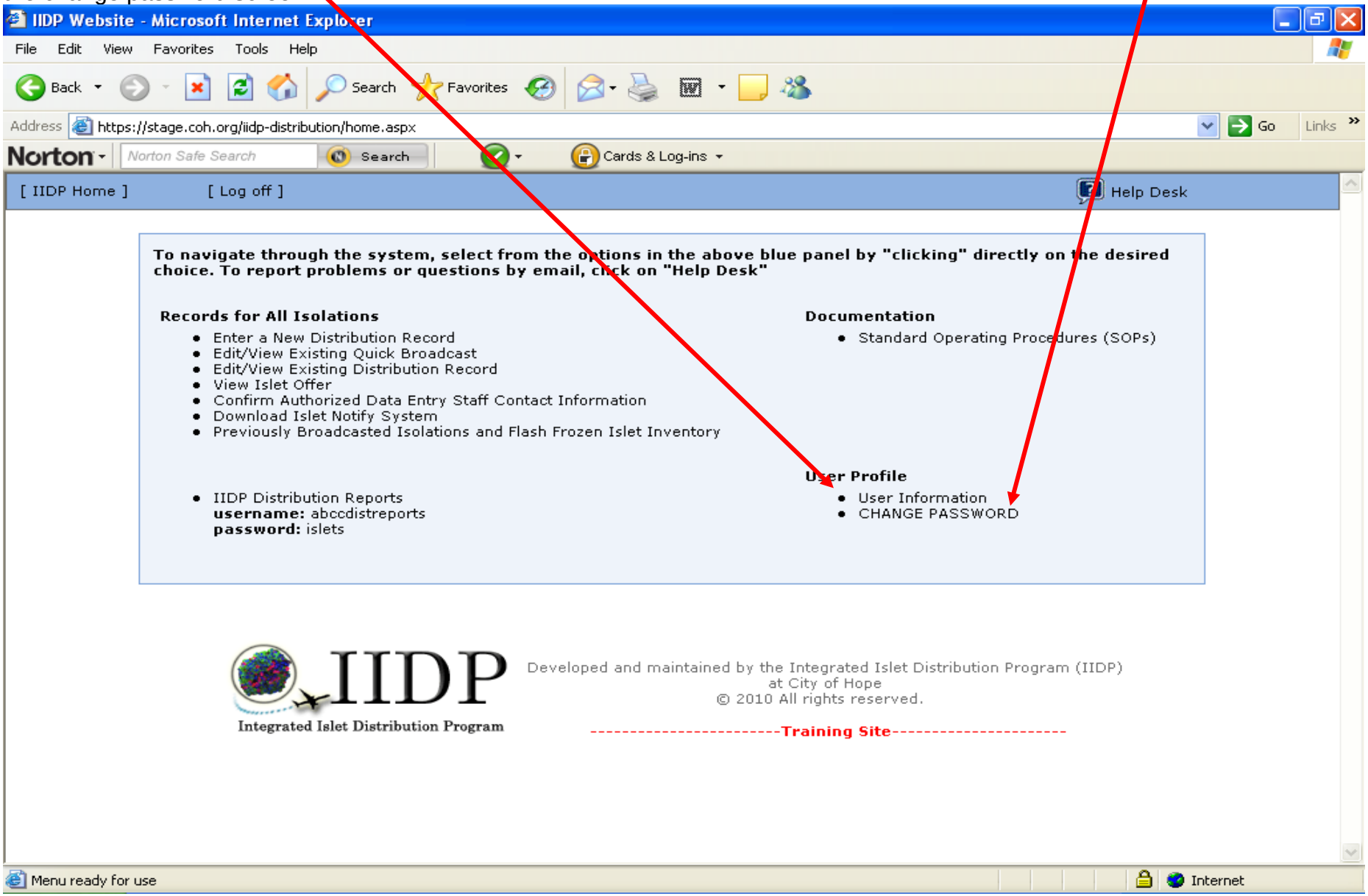
Confirm Contact Information screen – Edit as needed.



Click on **[Submit]** to save any changes and return to the Main Page.

10.0 View/Change your User Profile

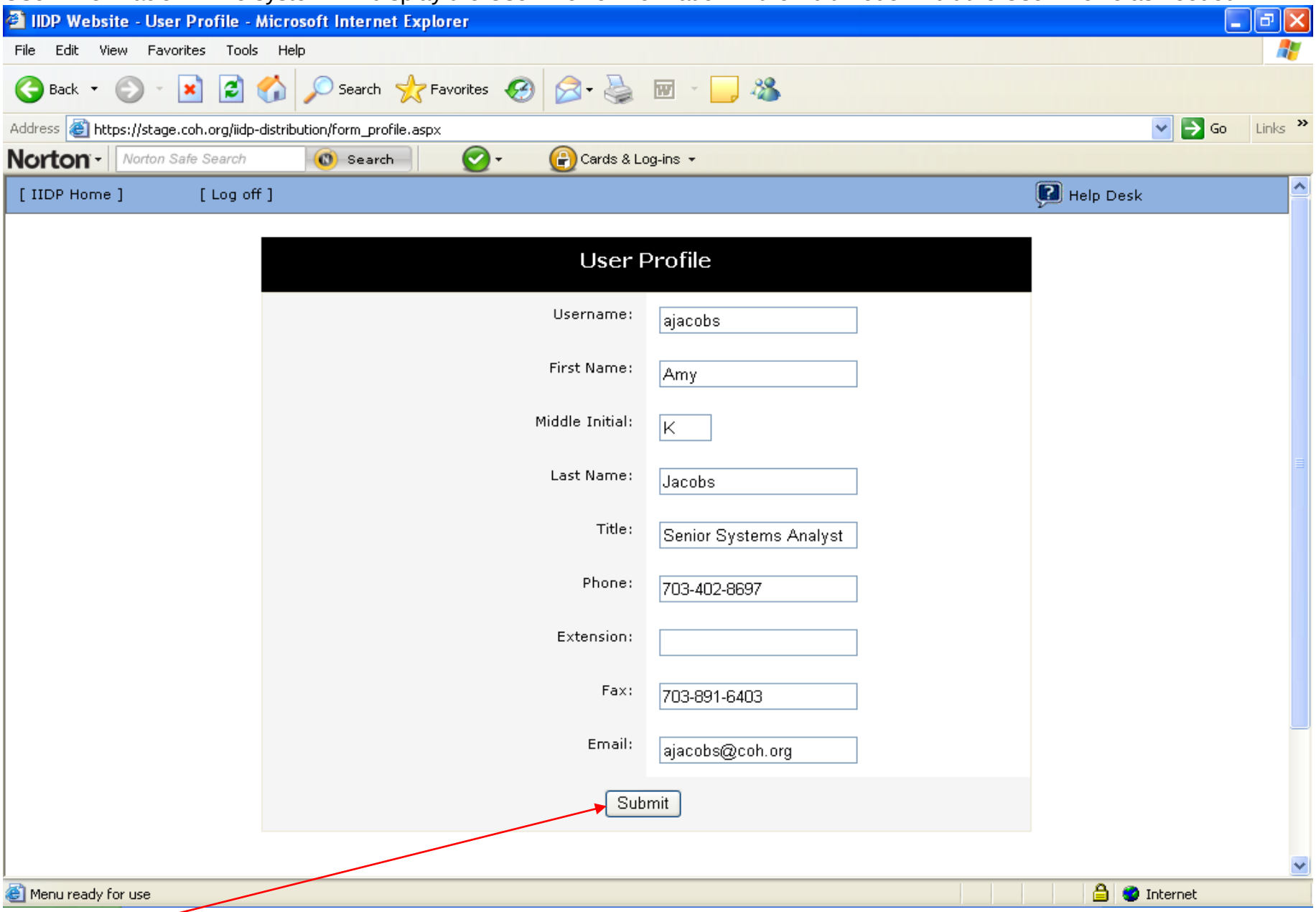
Main Page - Click on **[User Information]** to display the User Information screen or click on **[CHANGE PASSWORD]** to display the change password screen.



User Information - The system will display the User Profile if the user clicks on **[User Information].**

Review the information and click on **[Edit]** to make changes as needed -refer to the next page.
OR
Click on another menu option, if there are no required changes.

User Information - The system will display the User Profile information in the Edit Mode. Edit the User Profile as needed.



Click on **[Submit]** to submit the changes to the system.

User Information - The system will display the changed User Profile information for the user to review. If additional changes are needed, click on **[Edit]** and repeat the process to edit the User Profile information. Click on **[IIDP Home]** to return to the Main Page.

Change Password - The system will display the Change User Password if the user clicks on **[CHANGE PASSWORD].**

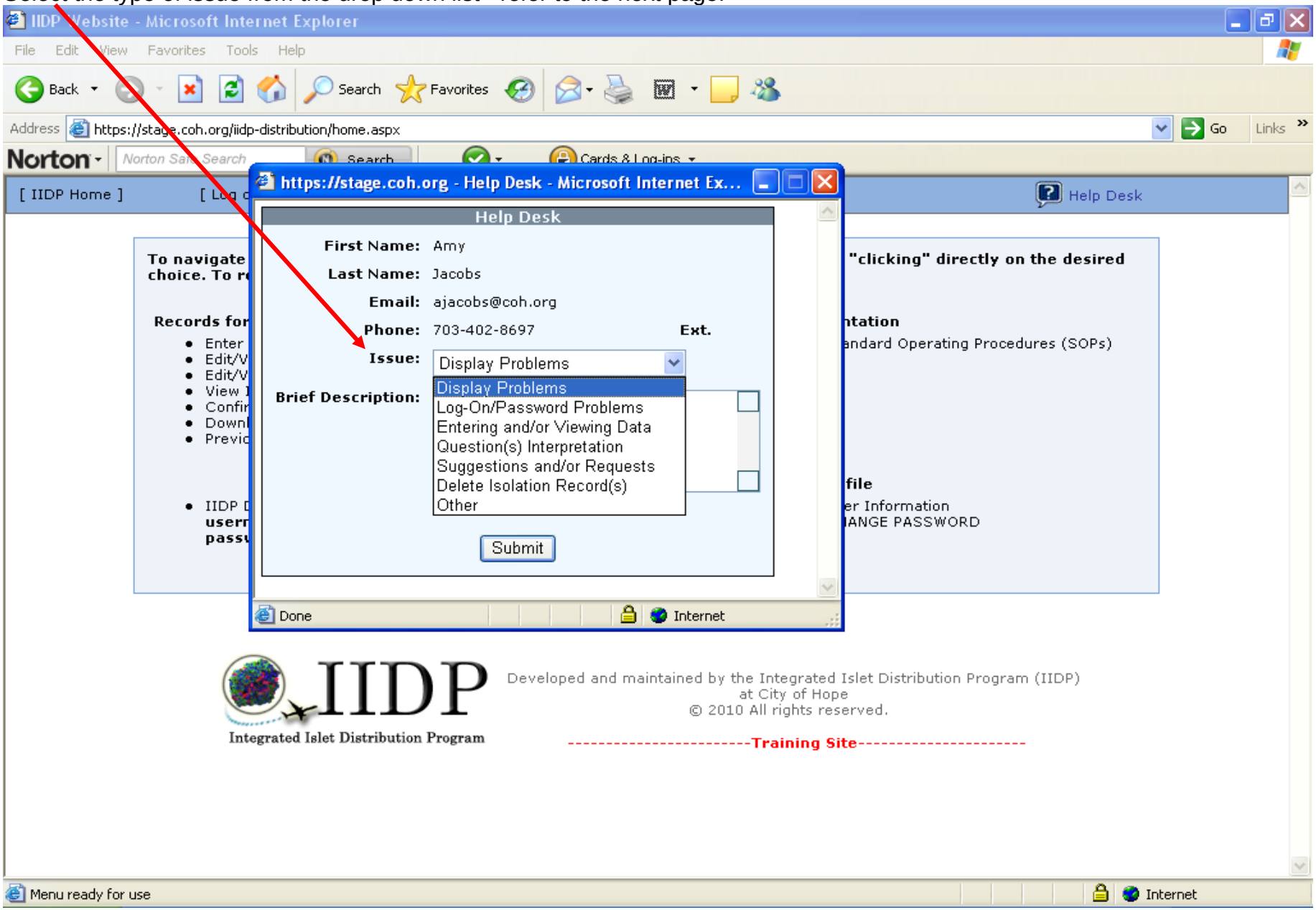
Change password and then click on **[Submit].** The system returns the user to the Main Page.

Main Page - Click on another menu option as desired to continue in the system OR click on **[Log off]** to exit the system.

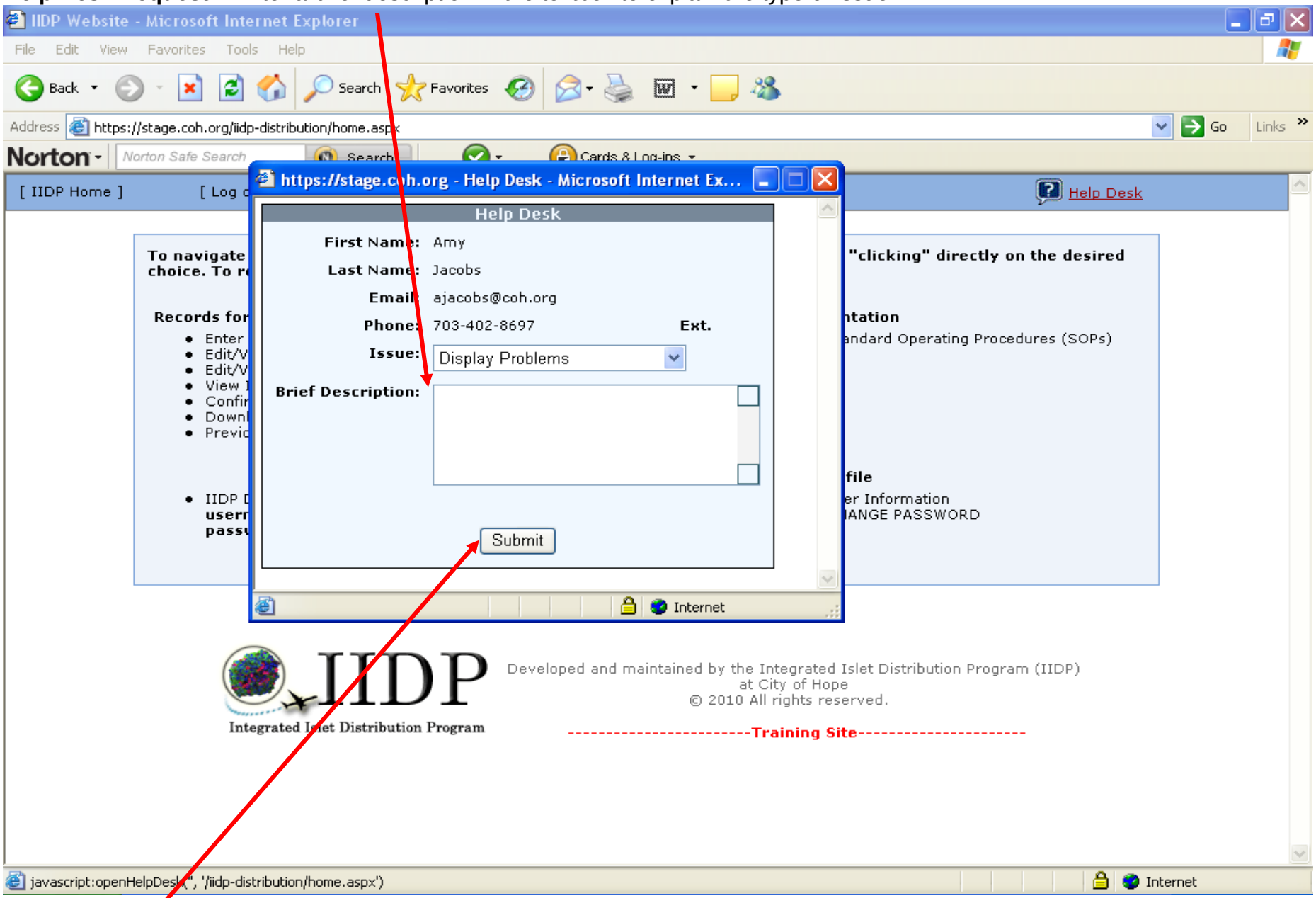
11.0 Submit Help Desk Requests to the Integrated Islet Distribution Program (IIDP)

Main Page - Click on **[Help Desk]** icon on the menu bar to submit help desk requests to IIDP. Your feedback is appreciated.

Help Desk Request - The system will display the help desk request box to enter and submit your help desk request to IIDP. Select the type of issue from the drop down list - refer to the next page.

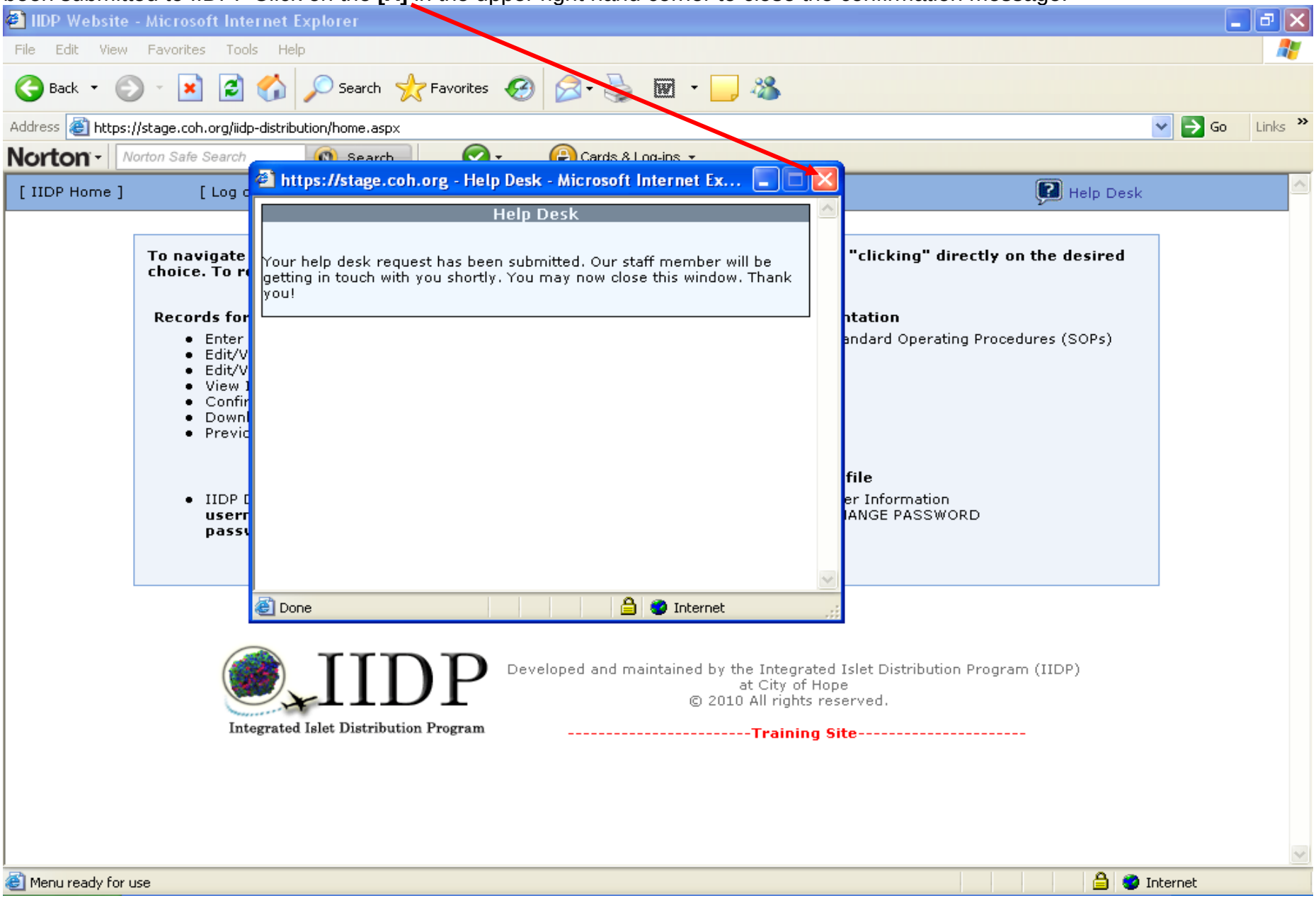


Help Desk Request – Enter a brief description in the textbox to explain the type of issue.



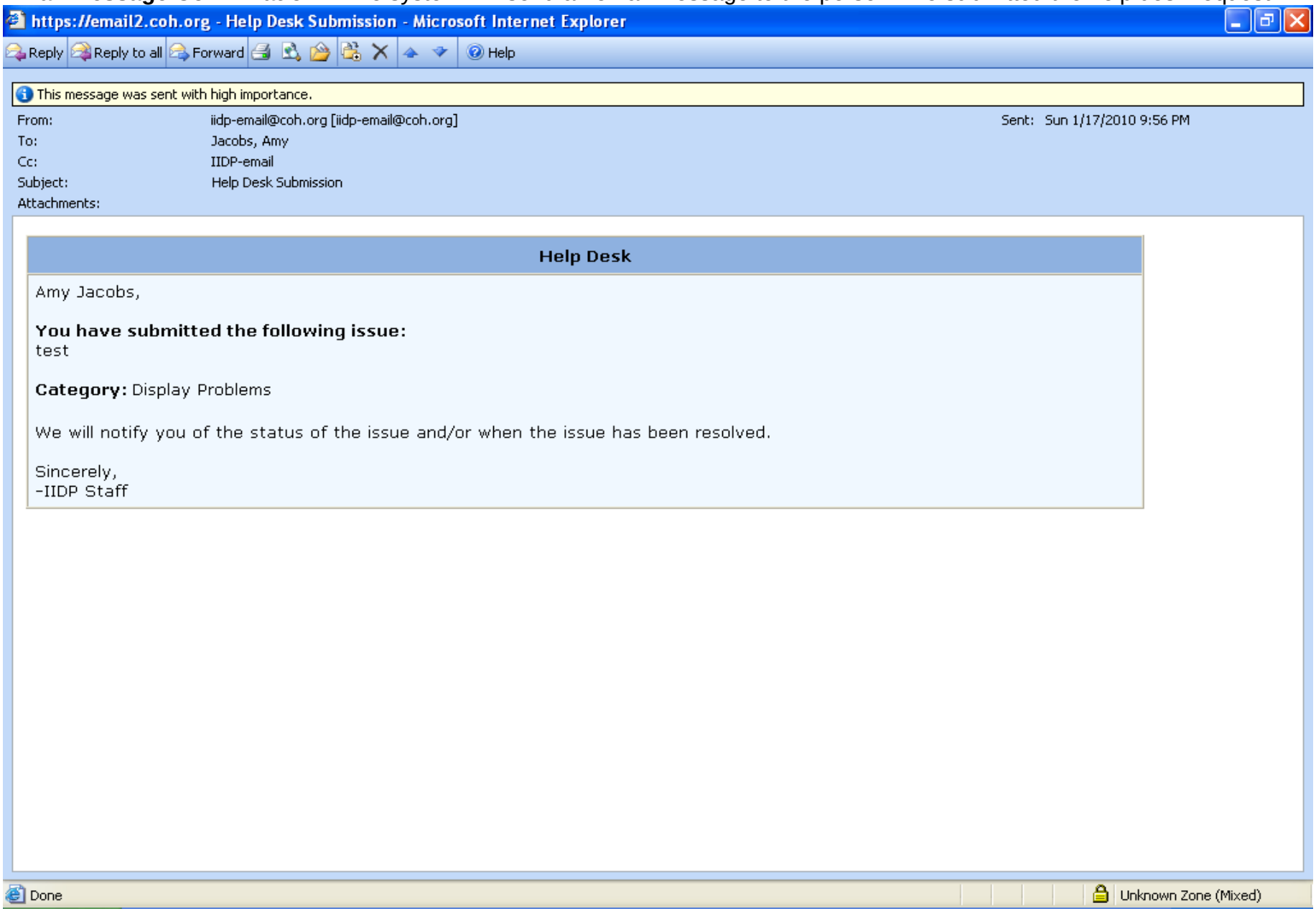
Click on **[Submit]** to send the help desk request to IIDP. A confirmation message will then be displayed - refer to the next page.

Help Desk Request – Confirmation Message - This message will be displayed to inform you that your help desk request has been submitted to IIDP. Click on the **[X]** in the upper right hand corner to close the confirmation message.



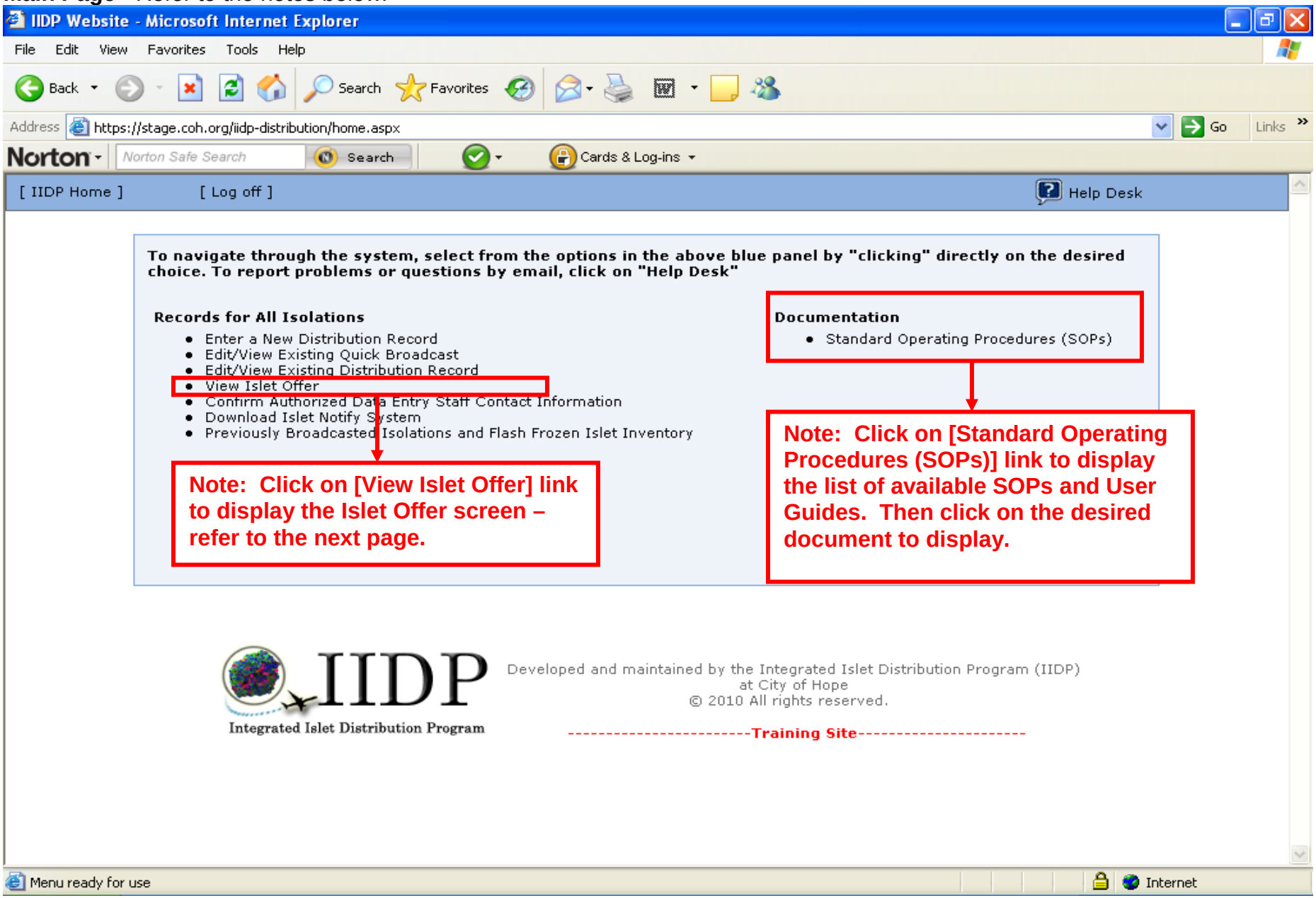
The system will also send an email message that the help desk request has been submitted – refer to the next page.

Email Message Confirmation – The system will send an email message to the person who submitted the help desk request.

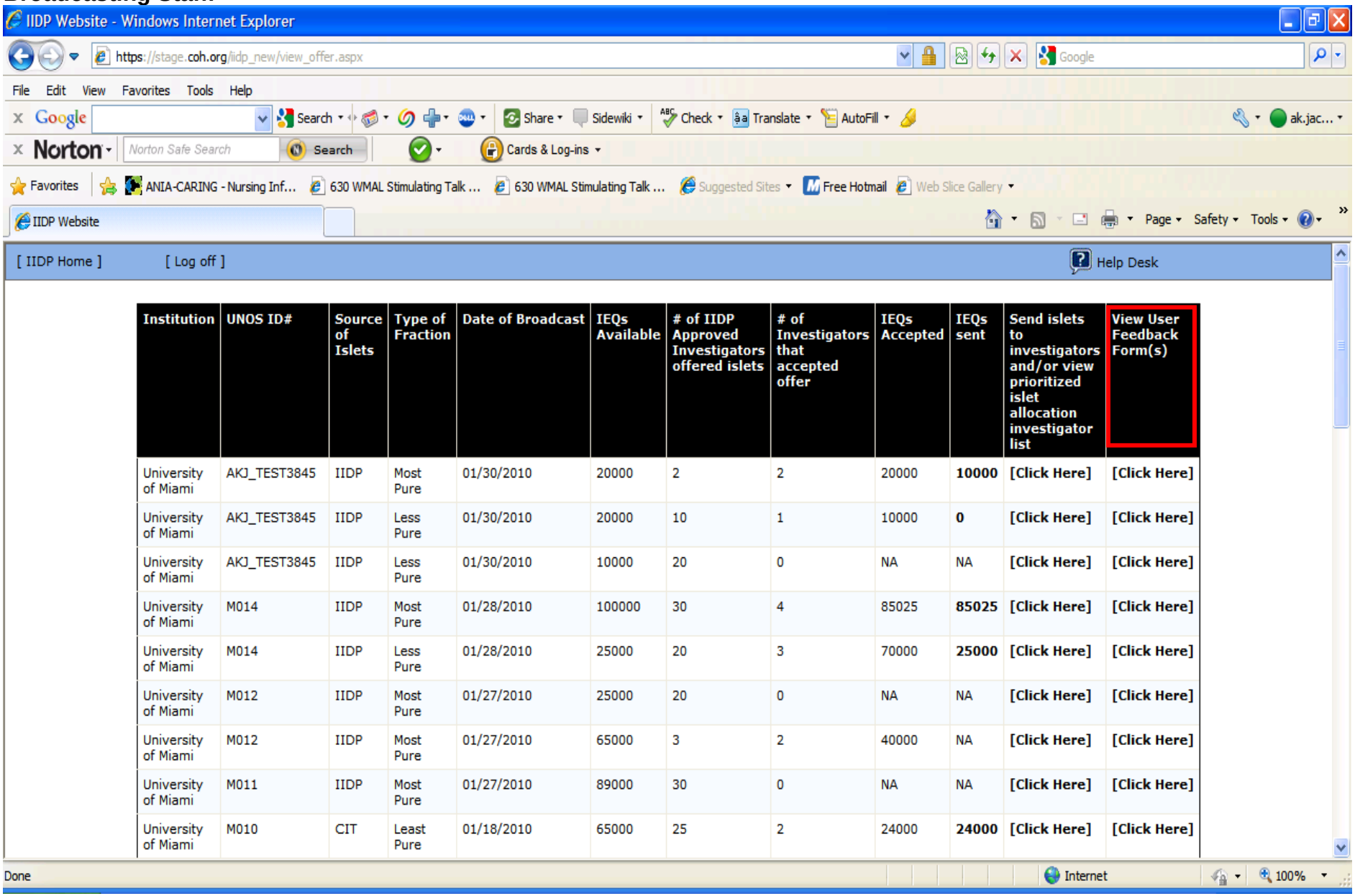


12.0 Other Functions

Main Page - Refer to the notes below.



Islet Offer screen – Click on **[Click Here]** under **[View User Feedback Form(s)]** – refer to the **UFF User Guide for Broadcasting Staff.**

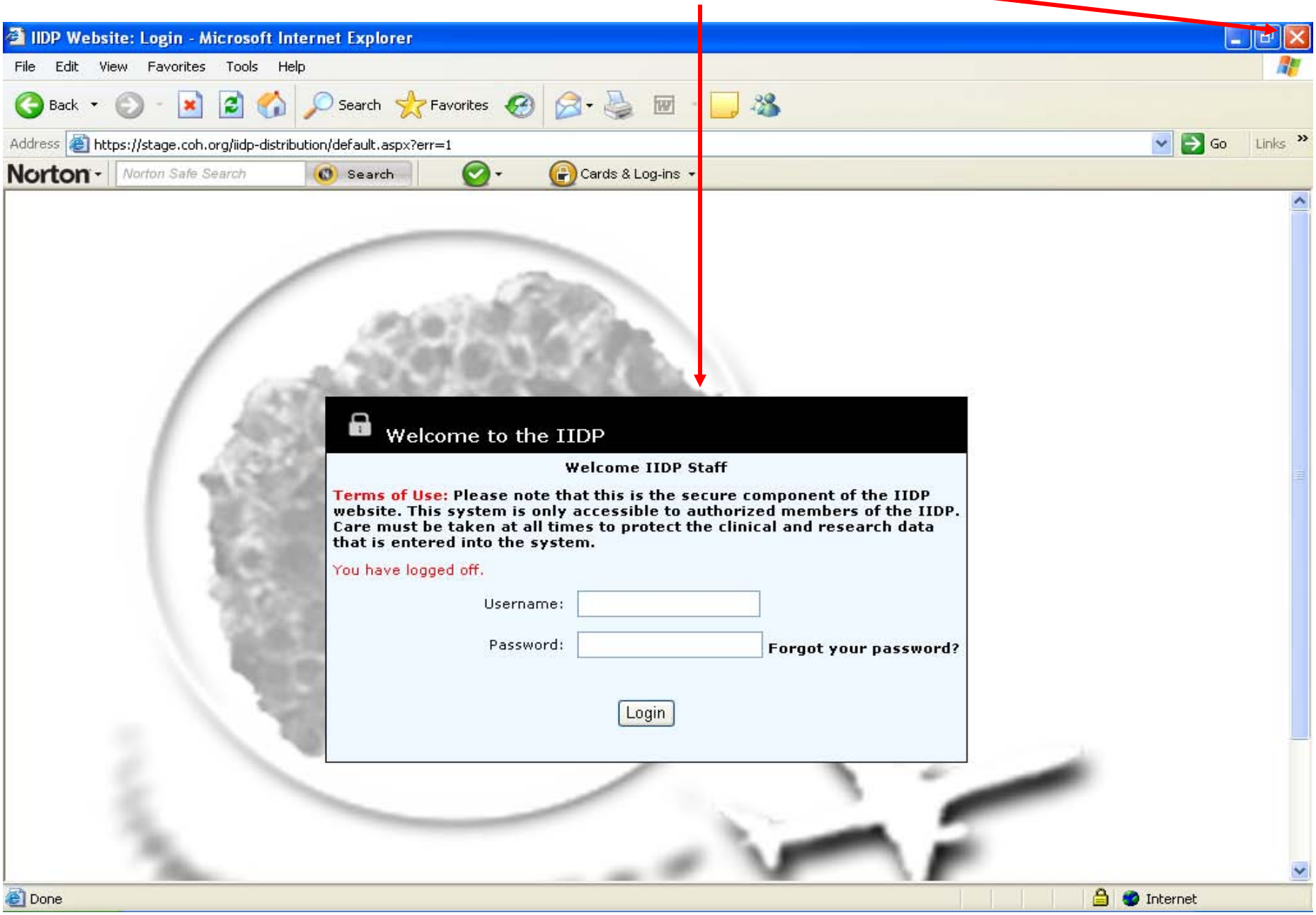


Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	View User Feedback Form(s)
University of Miami	AKJ_TEST3845	IIDP	Most Pure	01/30/2010	20000	2	2	20000	**10000**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	20000	10	1	10000	**0**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	10000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Most Pure	01/28/2010	100000	30	4	85025	**85025**	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Less Pure	01/28/2010	25000	20	3	70000	**25000**	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	25000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	65000	3	2	40000	NA	**[Click Here]**	**[Click Here]**
University of Miami	M011	IIDP	Most Pure	01/27/2010	89000	30	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M010	CIT	Least Pure	01/18/2010	65000	25	2	24000	**24000**	**[Click Here]**	**[Click Here]**

13.0 Log out of the Islet Data Entry System (IDES)

Main Page - click on **[Log off]** to log out of the Islet Data Entry System (IDES).

The system logs the user out of the system and displays the Login Screen. Click on the **[X]** to close out of the browser.



14.0 Frequently Asked Questions (FAQs)

Q1: Am I required to have a User ID and Password to access the system?
A1: You need a User ID and Password to access the Islet Data Entry System (IDES). The IIDP staff will assign you a User ID and Password.

Q2: What if I cannot complete the Quick Broadcast or Distribution Record at one time (e.g. do not have the data available or need to stop to proceed to another task (e.g. go to a meeting)).
A2:
1. Click on **[Submit]** of the designated section being completed.
2. Click on **[Submit]** on the Distribution Detail Summary screen.
3. The system will display a confirmation message that the data form is only partially completed.
4. When you are ready to complete the Islet Isolation Data Form, click on **[Edit/Add Existing Distribution Record]** under **[Records for All Isolations]** on the Main Page.
5. The system will display a list of all the Distribution Records in the system.
6. Find the desired UNOS ID# and/or Isolation ID # of the Data Form that you were completing and click on **[Edit].**
7. The system will display the desired Distribution Record.

Q3: When I am completing the form, how do I go back to a previous section to edit and/or add data to that previous section?
A3: Click on **[Submit]** in the current section. The system will return you to the Distribution Record Detail Summary or Quick Broadcast Detail Summary screen based on the form you are completing. Then you may click on **[Edit]** of the desired section to edit and/or add data.

ISLET DATA ENTRY SYSTEM

User Guide for Investigators 2010 for Acceptance of Islets Via the Web

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1.0. General Guidelines

1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Islet Offer screen (e.g. accept islet offer, change user profile, submit a help desk request, etc.). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for accepting an islet offer is primarily presented in the majority of the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the IDES data entry screens are designed to be a 'single page' in which the data for each section of the IDES data form are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the IDES Data Form to capture the data.

1.2.2.1 Text Boxes

- Data must be typed in
- Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen – e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the

validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

(mm/dd/yy)

The system will automatically enter the forward slashes **(/)** as you enter the date.

1.3.1.2 Time Field Formats

(hh:mm)

The system will automatically enter the colon **(:)** as you enter the time.

1.3.1.3 Date Field Ranges

06/04/2010 (mm/dd/yy)

The system will display a message that the date is out of range and that the latest date that may be entered is the current date.

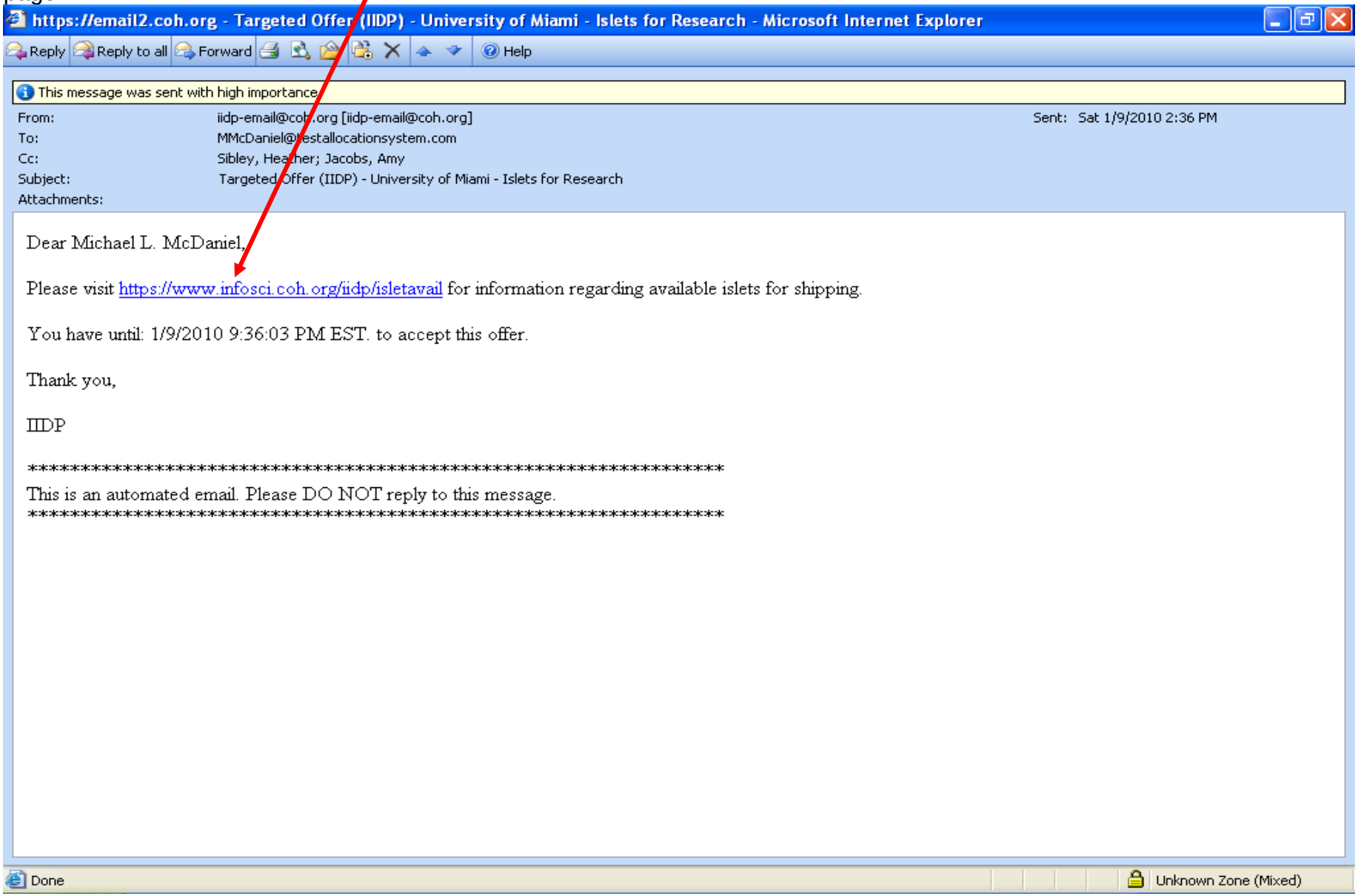
1.3.1.4 Numeric Field Formats

Percent of Trapped Islets (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

2.0 Receive Broadcast Message about Islet Availability

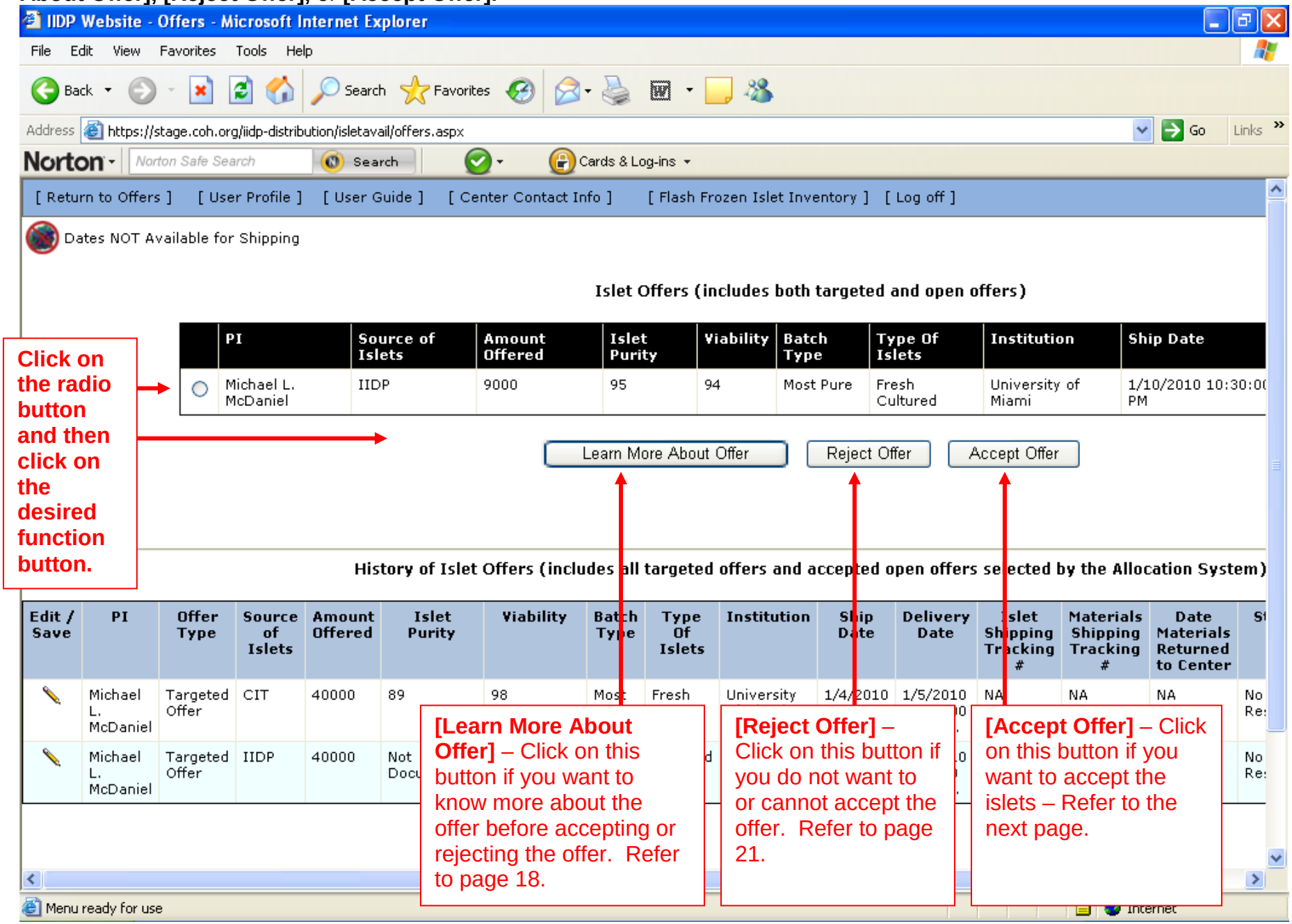
Email Broadcast Message - This is the email Broadcast Message that the designated investigator(s) will receive about the availability of islets. Click on the URL link in the broadcast message or cut and paste the URL into the browser – refer to the next page.



Login Screen - The system displays the login screen. Enter your username and password and then click on Login. IIDP assigns the username and password.

The islet offer will then be displayed – refer to the next page.

Islet Offer - Click on the radio button to the left of the PI name. Then click on one of the three (3) function buttons – **[Learn More About Offer], [Reject Offer],** or **[Accept Offer].**



Click on the radio button and then click on the desired function button.

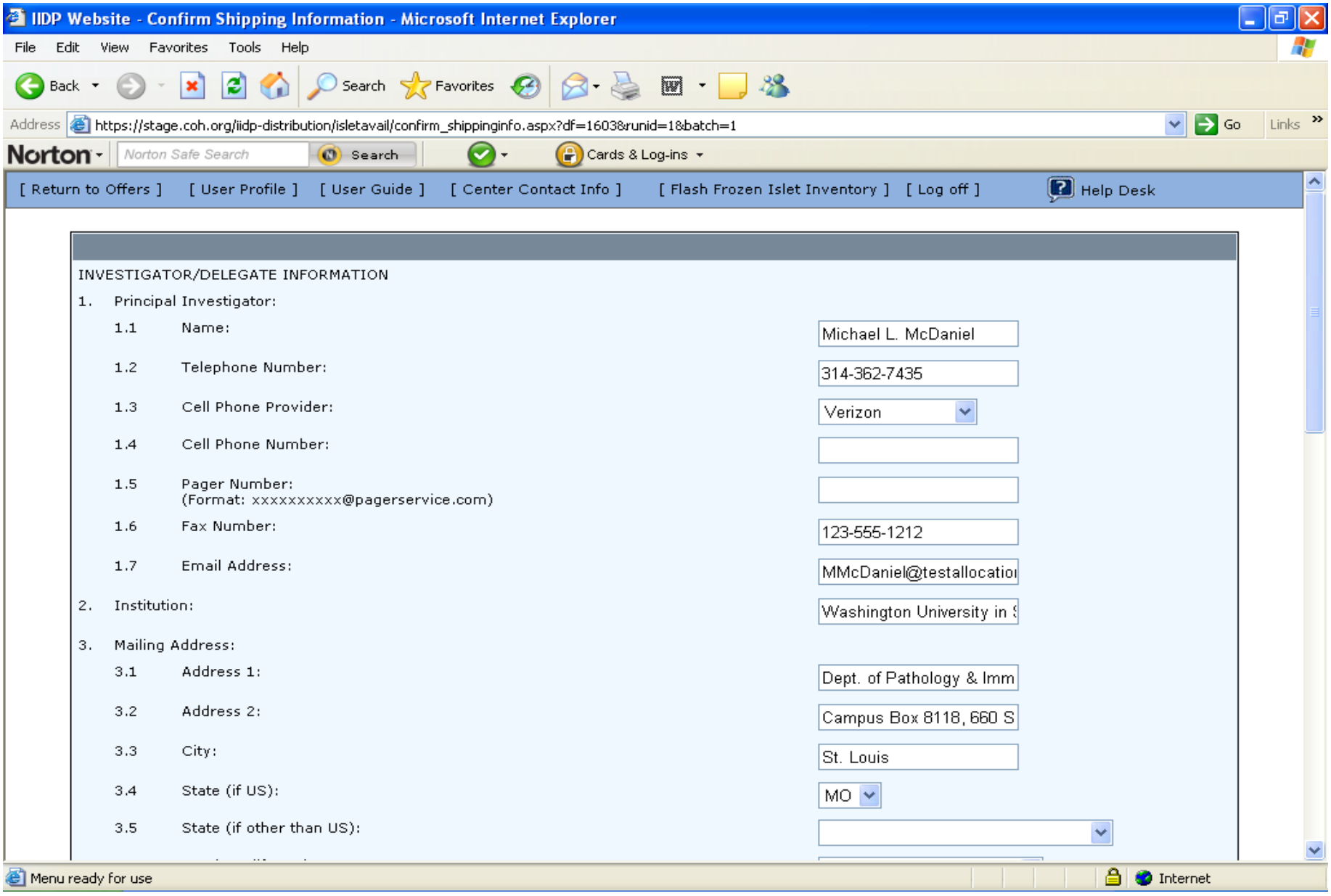
[Learn More About Offer] – Click on this button if you want to know more about the offer before accepting or rejecting the offer. Refer to page 18.

[Reject Offer] – Click on this button if you do not want to or cannot accept the offer. Refer to page 21.

[Accept Offer] – Click on this button if you want to accept the islets – Refer to the next page.

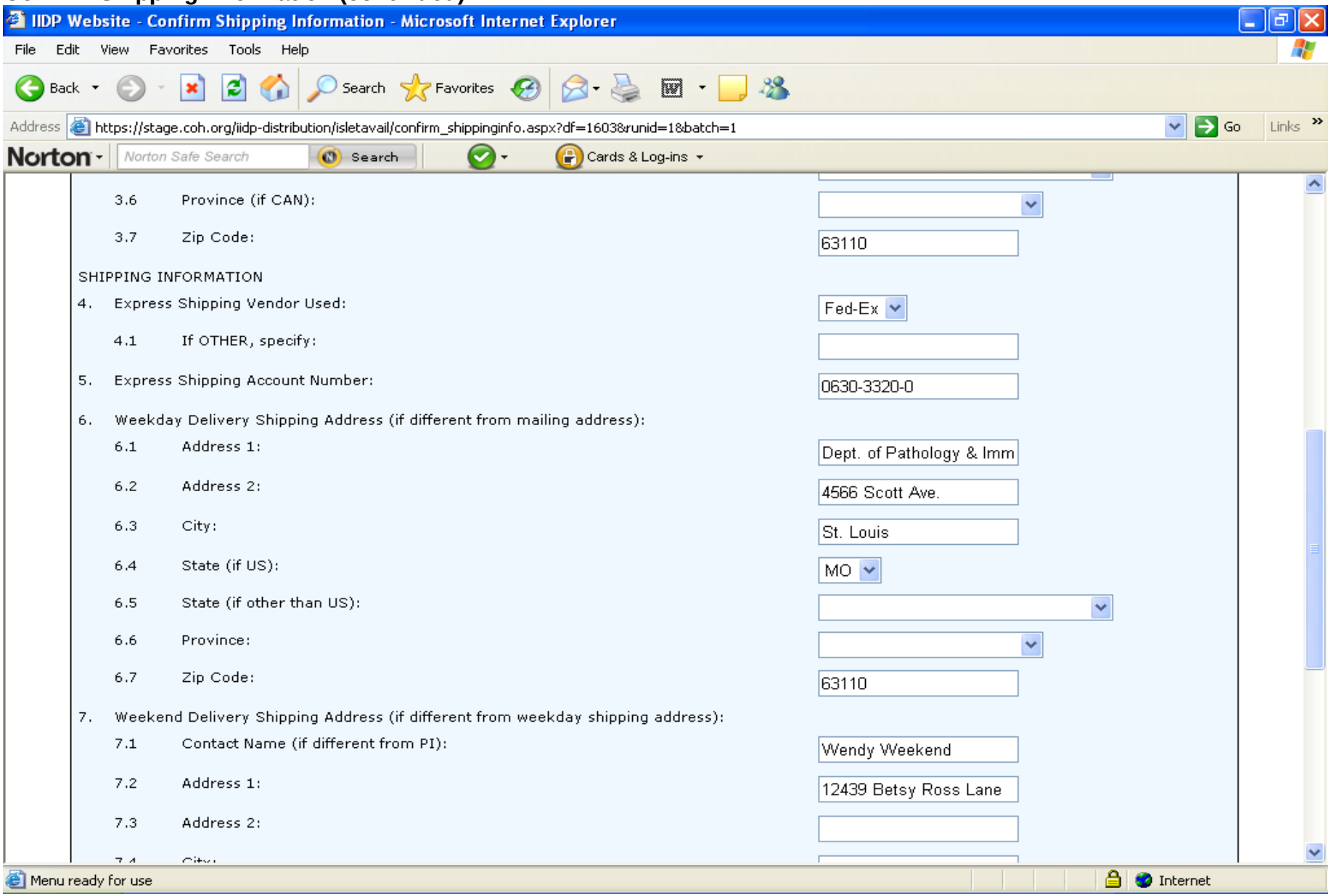
Accept Offer - Once you **[Accept Offer],** this screen is displayed and you will need to **[Confirm Shipping Information] AND [Confirm Islet Offer].** Click on **[View**] to confirm shipping information. Please note the expiration time of the islet offer.

Confirm Shipping Information – The system displays your shipping information that has been entered into the system. Review the information and edit and /or add to the data as needed.



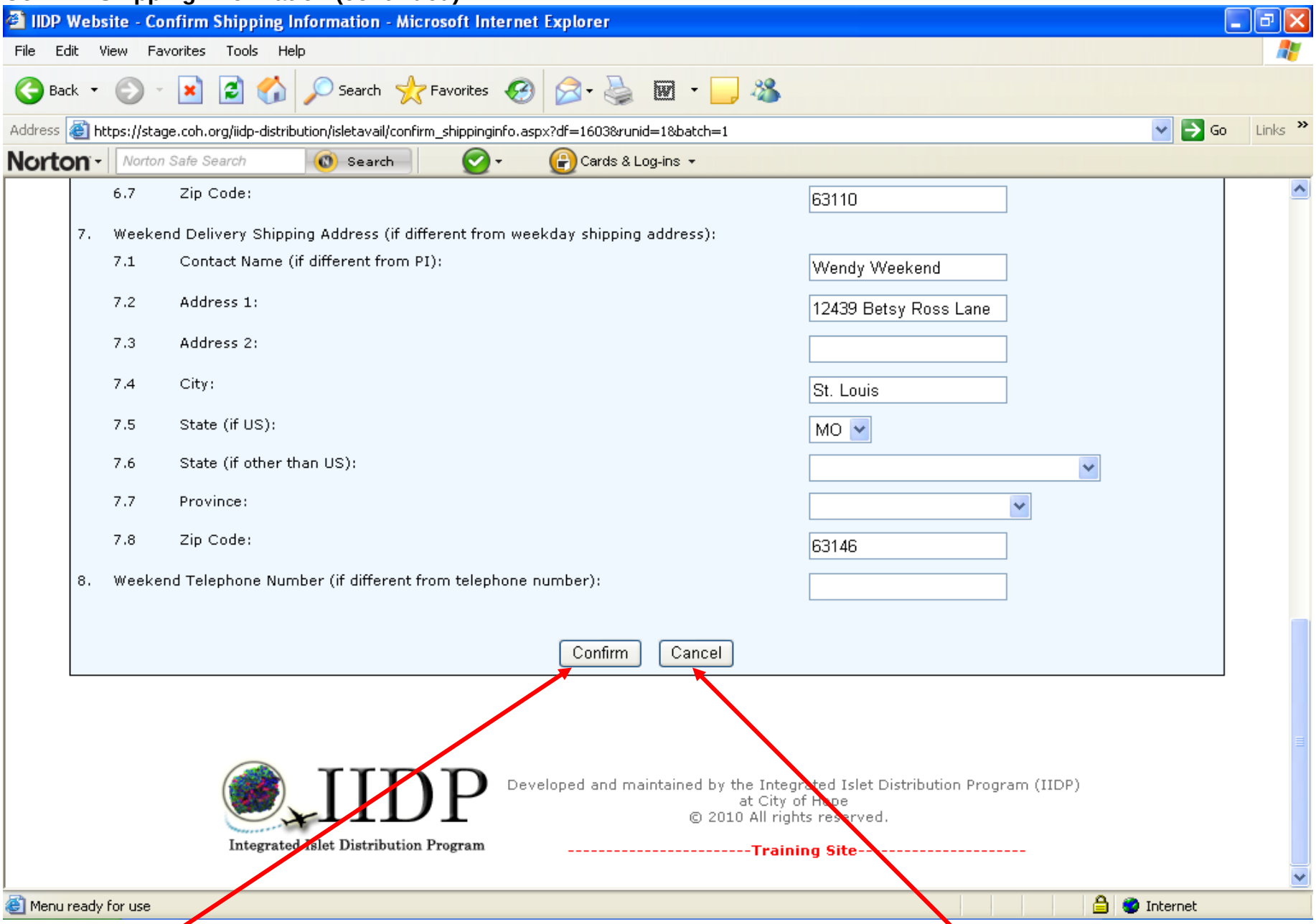
Use the **scroll bar** to scroll down to the bottom of the page. The **[Confirm Shipping Information]** screen continues on the next page.

Confirm Shipping Information (continued)



Use the **scroll bar** to scroll down to the bottom of the page. The **[Confirm Shipping Information]** screen continues on the next page.

Confirm Shipping Information (continued)

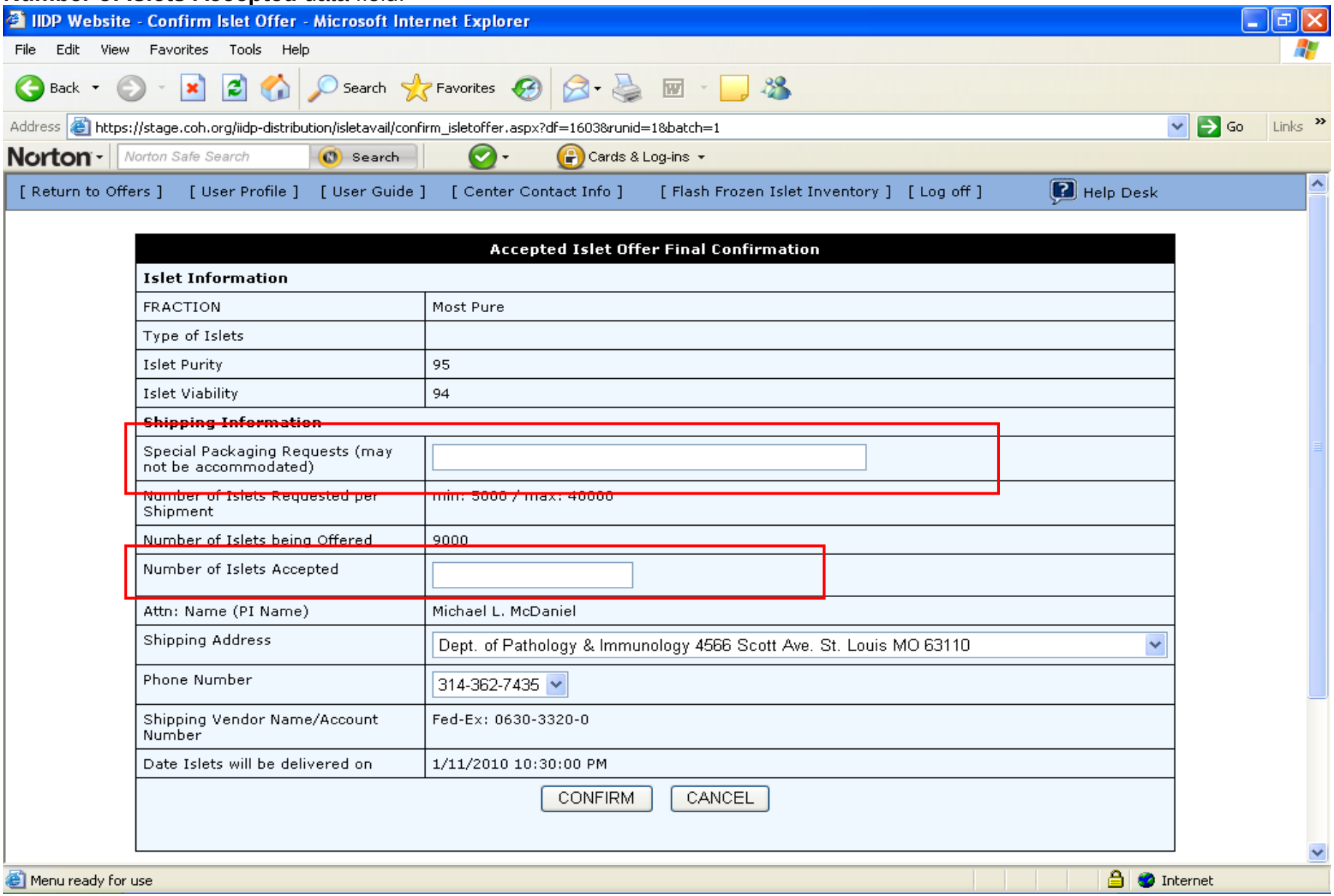


Click on **[Confirm]** to confirm your shipping information – refer to the next page **OR** click on **[Cancel]** to return to the **[Accept Offer]** screen – refer to page 8.

Accept Islet Offer – After confirming your shipping information the system returns you to the **[Accept Islet Offer]** screen. Please not the change in the function button for the shipping information from **[View]** to **[Confirmed].**

Click on **[View]** for the **[Confirm Islet Offer]** to proceed to the next step of the islet acceptance process – refer to the next page.

Confirm Islet Offer – The system displays the Islet Offer screen. Complete the **Special Packaging Requests** data field and the **Number of Islets Accepted** data field.

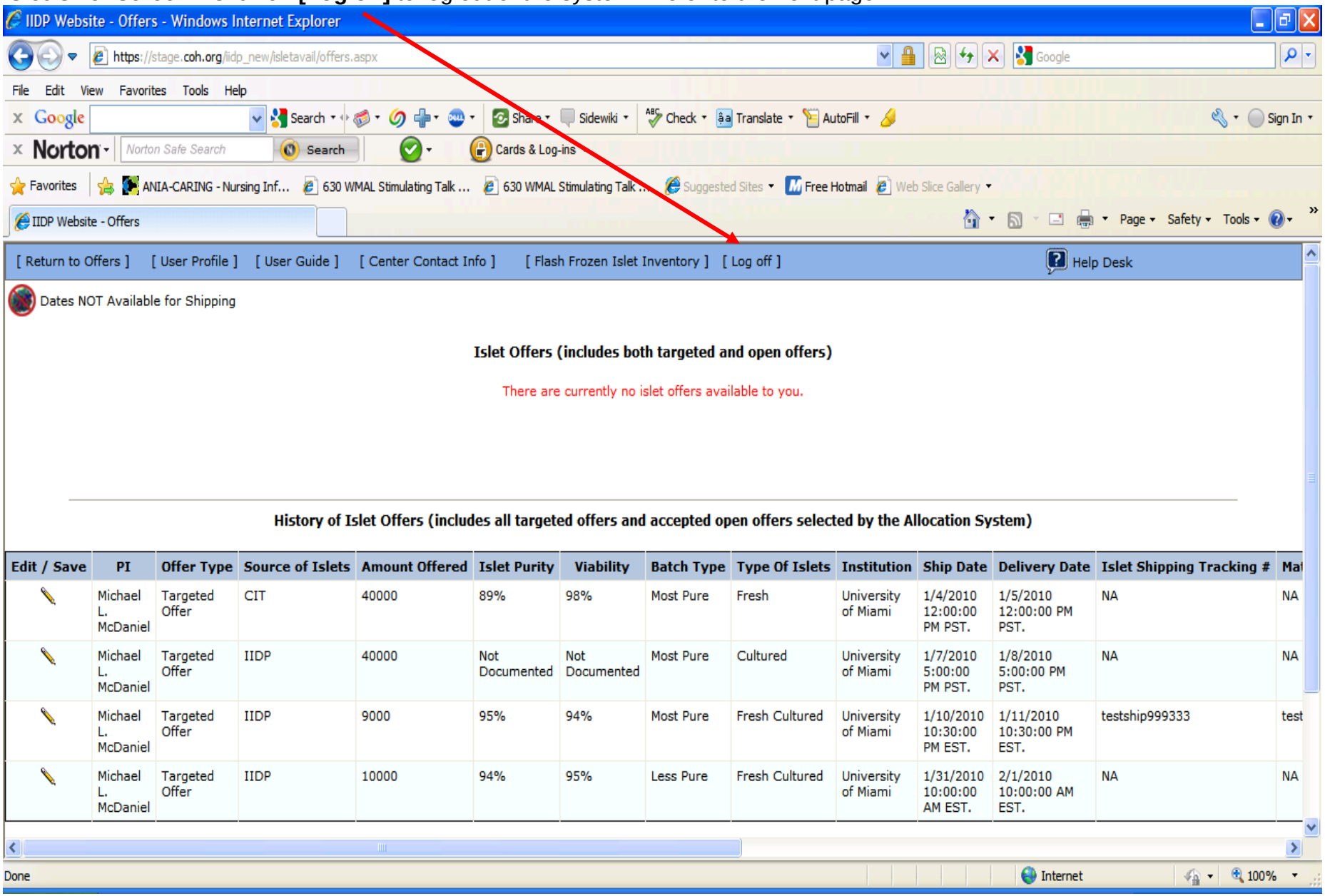


Click on **[CONFIRM]** to confirm the islet offer – refer to the next page **OR** click on **[CANCEL]** and not confirm the islet offer – refer to page 8.

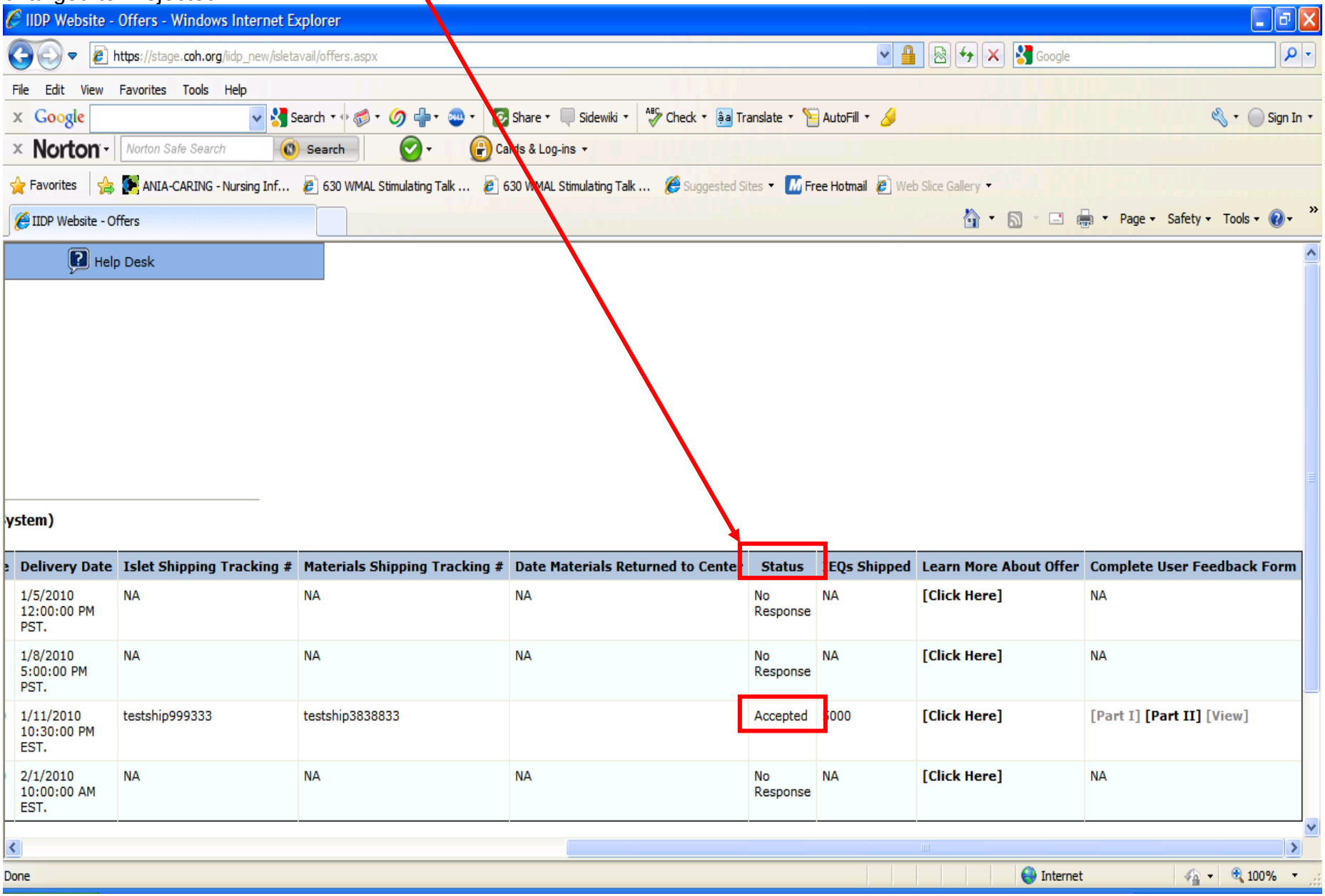
Accept Islet Offer – Once the shipping information and the islet offer have been confirmed, then the **[Accept Islets For Shipping]** button will be functional Click on **[Accept Islets For Shipping]** to complete the last step of the islet offer acceptance process.

Accept Islet Offer Confirmation Message – The system will display a confirmation message that the islet offer has been accepted and saved in the system. Click on **[Return to Offers]** or **[Close]** to return to the islet offer – refer to the next page.

Islet Offer screen - Click on **[Log off]** to log out of the system – refer to the next page.

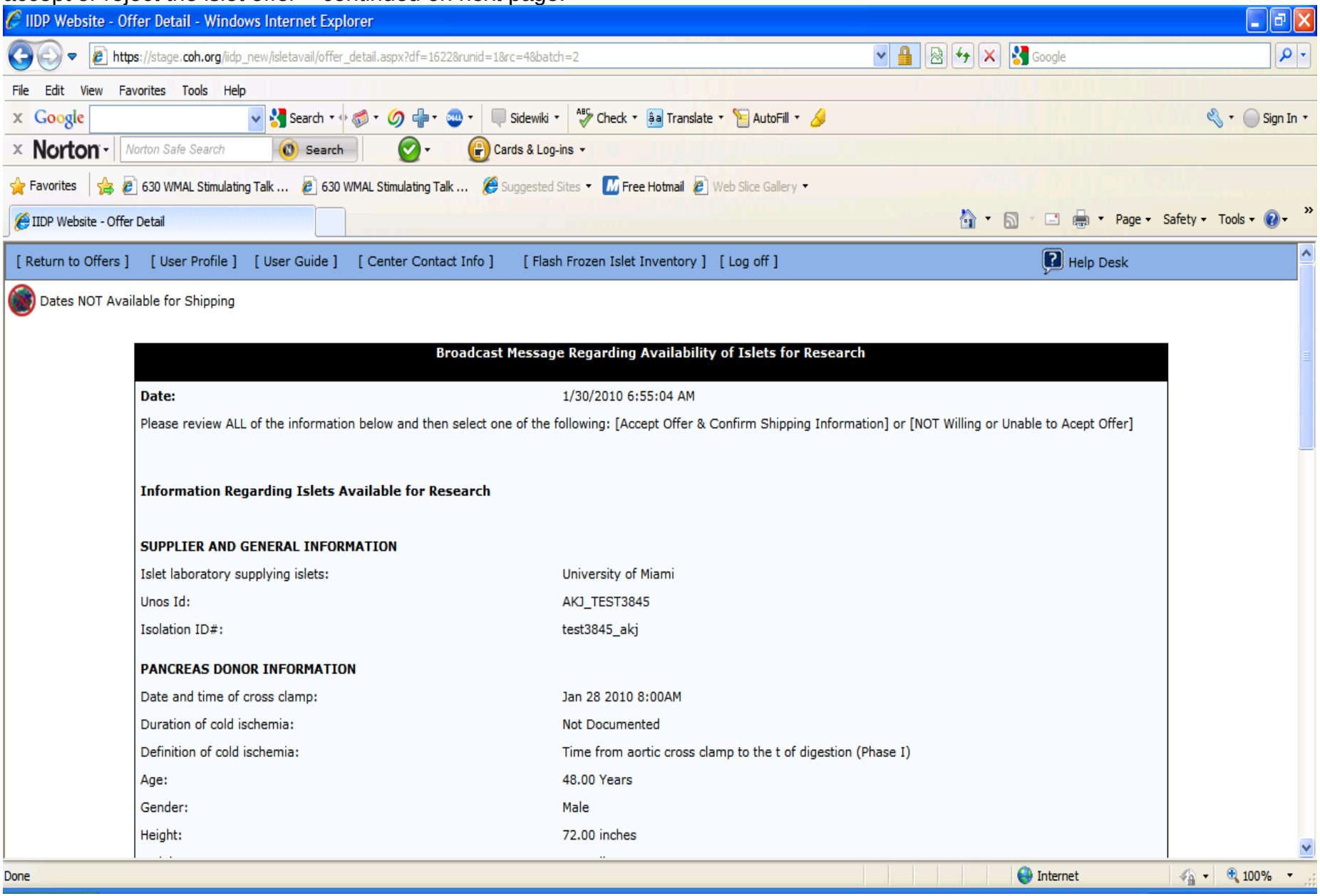


Islet Offer screen (continued) - Note the **[Status]** column (the status of the acceptance of the islet offer) - the default value of 'No Response' had been updated to 'Accepted'. If the islet offer had been rejected then the status value would have been changed to 'Rejected'.

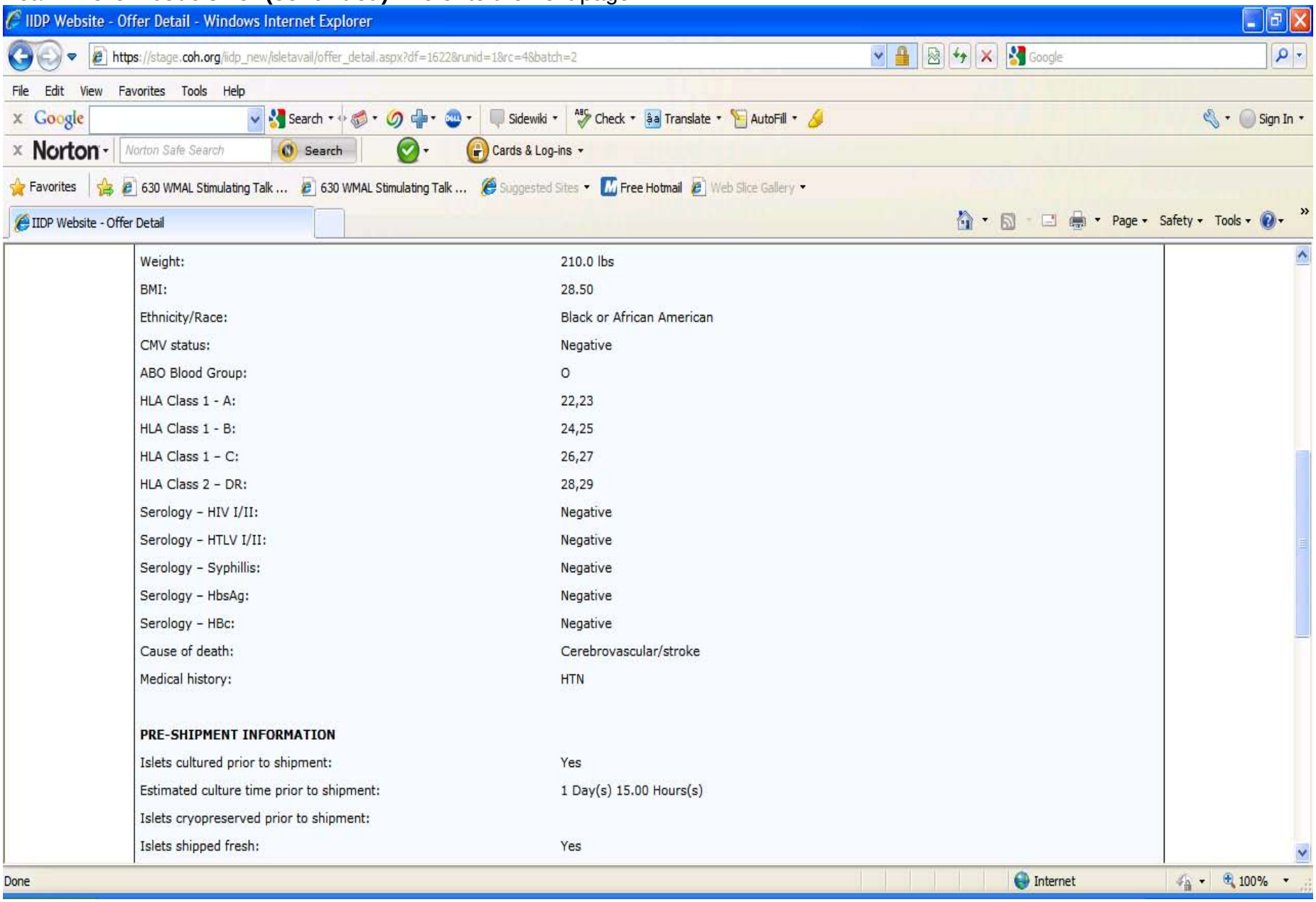


Login Screen – The system displays the log in screen. Log in **OR** click on the **[X]** to close the browser.

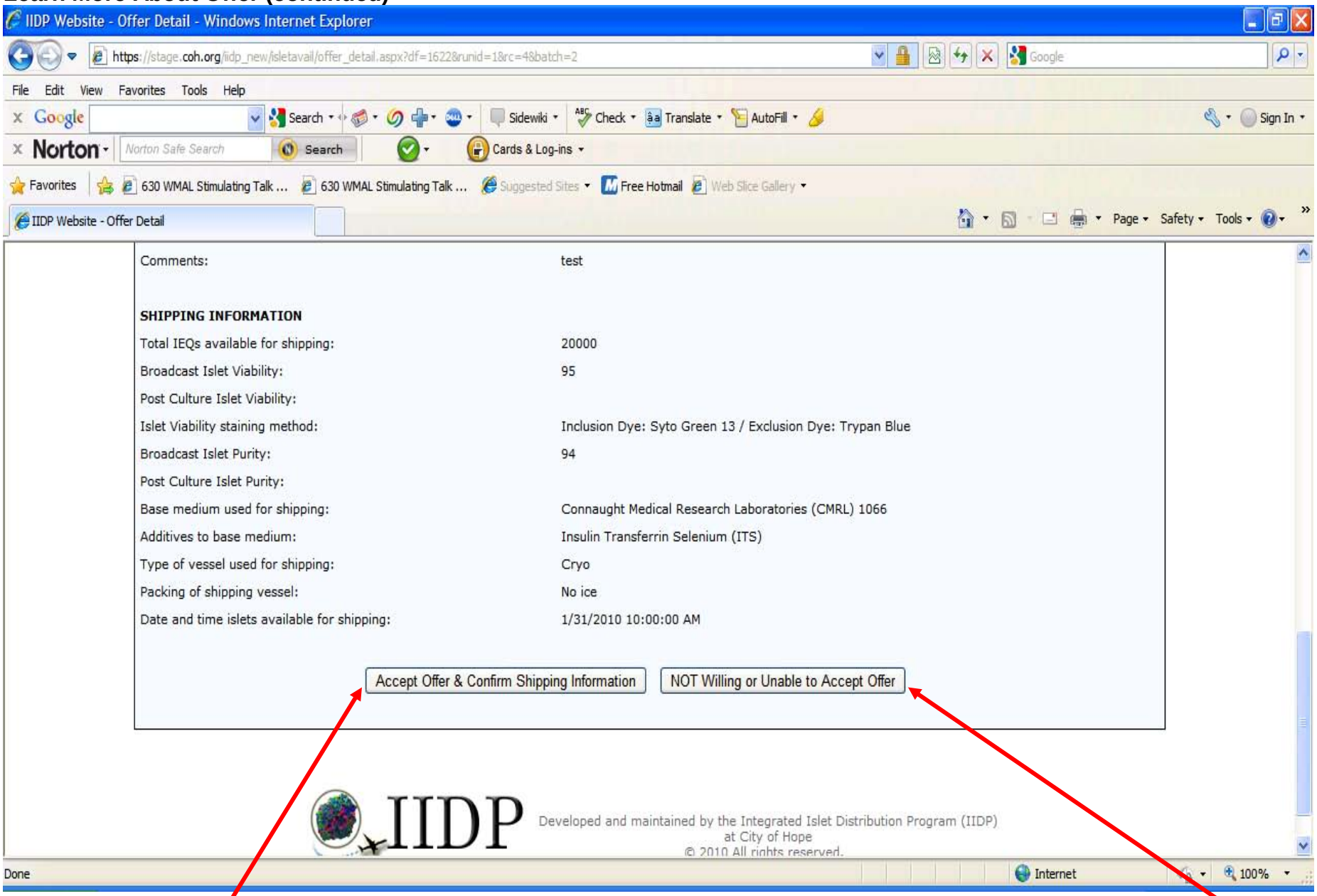
Learn More About Offer – The system displays more information about the islet offer to review before making a decision to accept or reject the islet offer – continued on next page.



Learn More About Offer (continued) – refer to the next page.

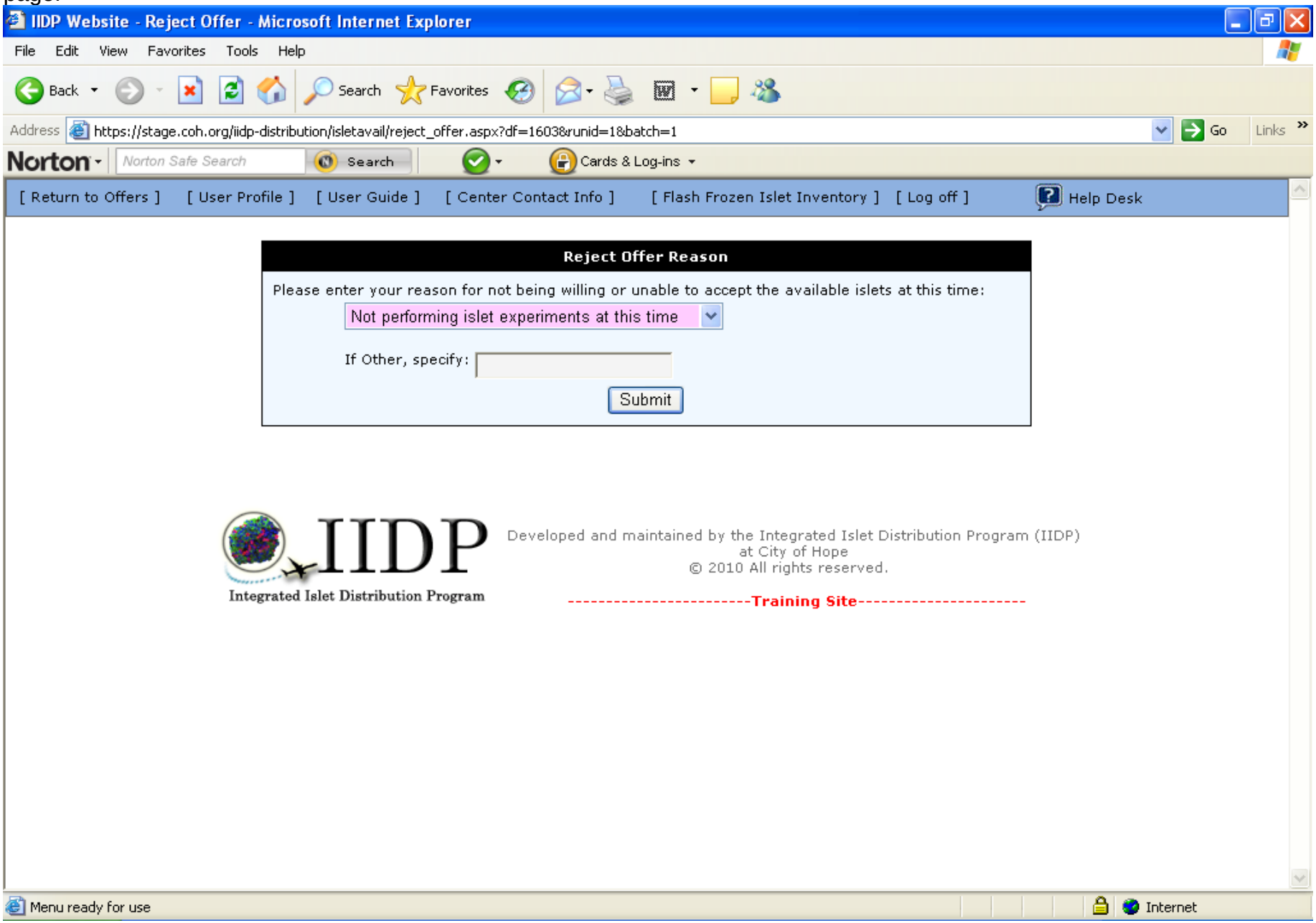


Learn More About Offer (continued)

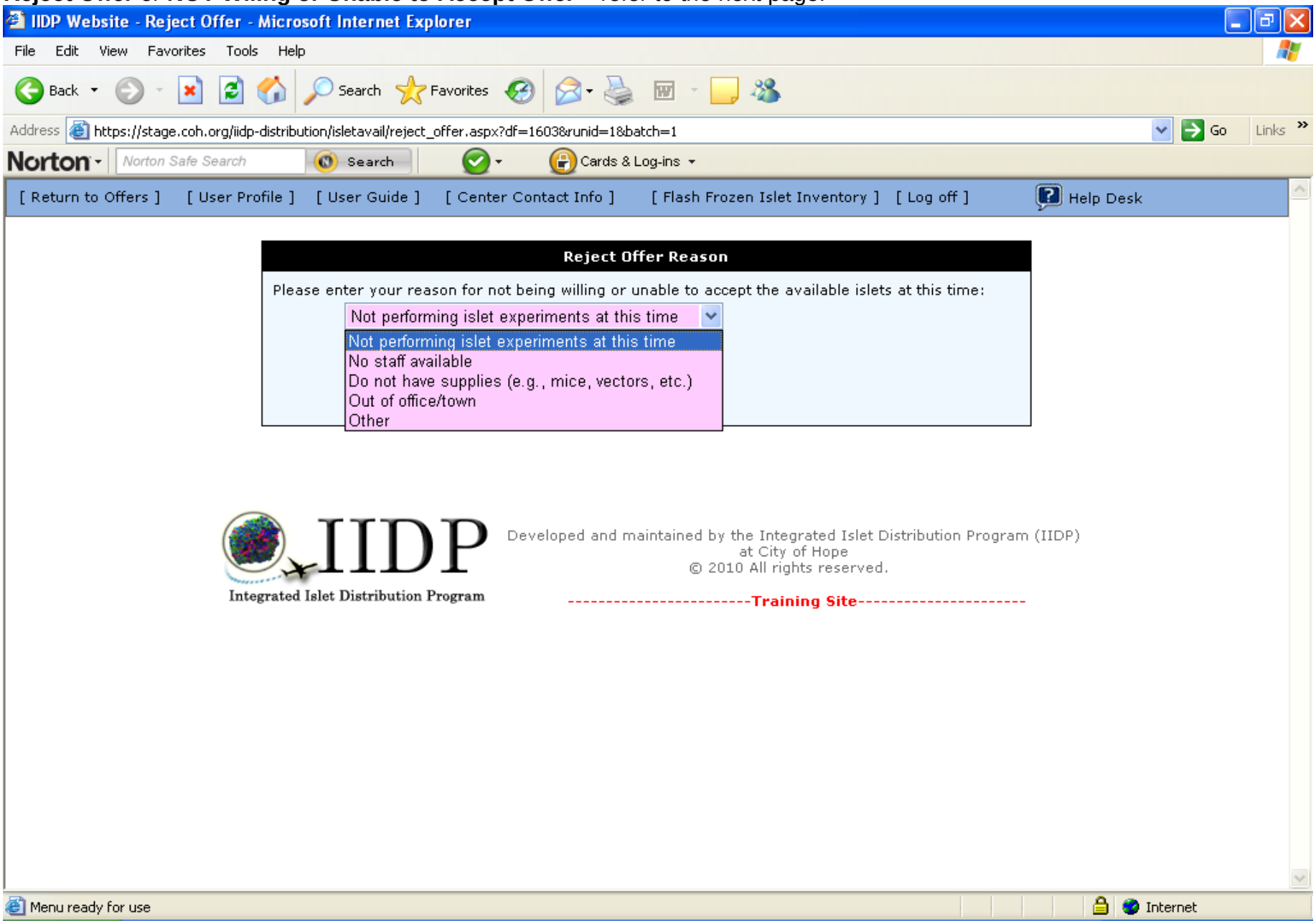


Click on **[Accept Offer & Confirm Shipping Information]** to accept the islet offer – refer to pages 8 - 17. Click on **[NOT Willing or Unable to Accept Offer]** to reject the islet offer – refer to the next page.

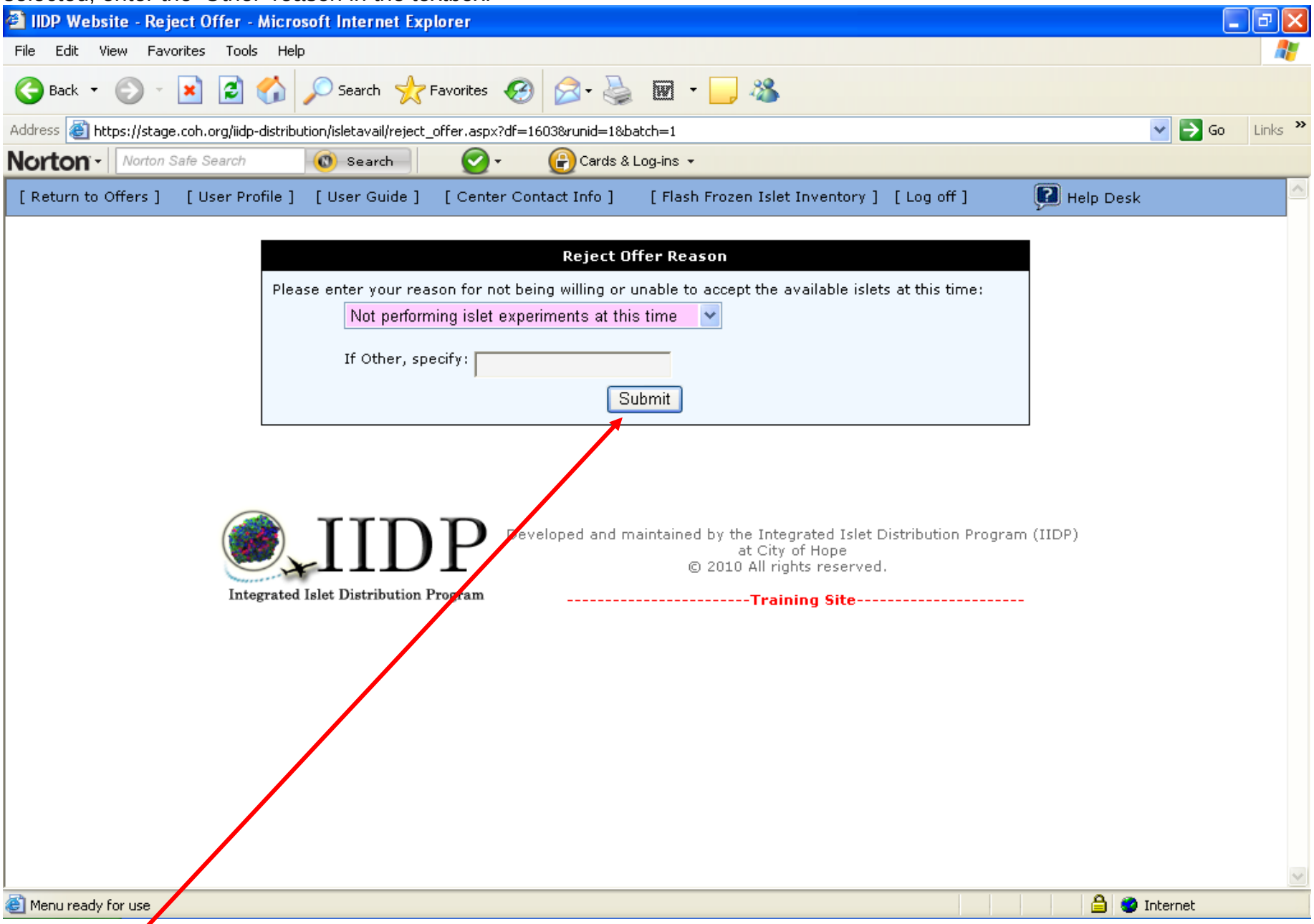
Reject Offer or **NOT Wiling or Unable to Accept Offer –** Select the rejection reason from the drop down menu – refer to the next page.



Reject Offer or **NOT Wiling or Unable to Accept Offer –** refer to the next page.

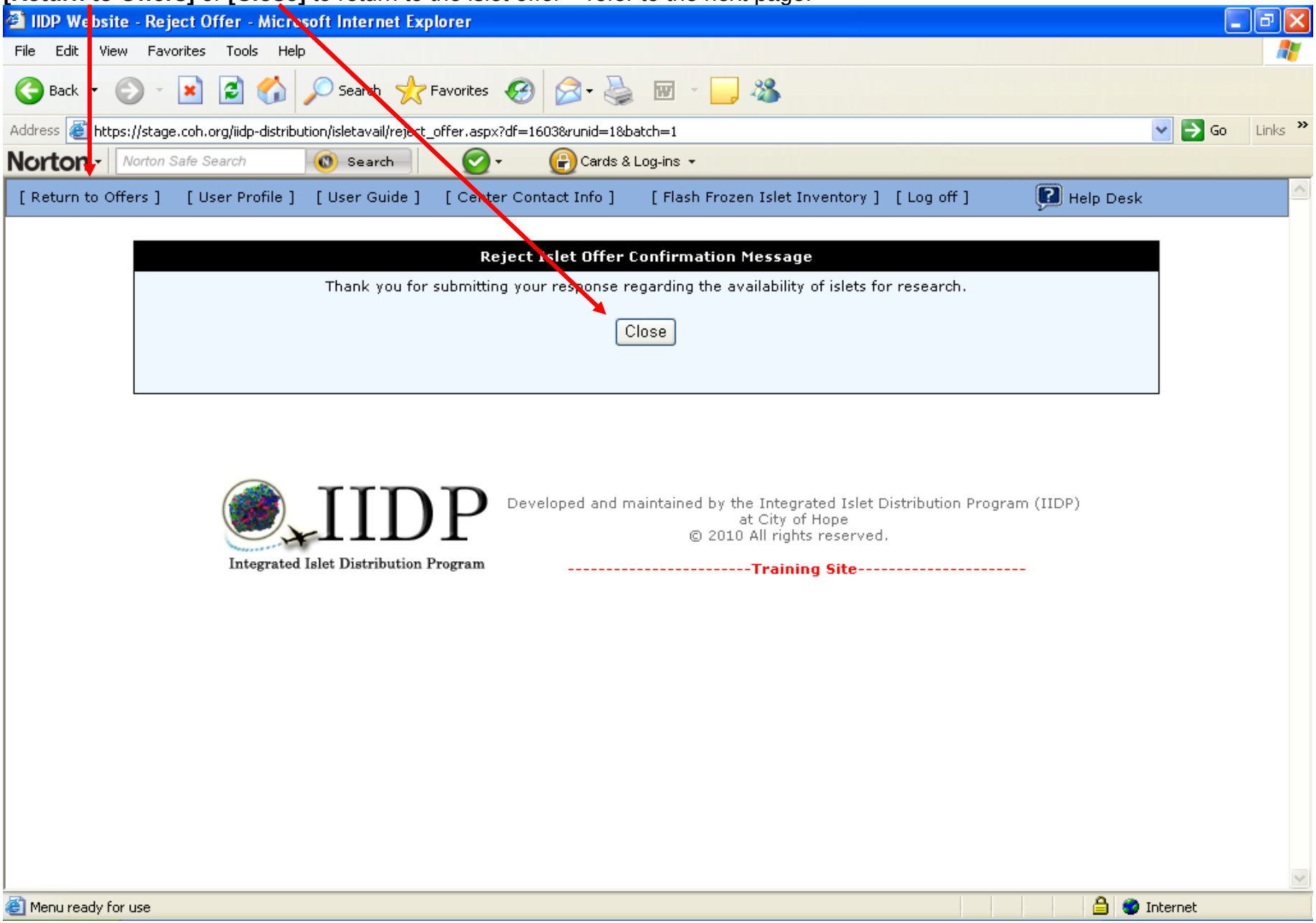


Reject Offer or **NOT Wiling or Unable to Accept Offer –** Select the rejection reason from the drop down menu. If 'Other' is selected, enter the 'Other' reason in the textbox.

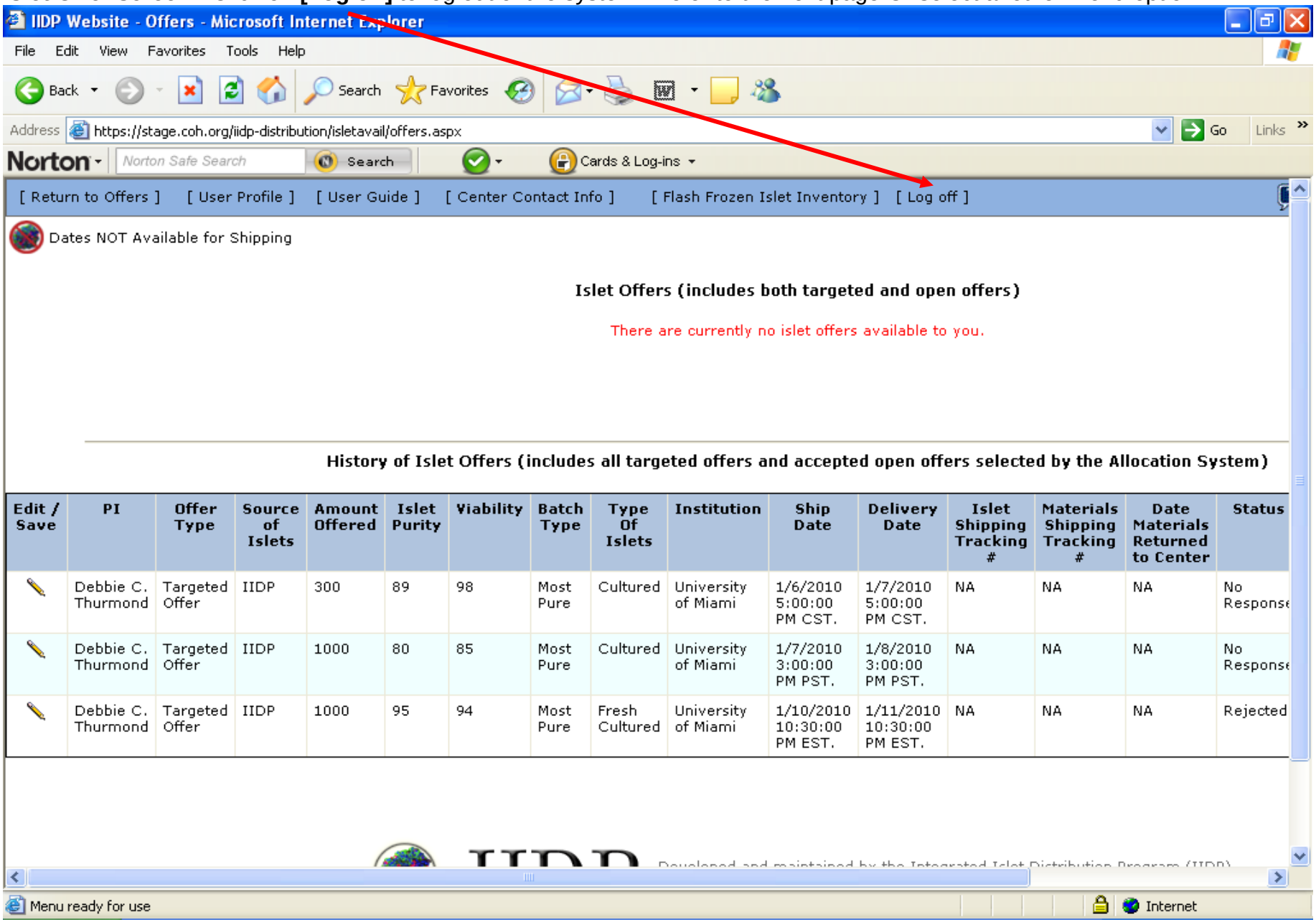


Click on **[Submit]** to submit the rejection reason to the system – refer to the next page.

Rejection of Islet Offer Confirmation Message – The system displays a message that the islet offer has been rejected. Click on **[Return to Offers]** or **[Close]** to return to the islet offer – refer to the next page.

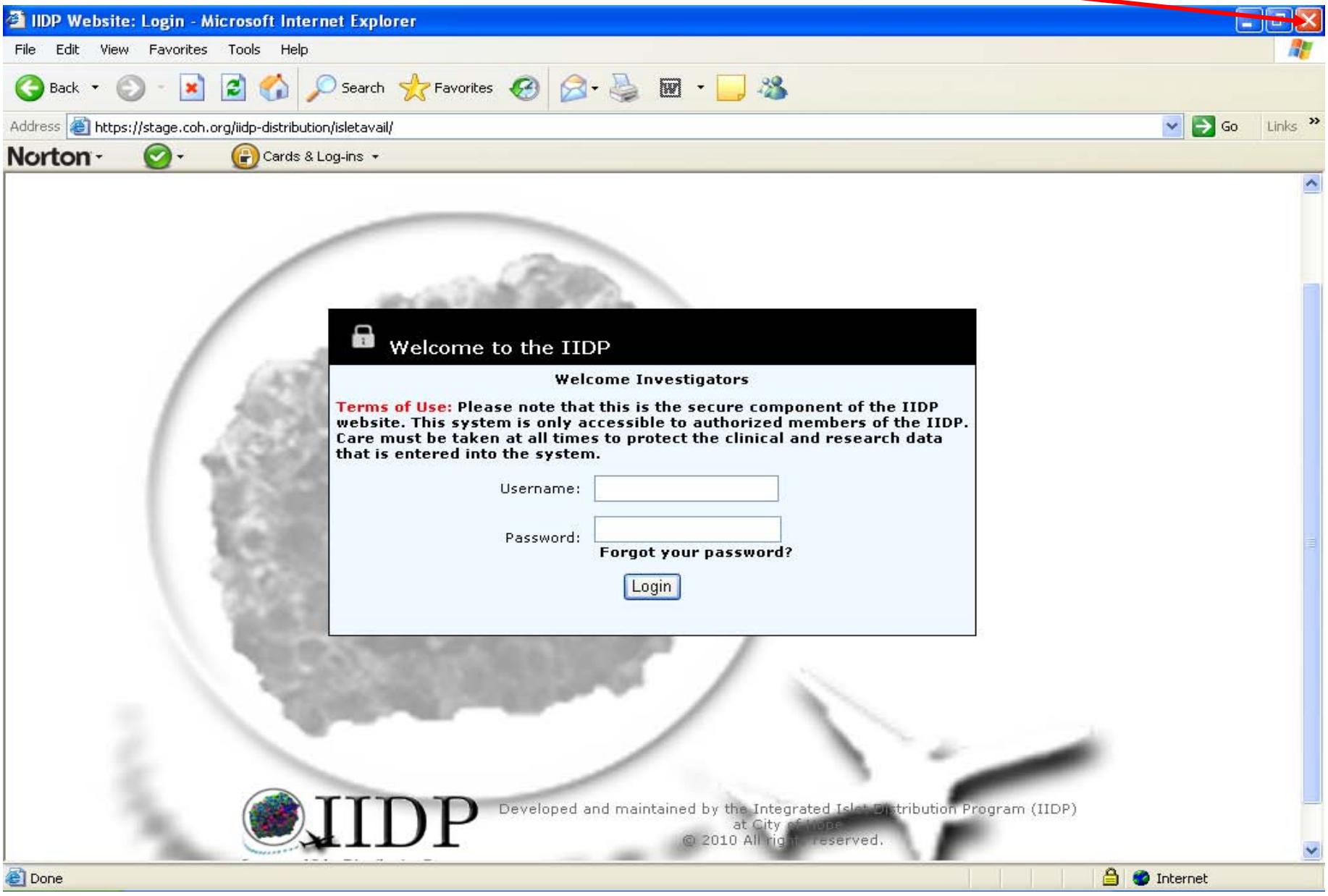


Islet Offer screen - Click on **[Log off]** to log out of the system – refer to the next page Or select another menu option.



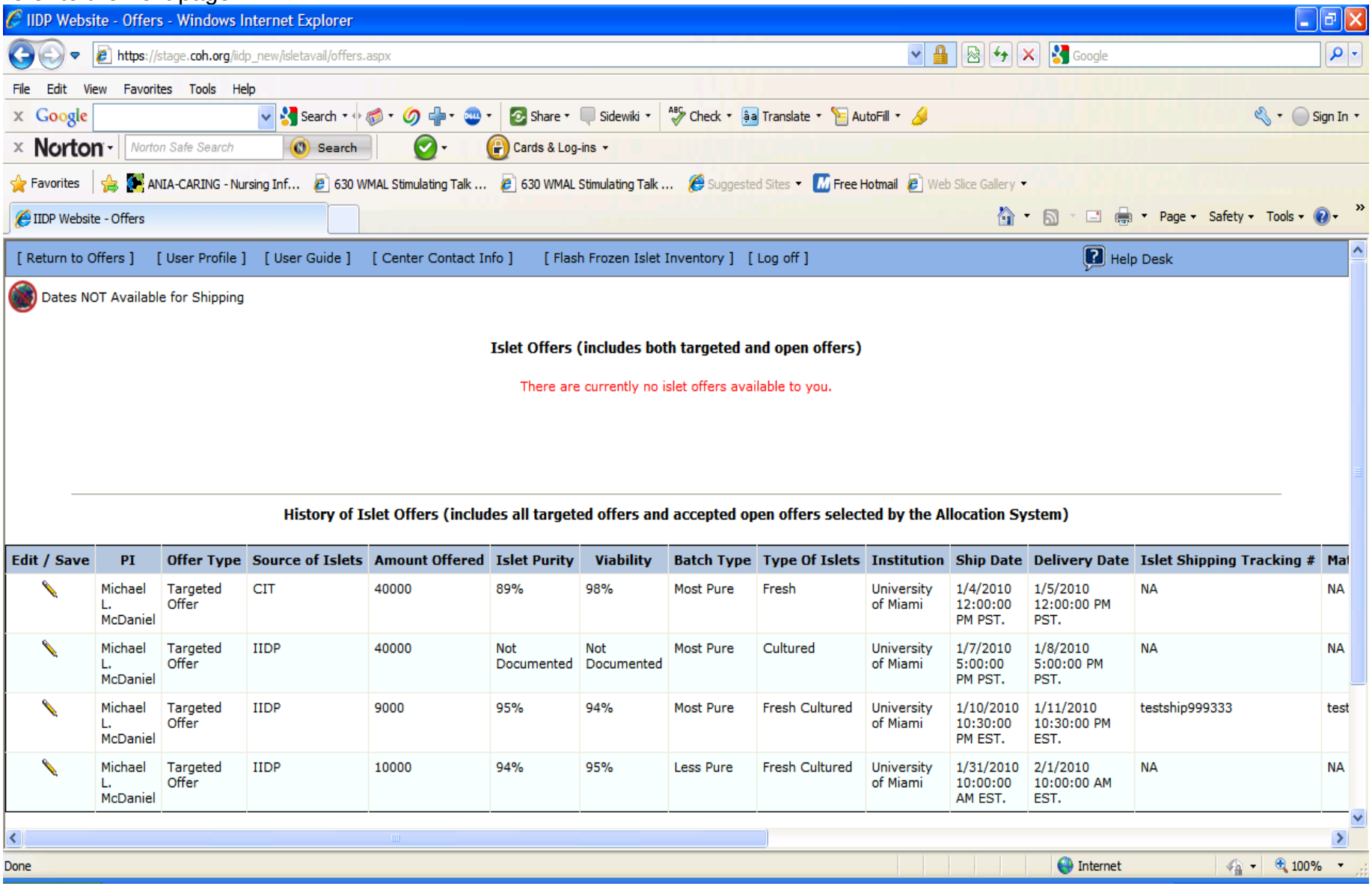
Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected

Login Screen – The system displays the log in screen. Log in **OR** click on the **[X]** to close the browser.



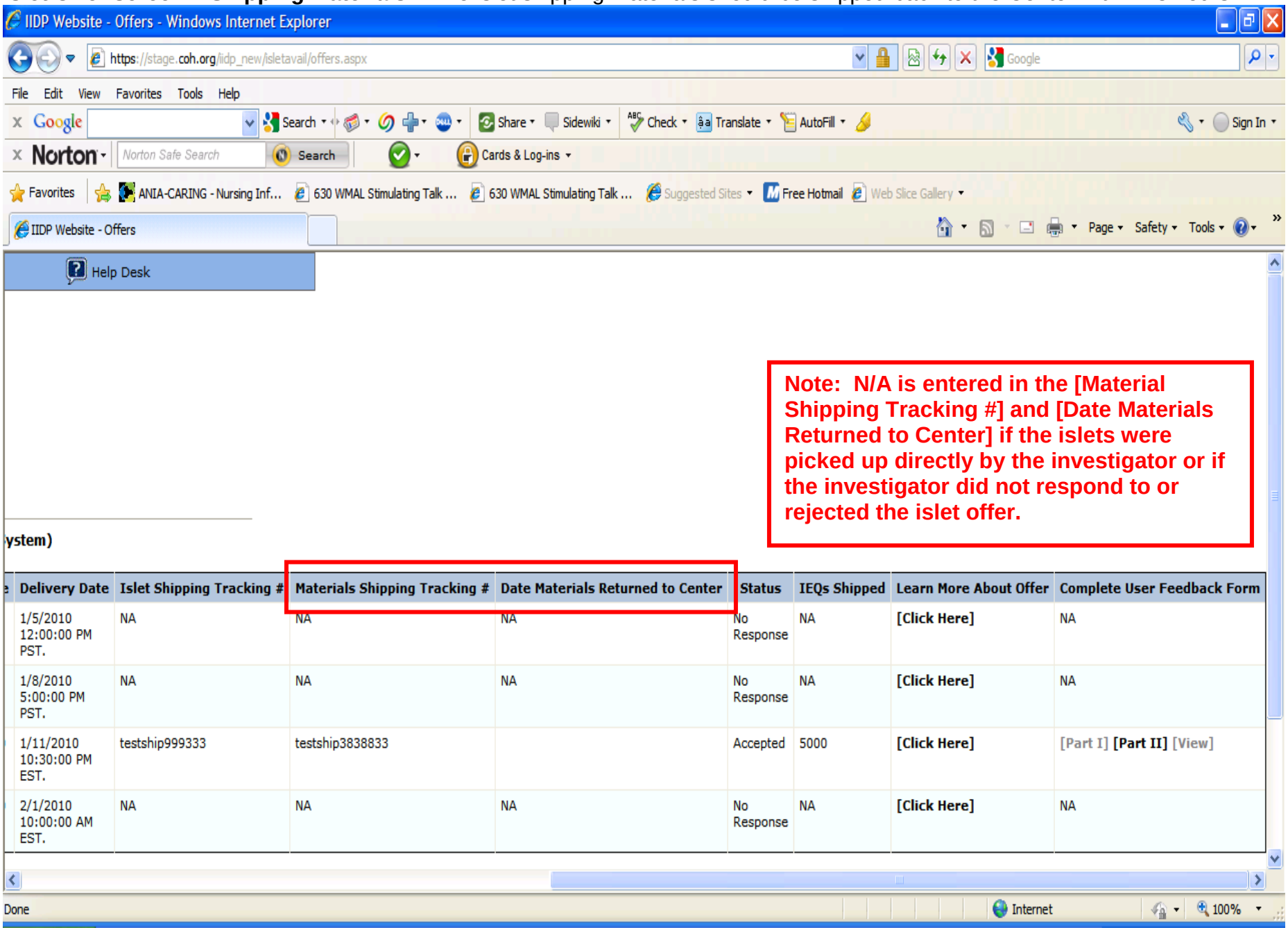
3.0 Return Shipping Materials to Center

Islet Offer screen – Shipping Materials – The islet shipping materials should be shipped back to the Center within 48 hours – refer to the next page.

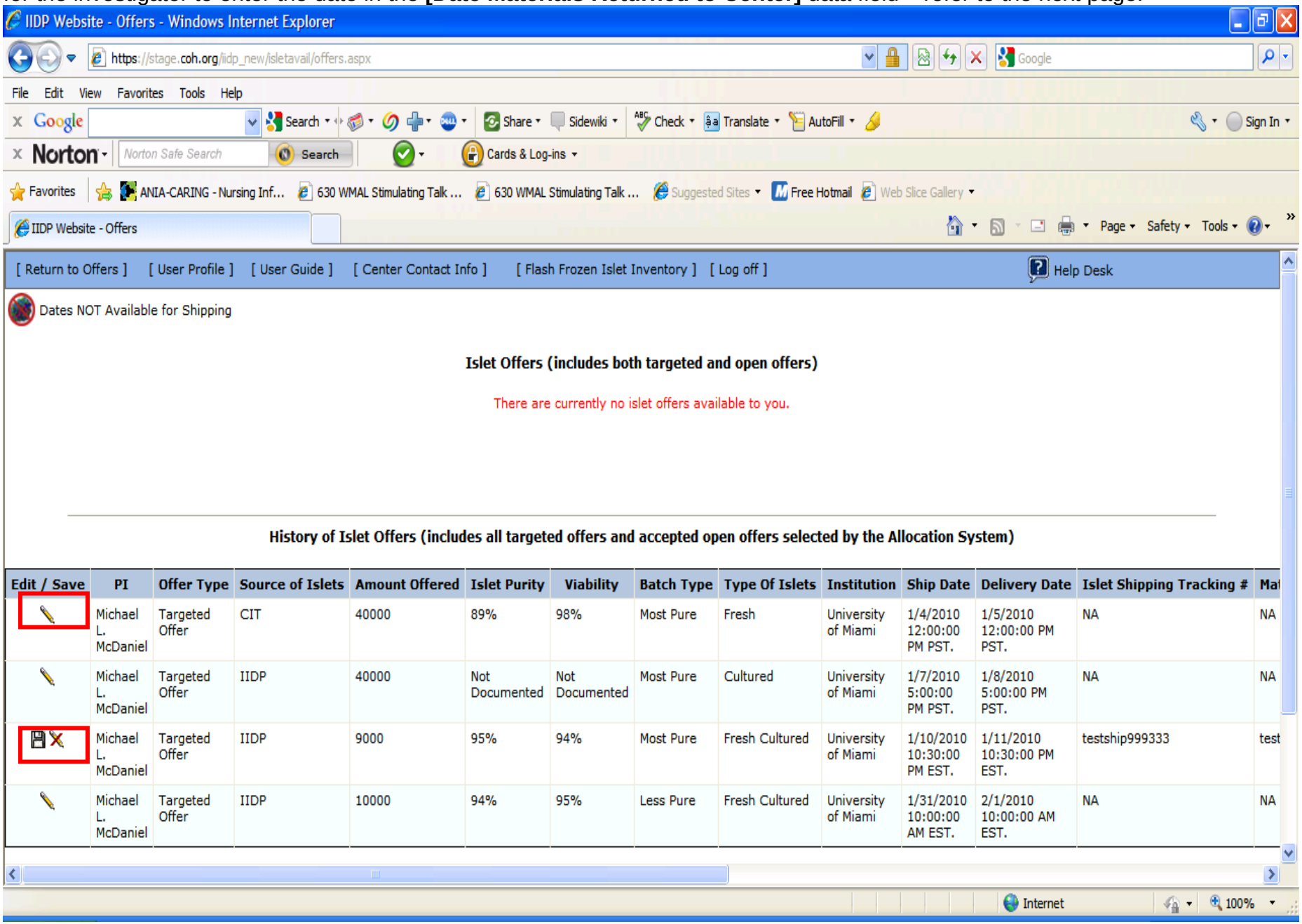


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mat
	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	40000	Not Documented	Not Documented	Most Pure	Cultured	University of Miami	1/7/2010 5:00:00 PM PST.	1/8/2010 5:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	testship999333	test
	Michael L. McDaniel	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010 10:00:00 AM EST.	2/1/2010 10:00:00 AM EST.	NA	NA

Islet Offer screen – Shipping Materials – The islet shipping materials should be shipped back to the Center within 48 hours.

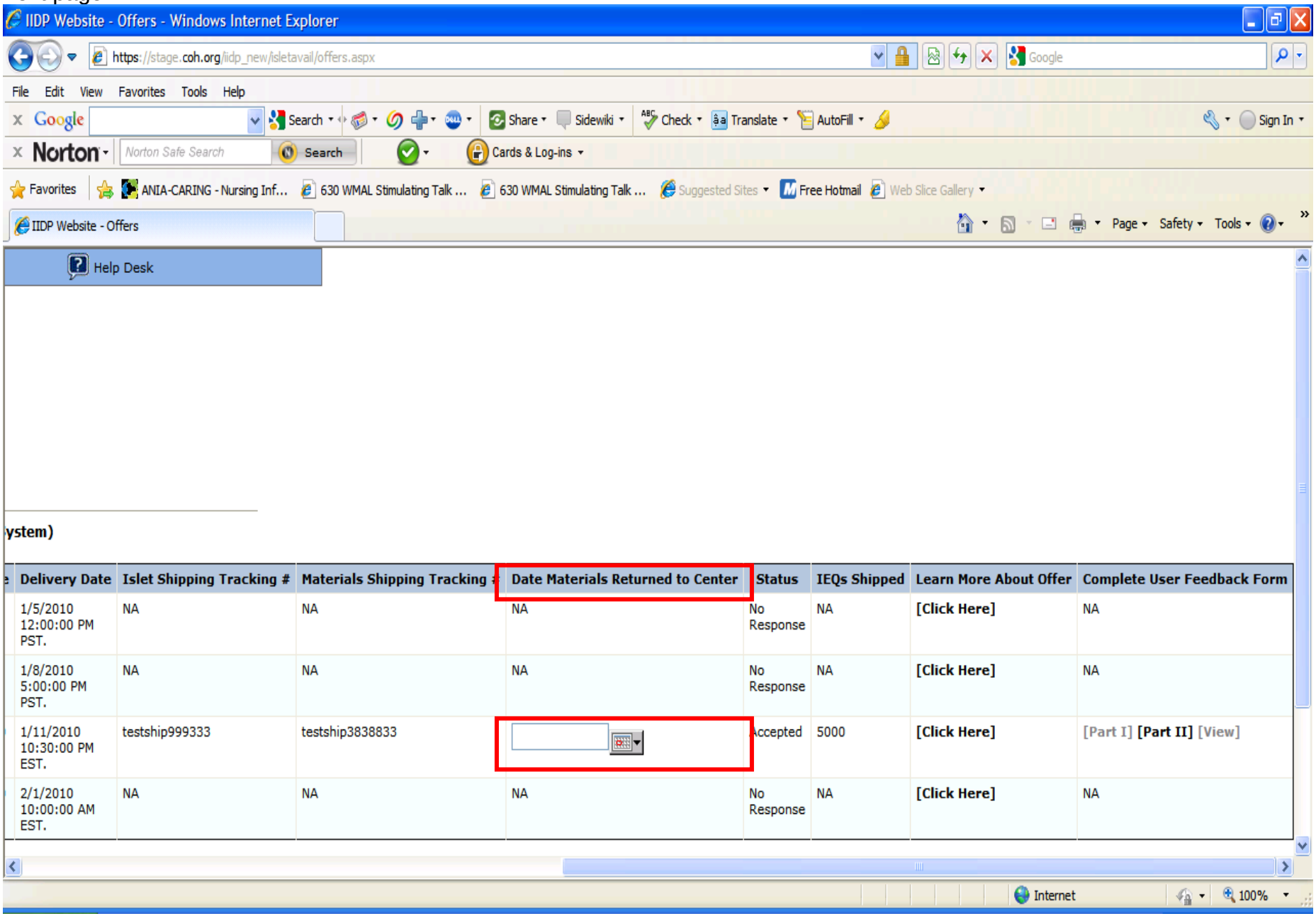


Islet Offer screen – Shipping Materials – Click on the **[pencil icon]** for the system to change the desired islet offer to edit mode for the investigator to enter the date in the **[Date Materials Returned to Center]** data field – refer to the next page.

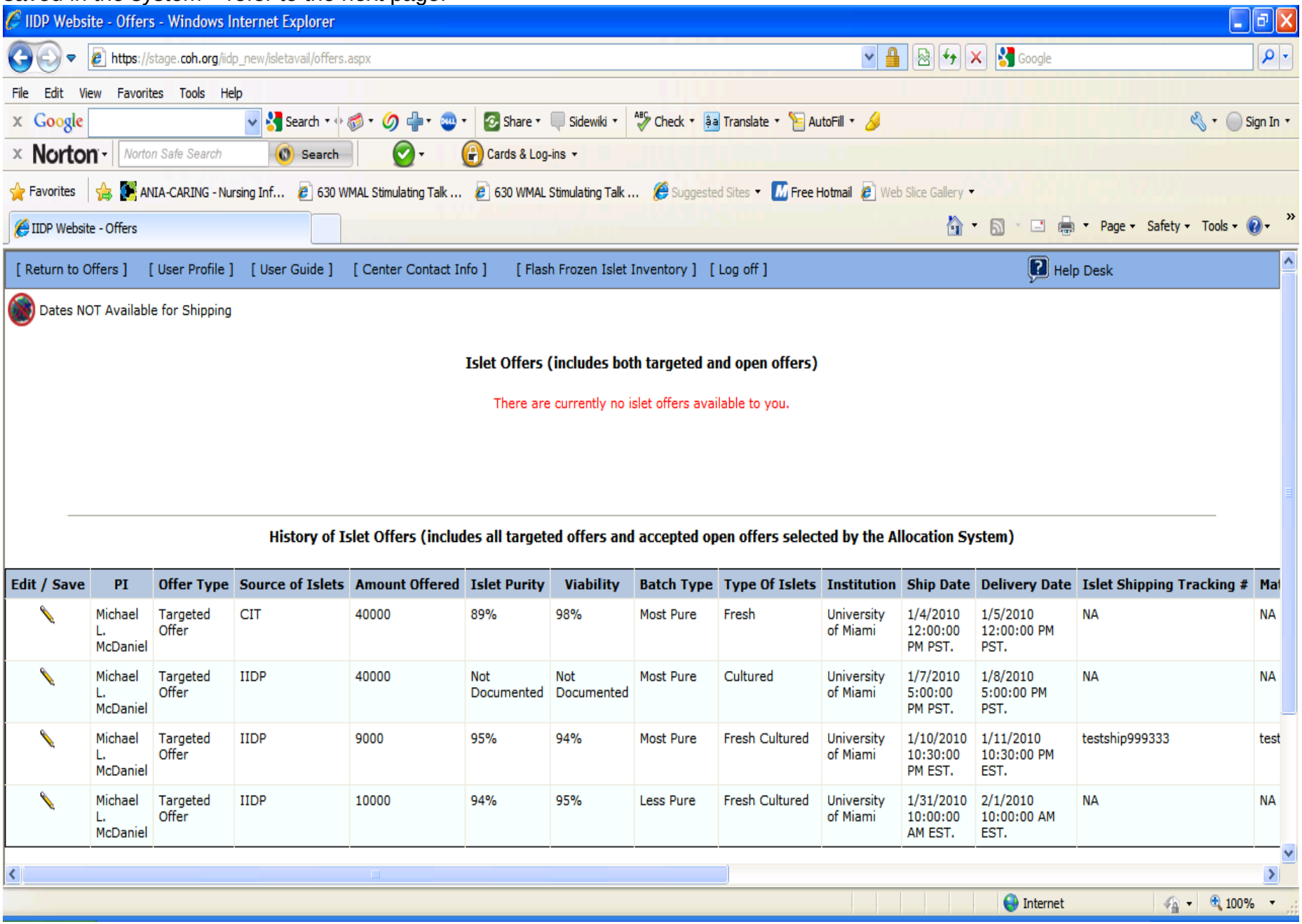


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mat
	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	40000	Not Documented	Not Documented	Most Pure	Cultured	University of Miami	1/7/2010 5:00:00 PM PST.	1/8/2010 5:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	testship999333	test
	Michael L. McDaniel	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010 10:00:00 AM EST.	2/1/2010 10:00:00 AM EST.	NA	NA

Islet Offer screen – Shipping Materials – Click on the **[calendar icon]** to select a date to enter in the **[Date Materials Returned to Center]** data field then click on the **[Save icon]** (on the previous page of the first part of the Islet Offer screen) – refer to the next page.

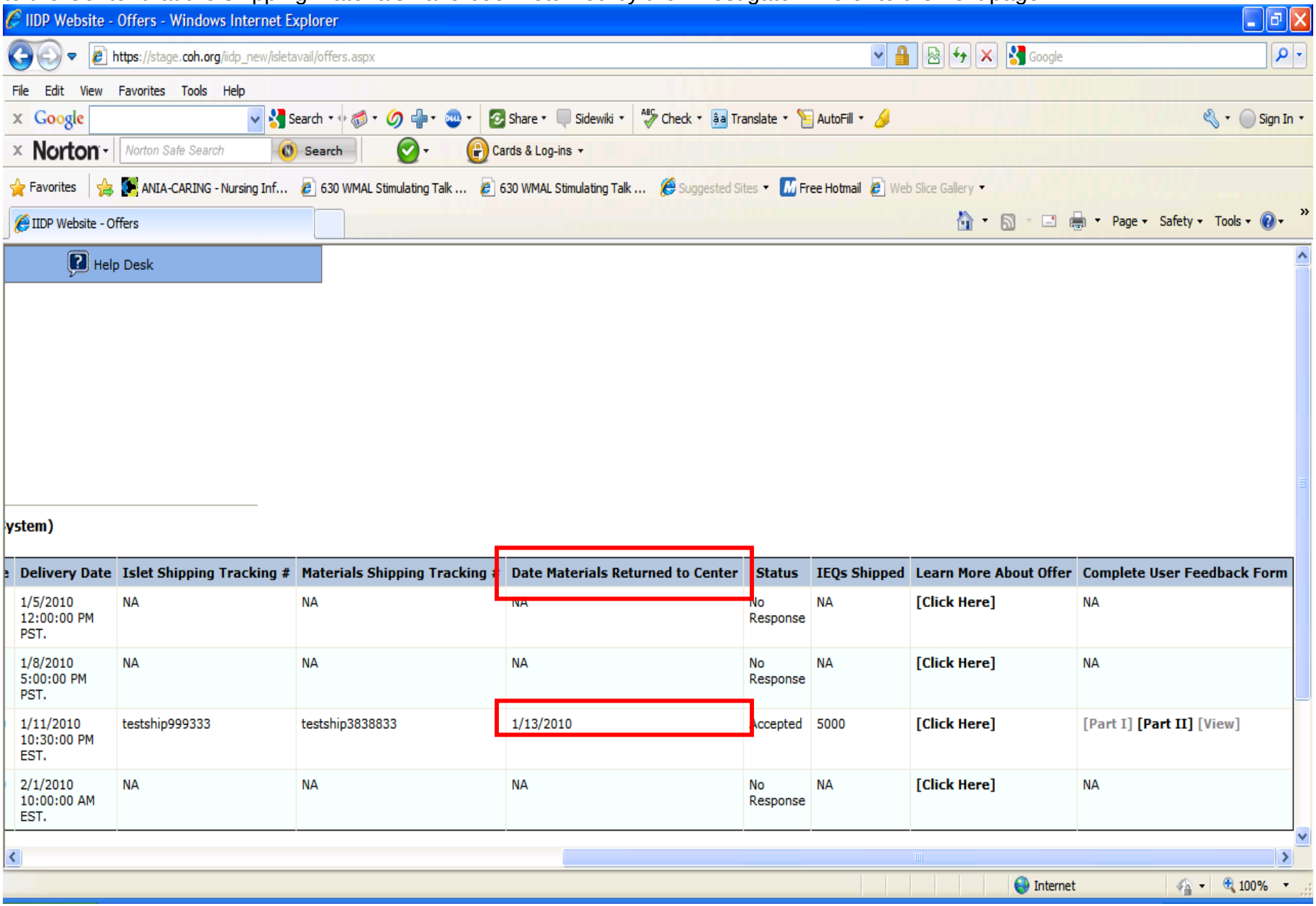


Islet Offer screen – Shipping Materials – The date the shipping materials were returned to the Center has been entered and saved in the system – refer to the next page.

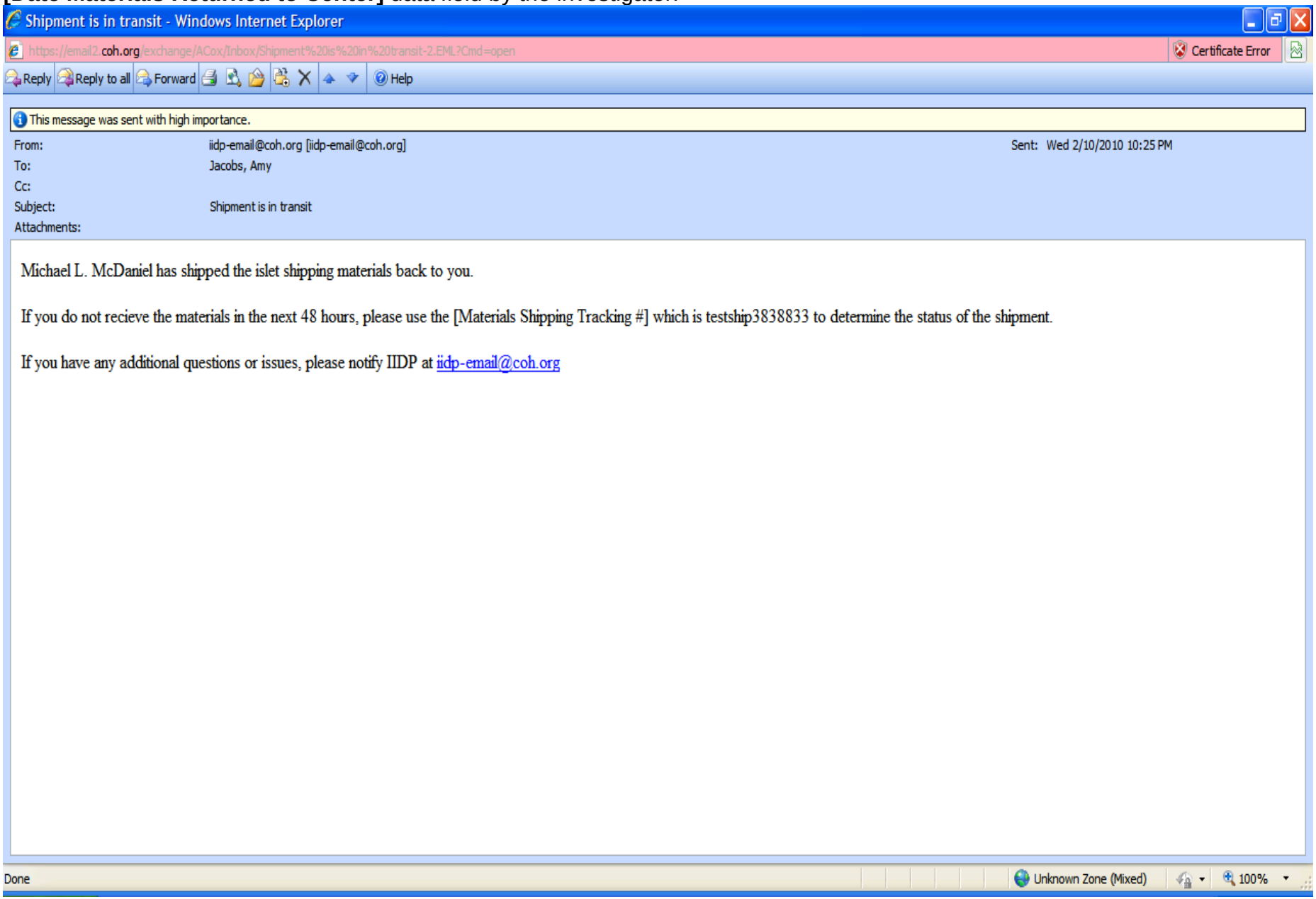


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mat
	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	40000	Not Documented	Not Documented	Most Pure	Cultured	University of Miami	1/7/2010 5:00:00 PM PST.	1/8/2010 5:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	testship999333	test
	Michael L. McDaniel	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010 10:00:00 AM EST.	2/1/2010 10:00:00 AM EST.	NA	NA

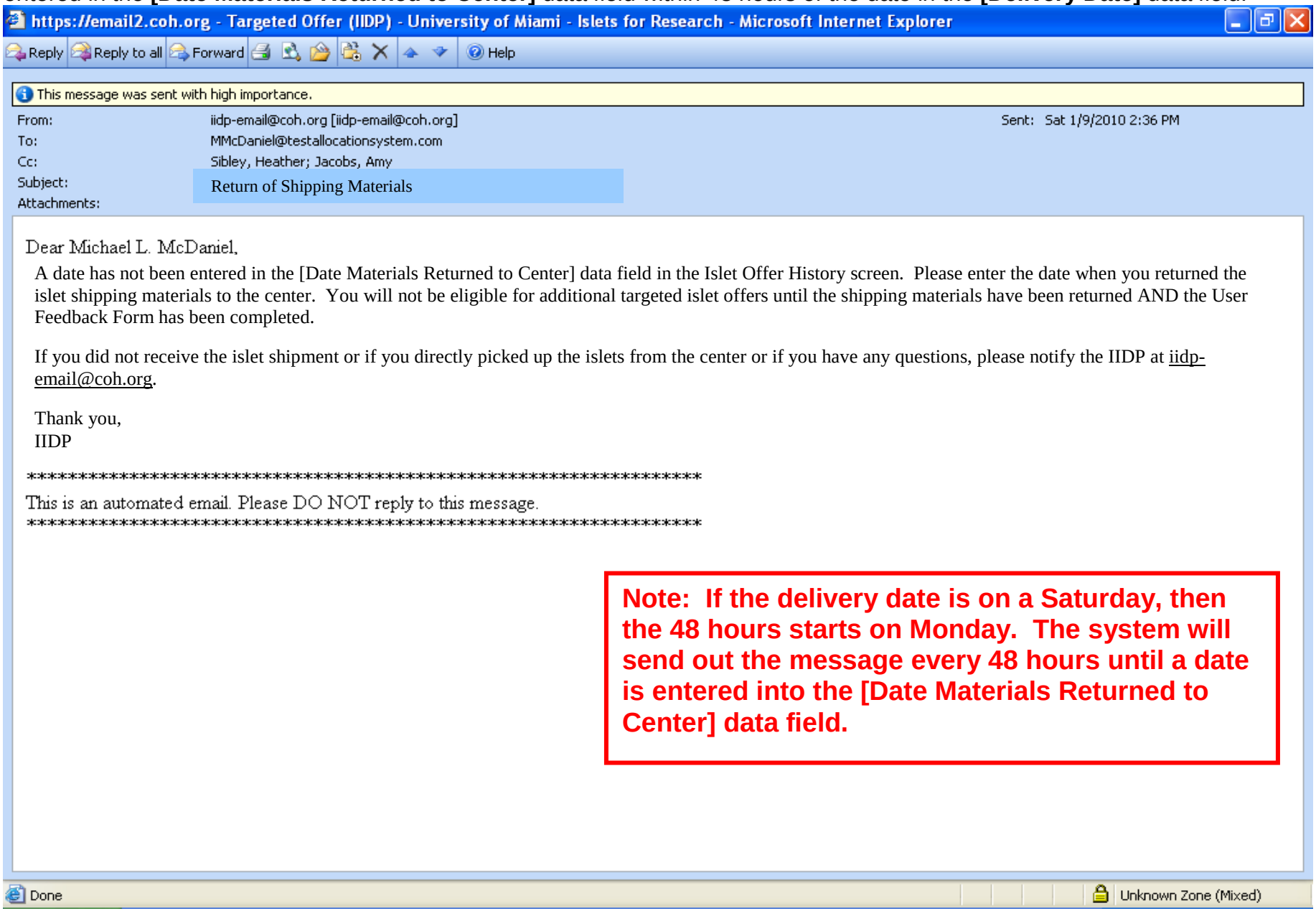
Islet Offer screen – Shipping Materials – The date is saved in the system and the system will send a notification email message to the Center that the shipping materials have been returned by the investigator – refer to the next page.



Islet Offer screen – Shipping Materials – The email message that the system sends to the Center when a date is entered in the **[Date Materials Returned to Center]** data field by the investigator.

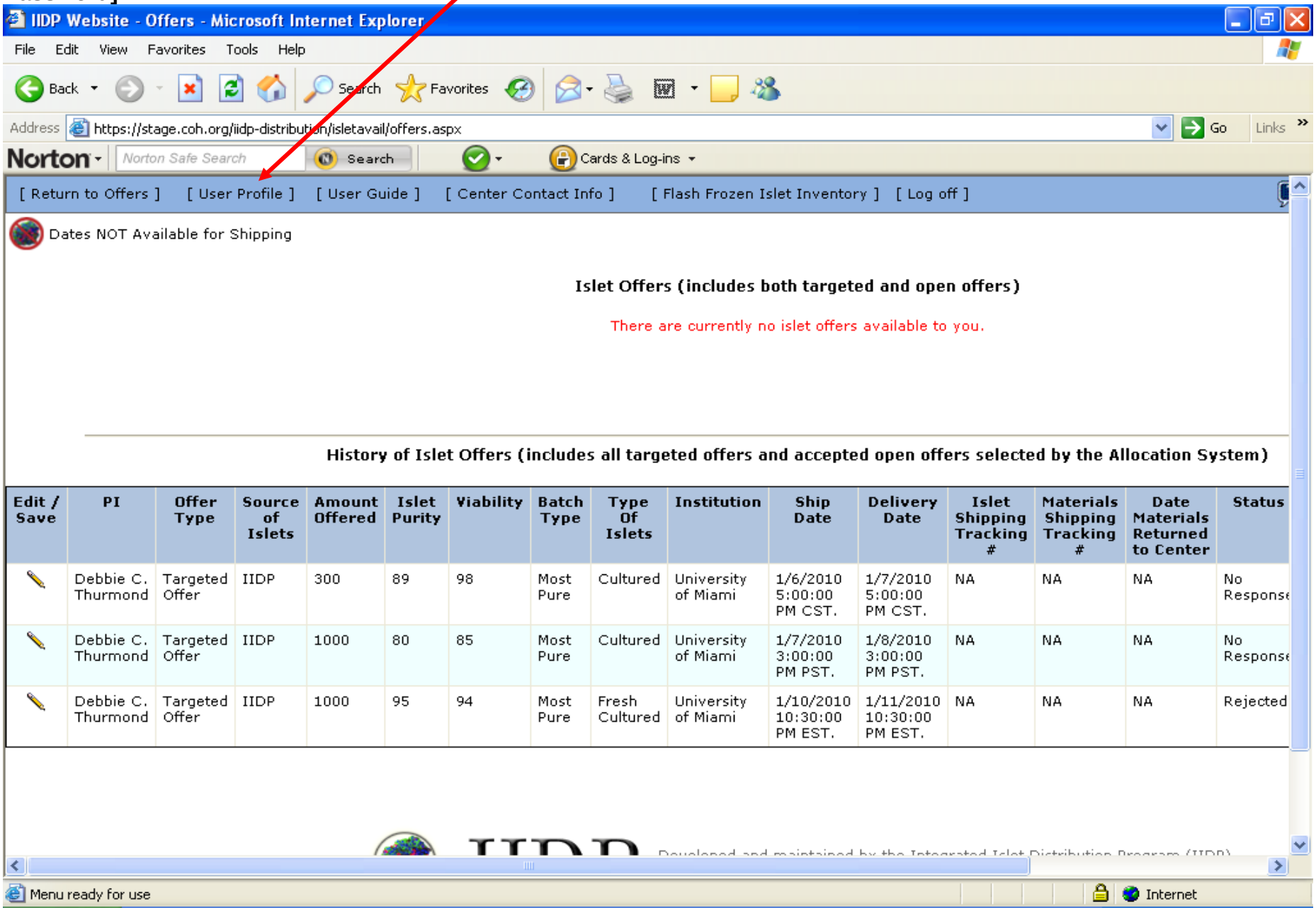


Islet Offer screen – Shipping Materials – The email message that the system sends to an investigator when a date has not been entered in the **[Date Materials Returned to Center]** data field within 48 hours of the date in the **[Delivery Date]** data field.



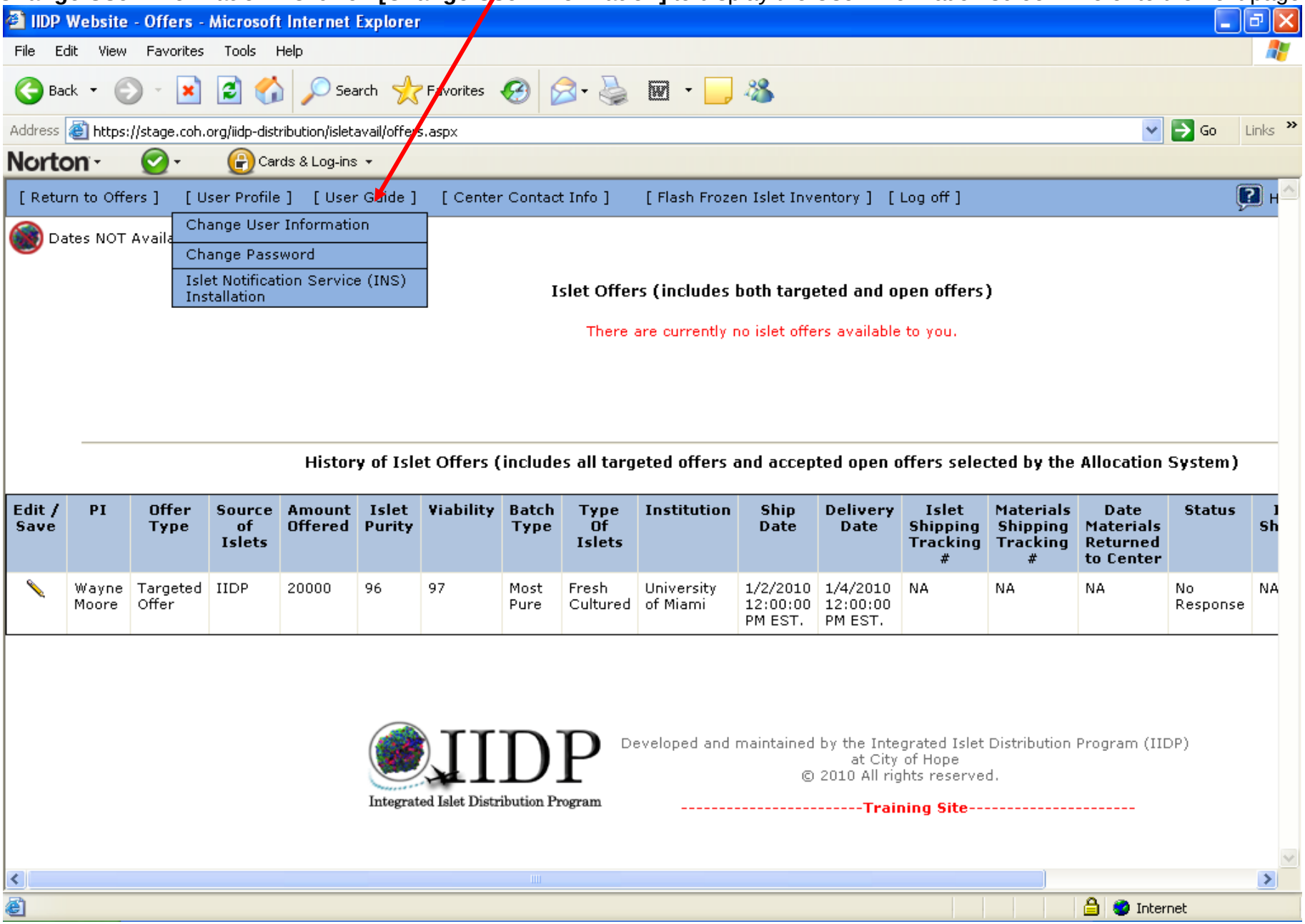
4.0 View/Change your User Profile

View/Change your User Profile - Click on **[User Profile]** to display the options of **[Change User Information]** and **[Change Password].**

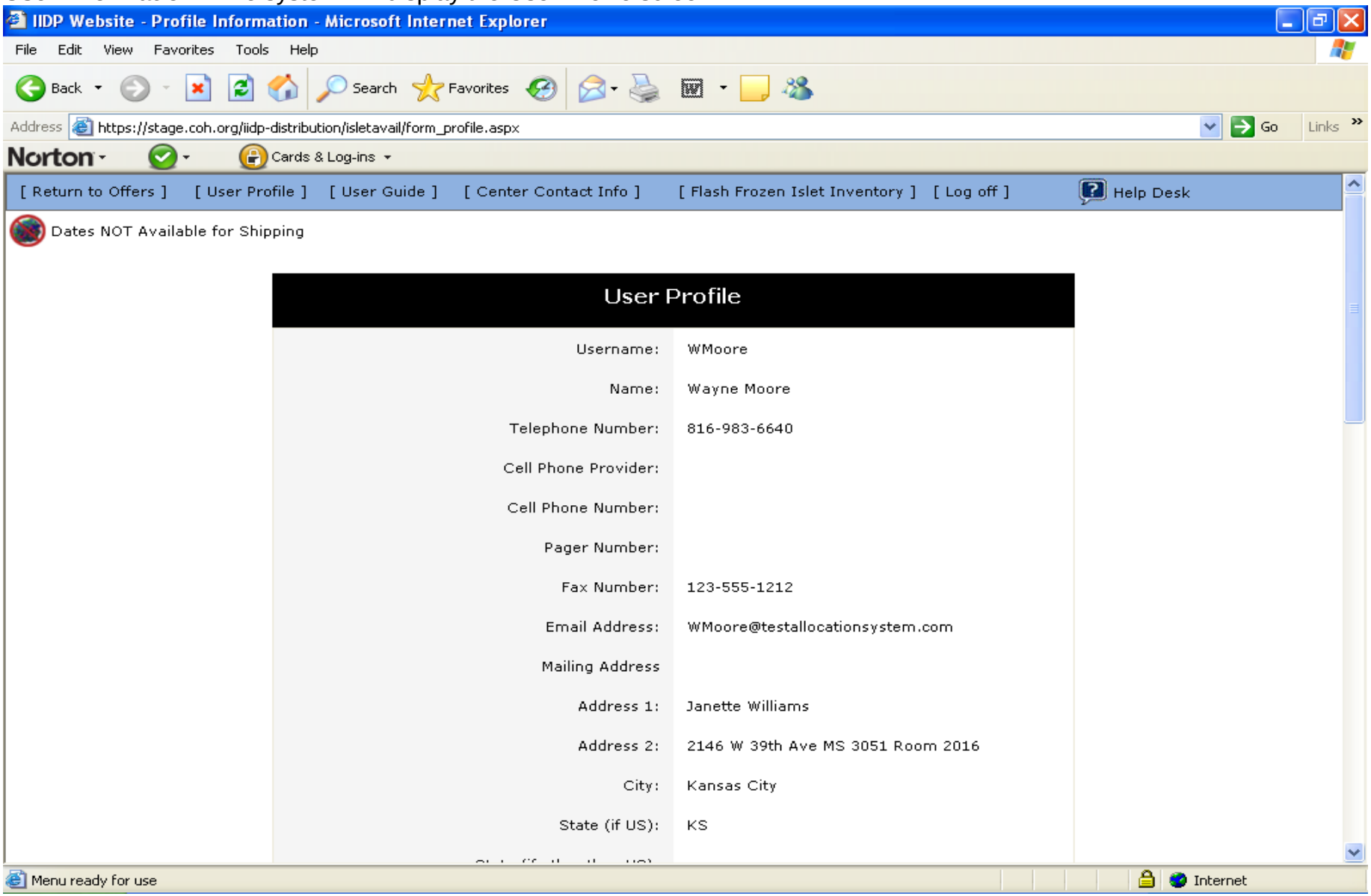


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected

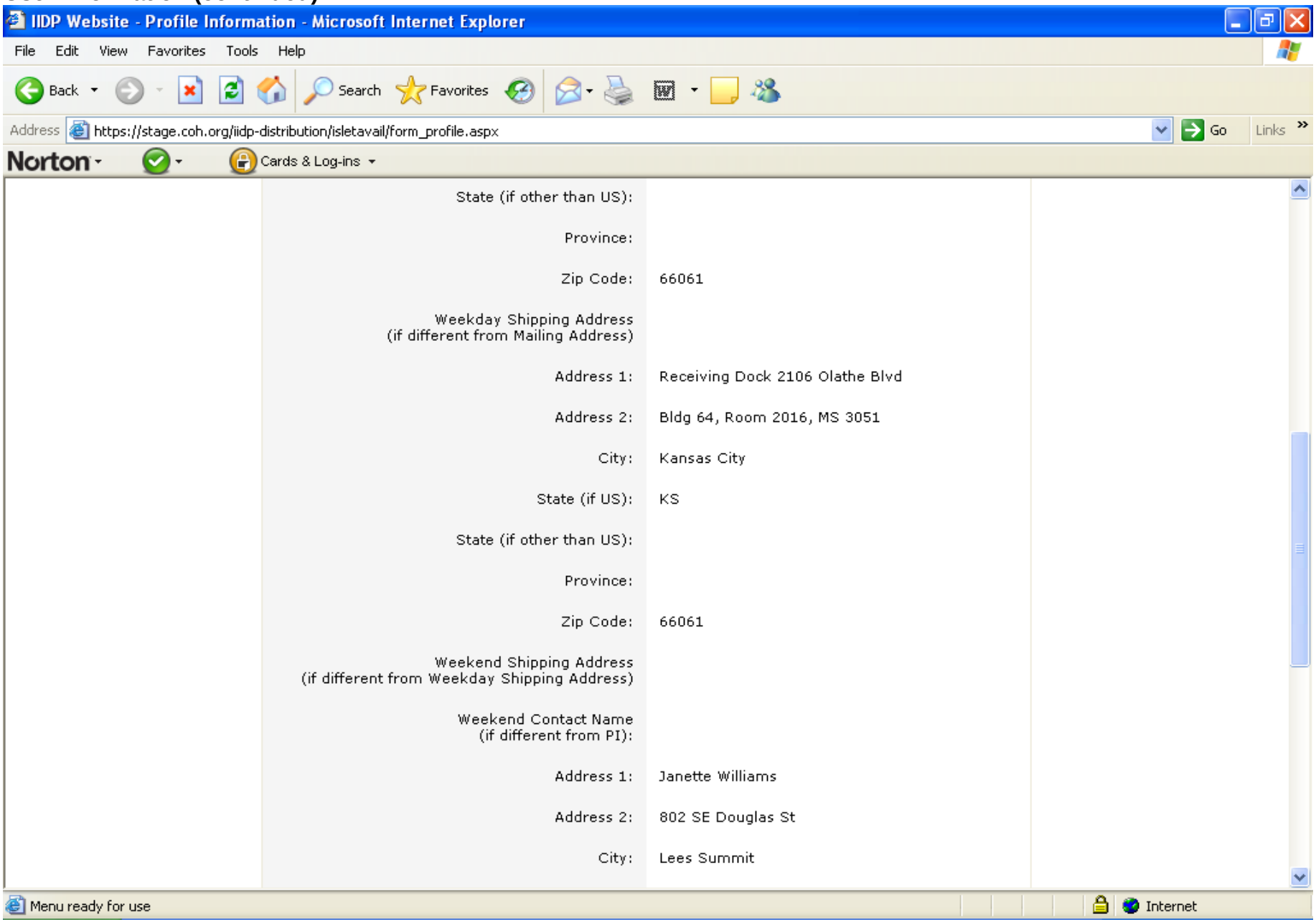
Change User Information - Click on **[Change User Information]** to display the User Information screen – refer to the next page.



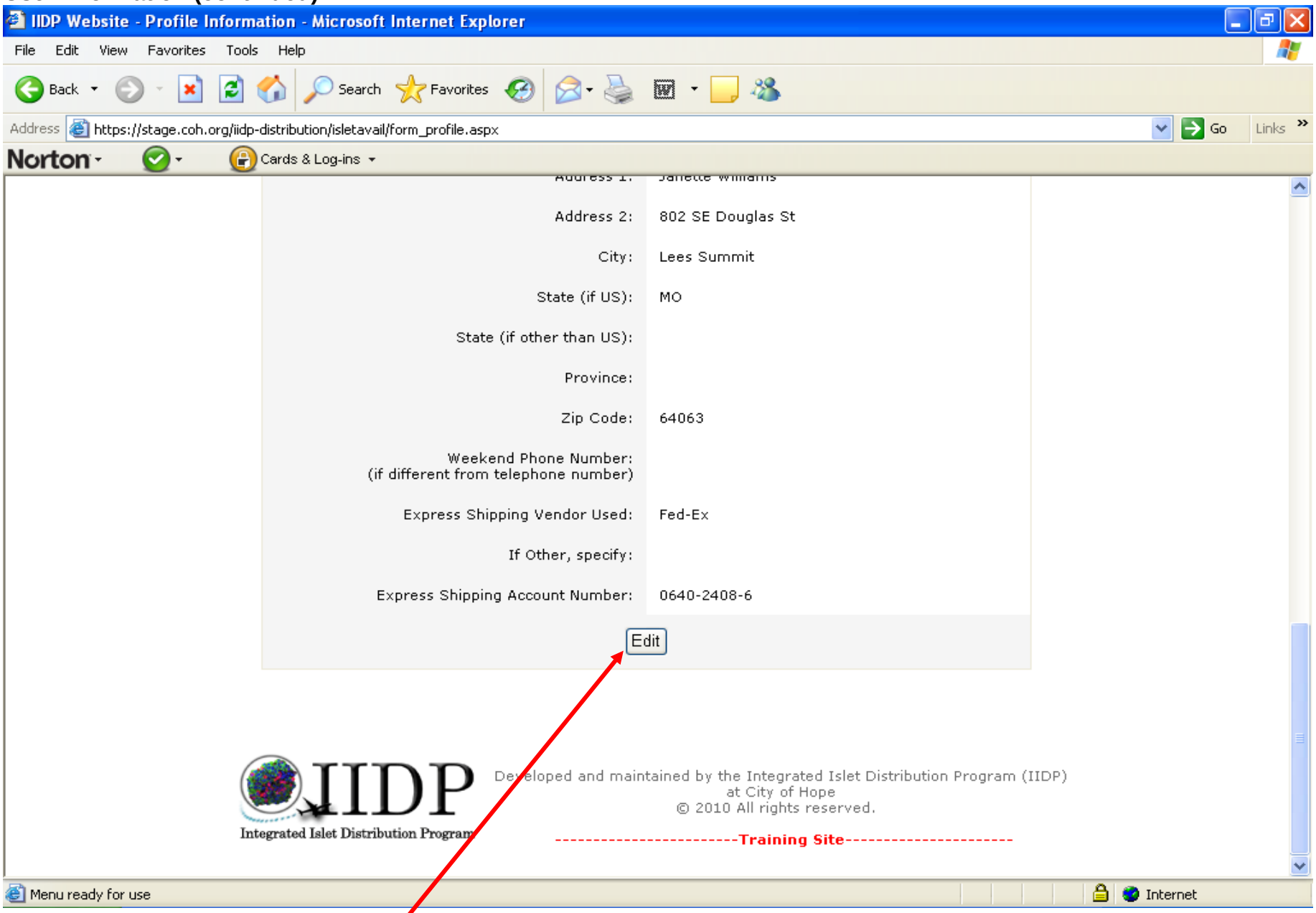
User Information - The system will display the User Profile screen.



User Information (continued)



User Information (continued)

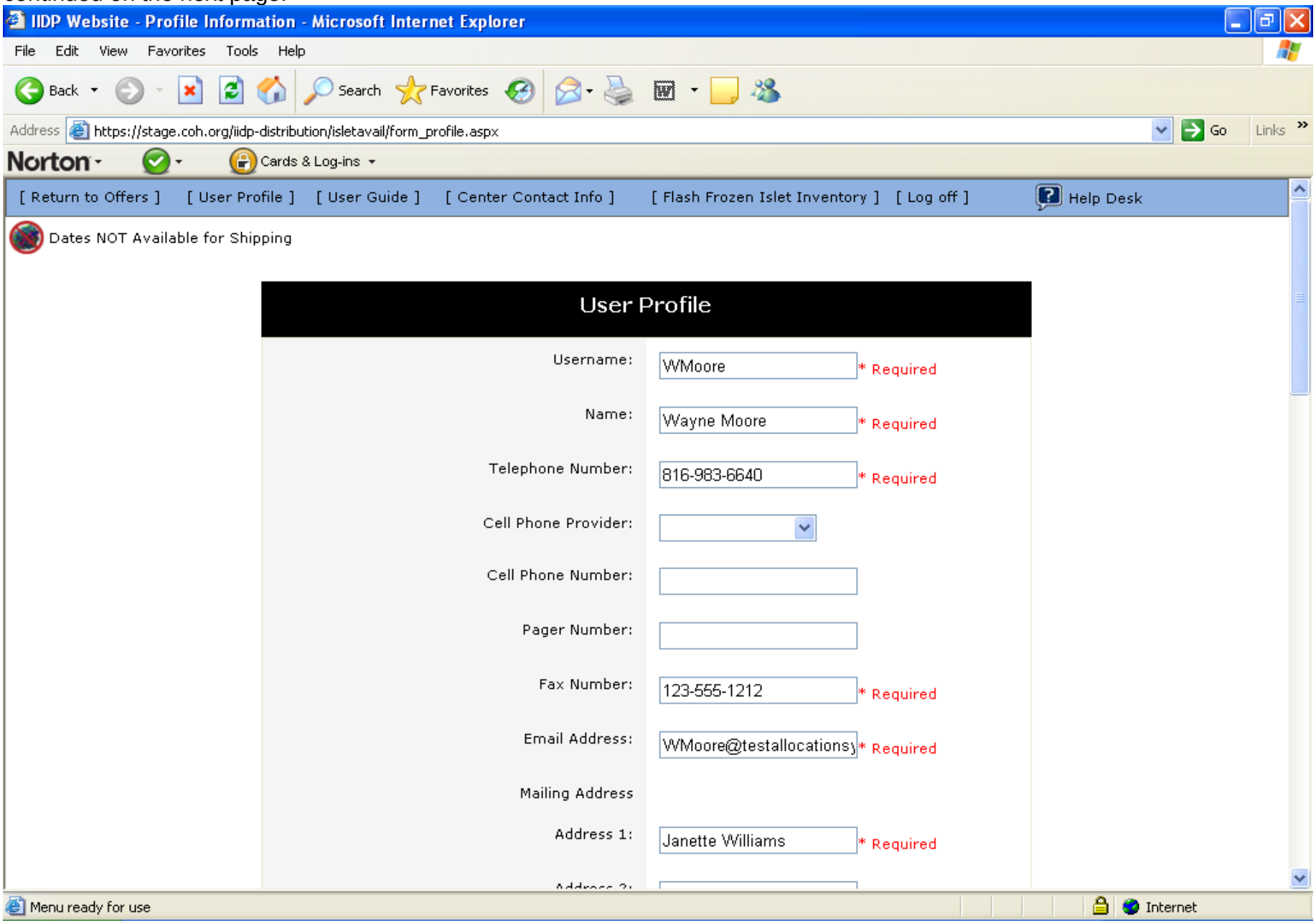


Review the information and click on **[Edit]** to make changes as needed - refer to the next page.

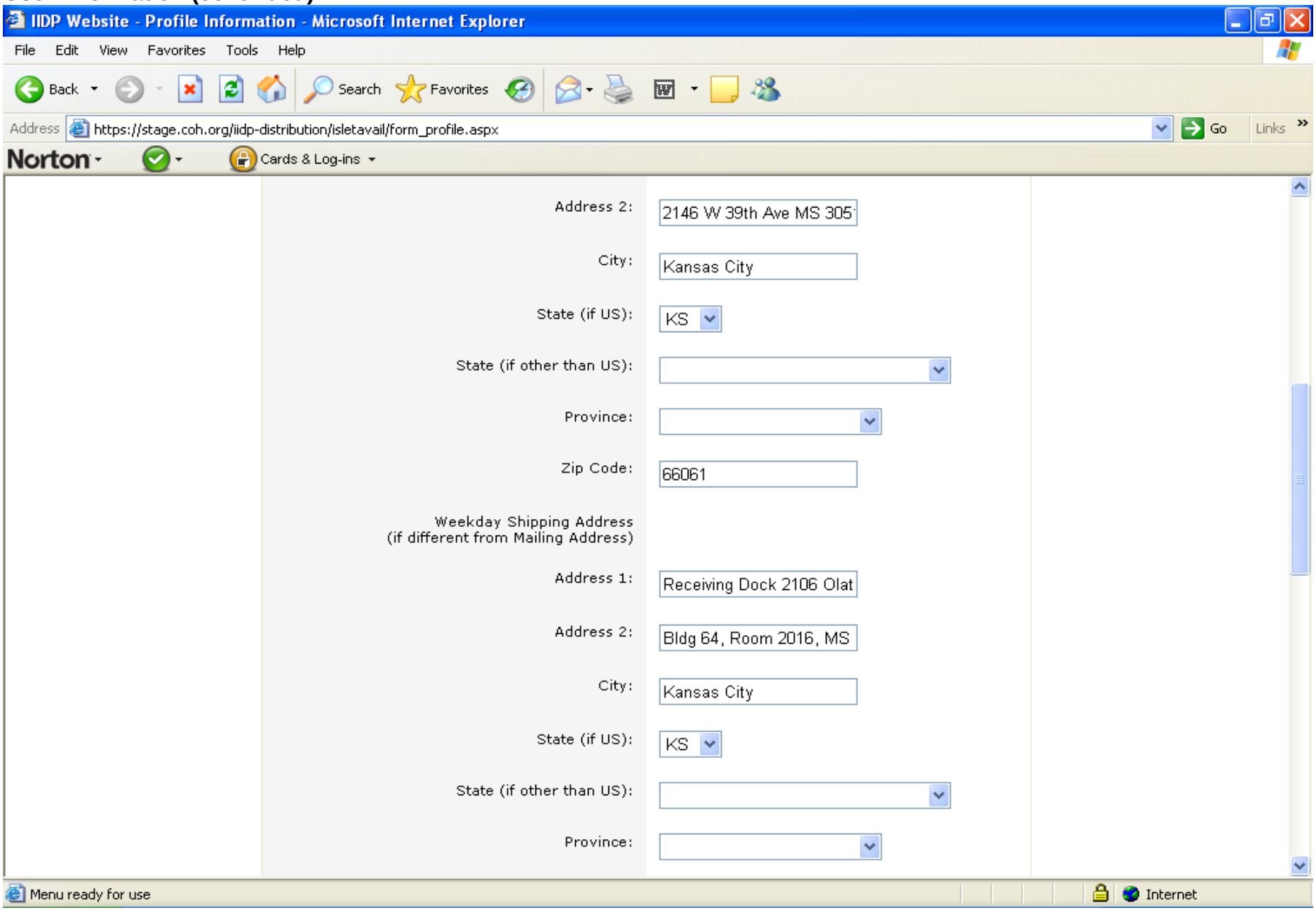
OR

Click on another menu option, if there are no required changes.

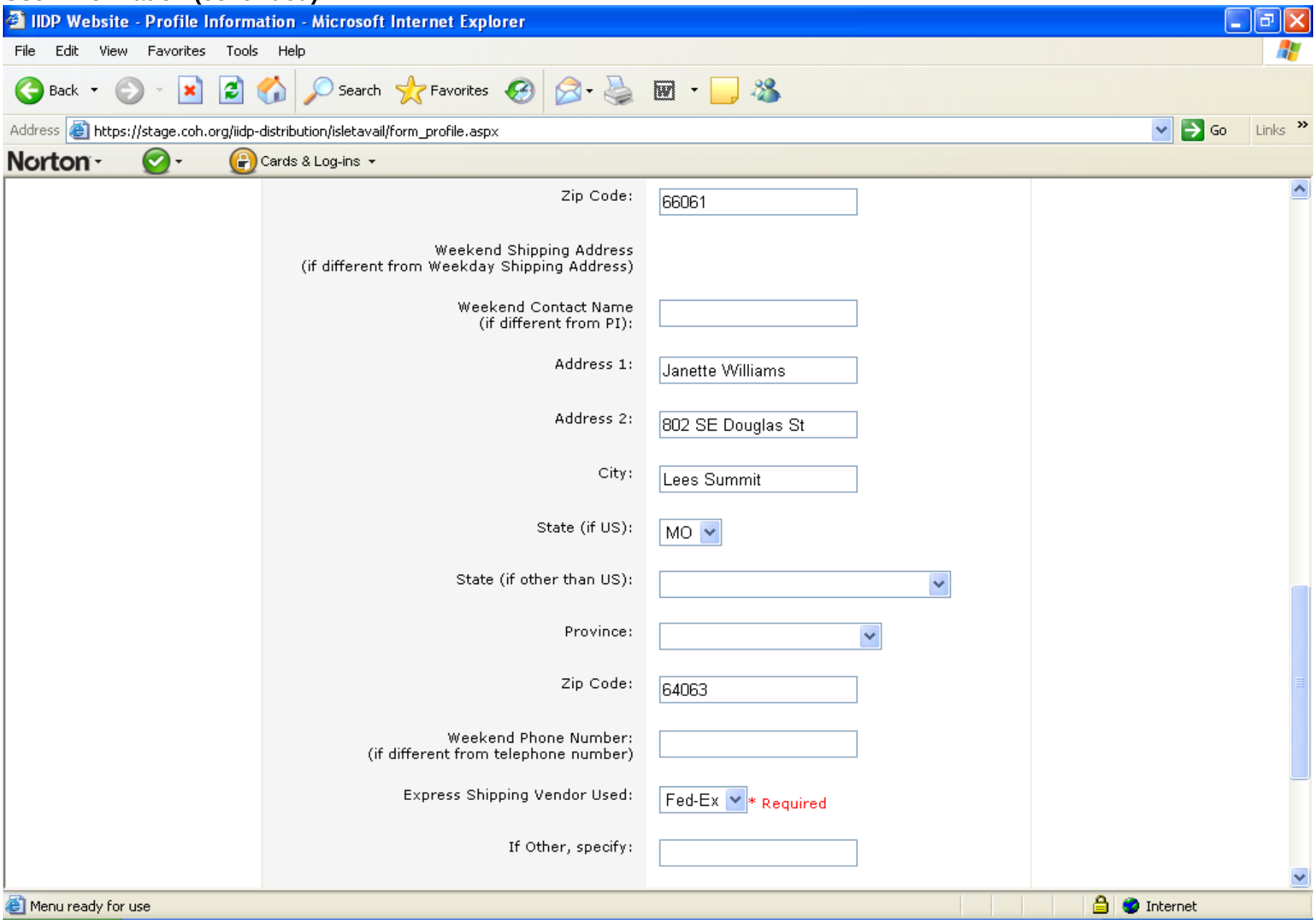
User Information - the system will display the User Profile information in the Edit Mode. Edit the User Profile as needed – continued on the next page.



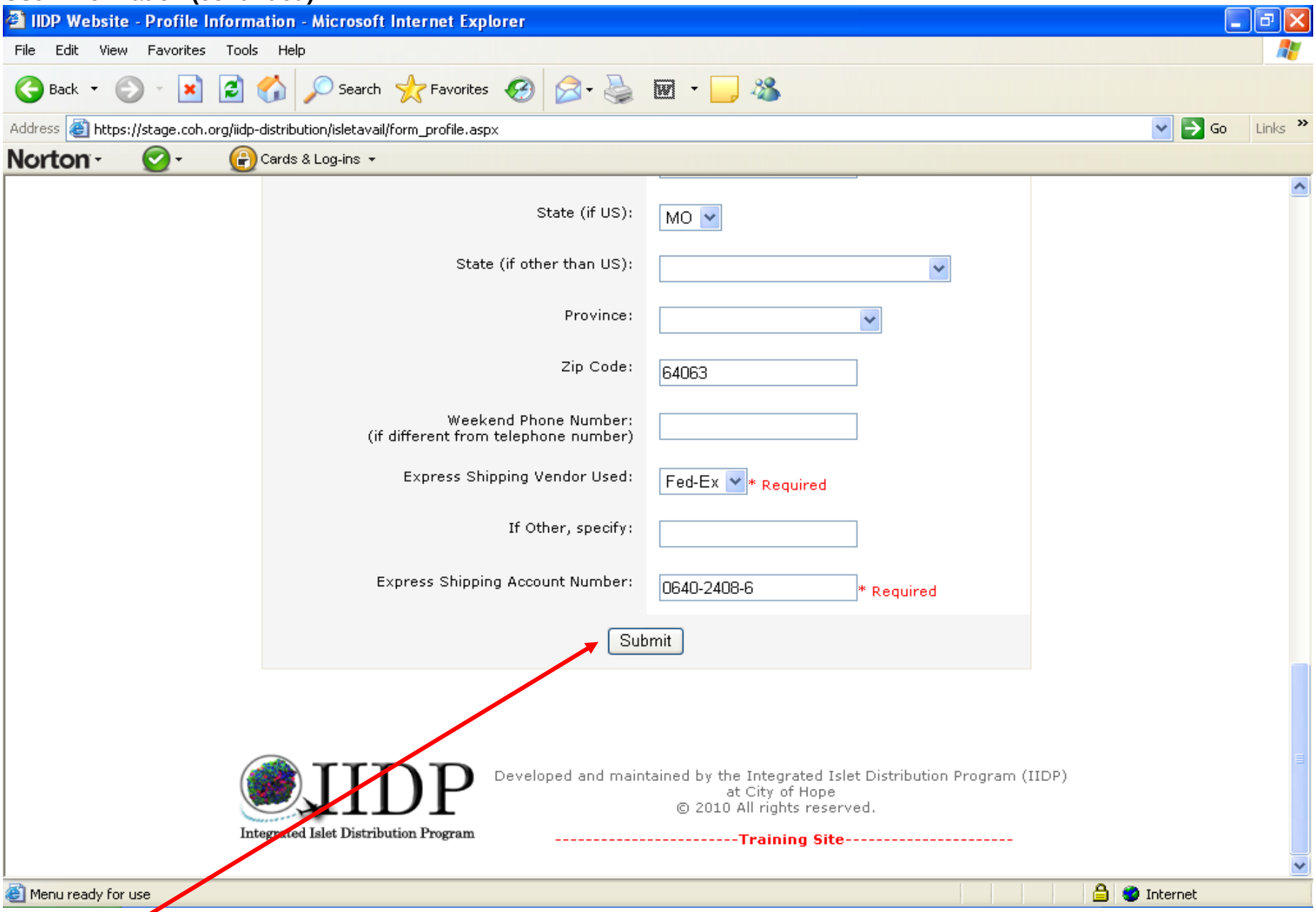
User Information (continued)



User Information (continued)

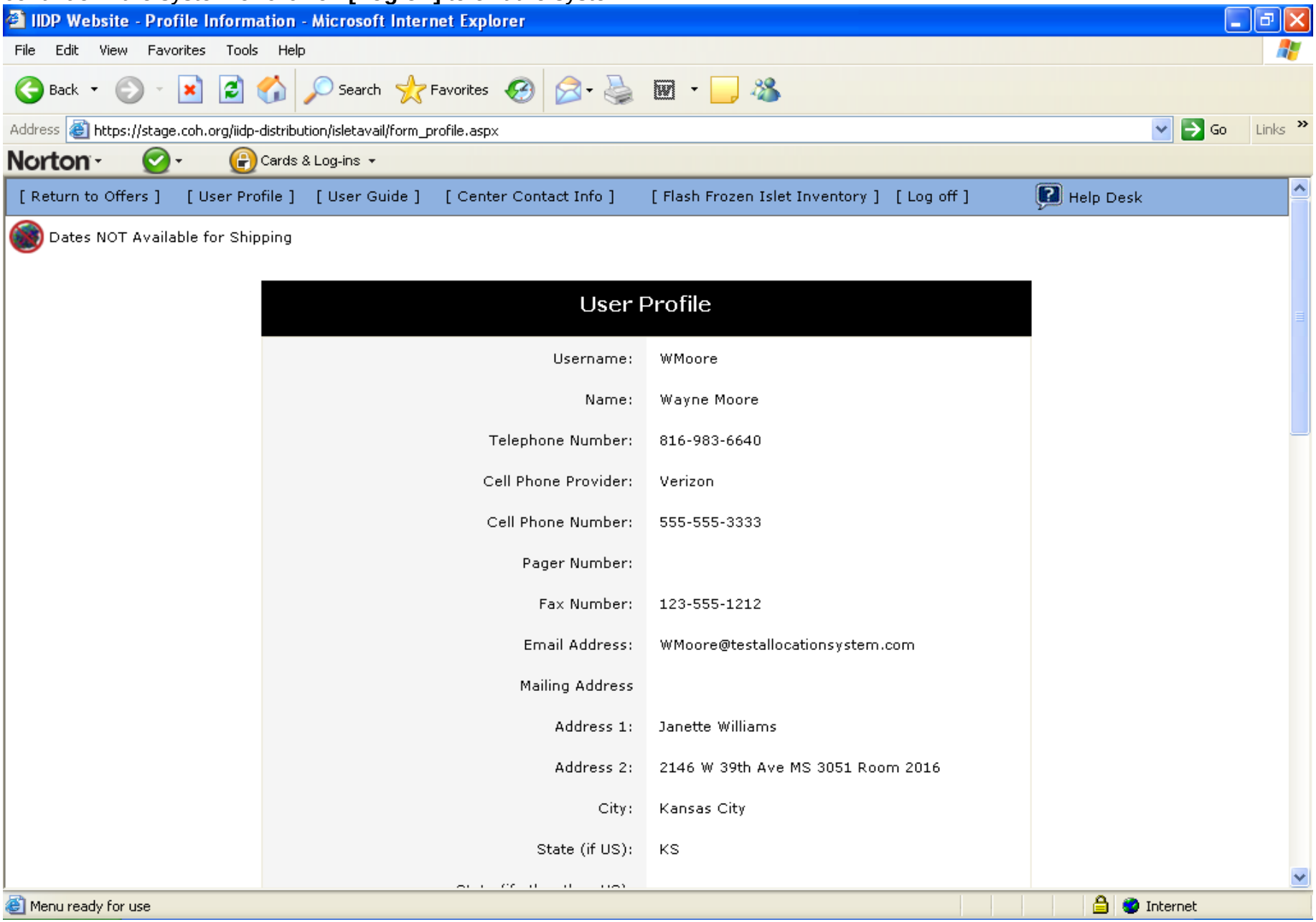


User Information (continued)

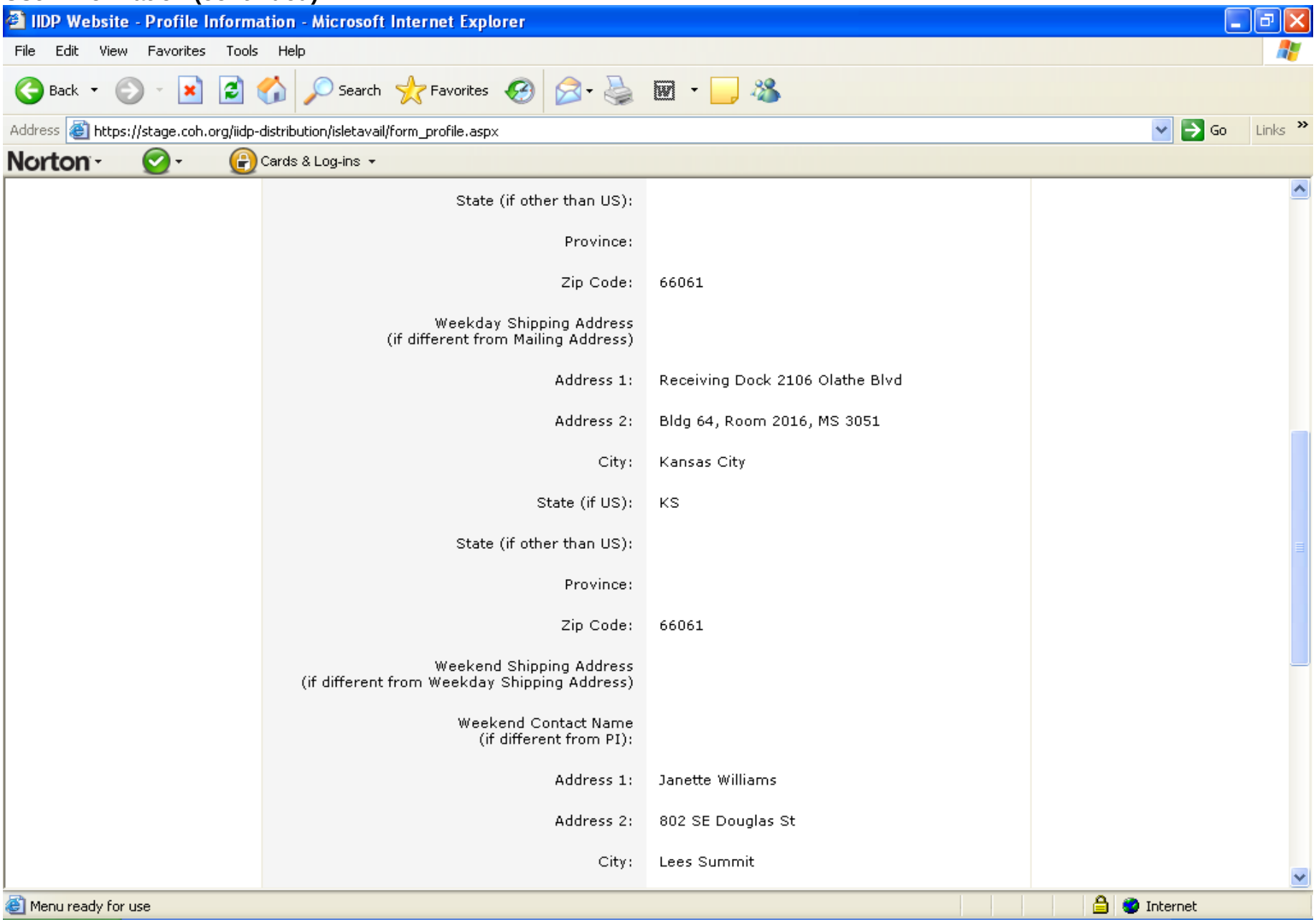


Click on **[Submit]** to submit the changes to the system.

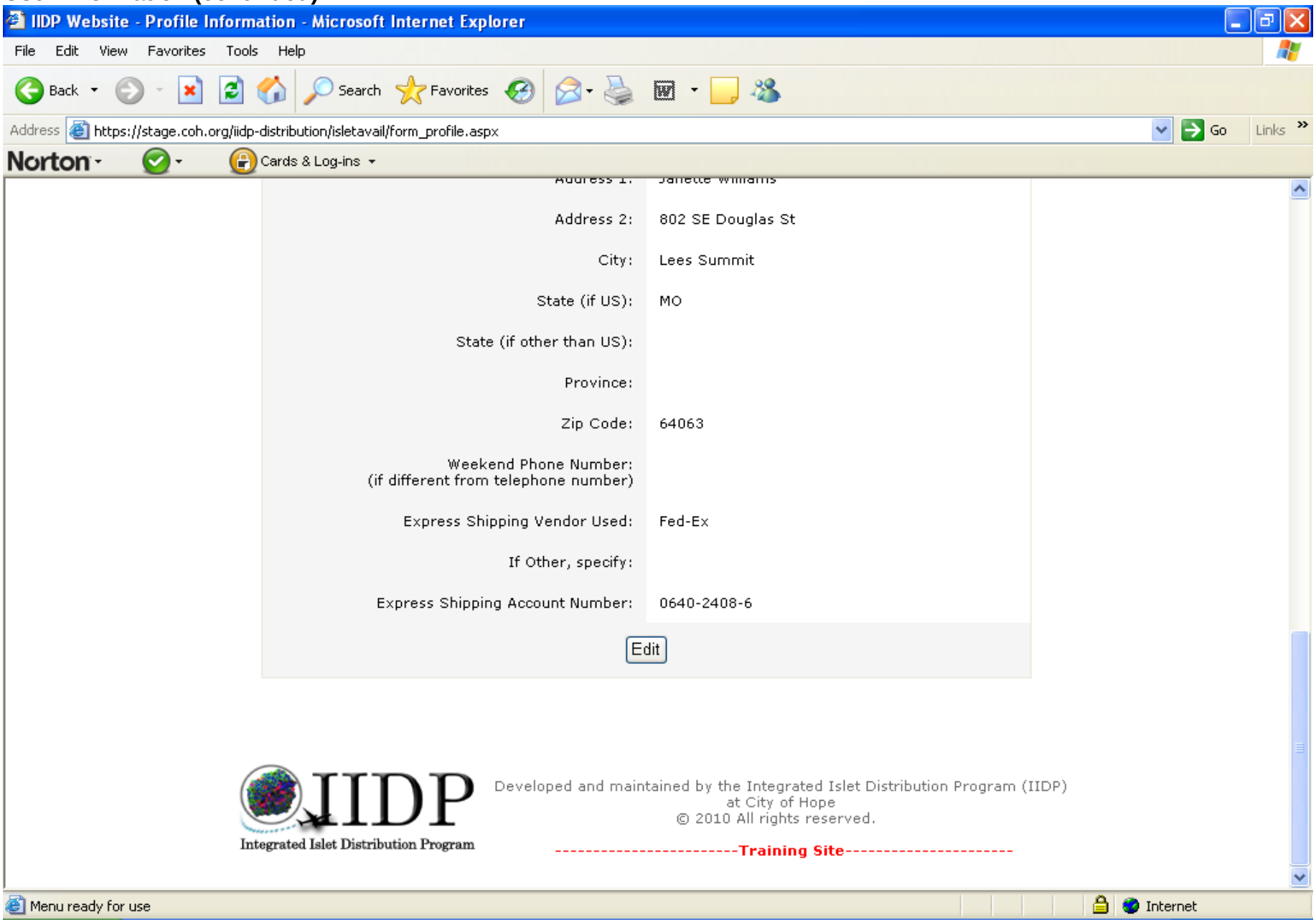
User Information - The system will display the changed User Profile information for the user to review. If additional changes are needed, click on **[Edit]** and repeat the process to edit the User Profile information. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.



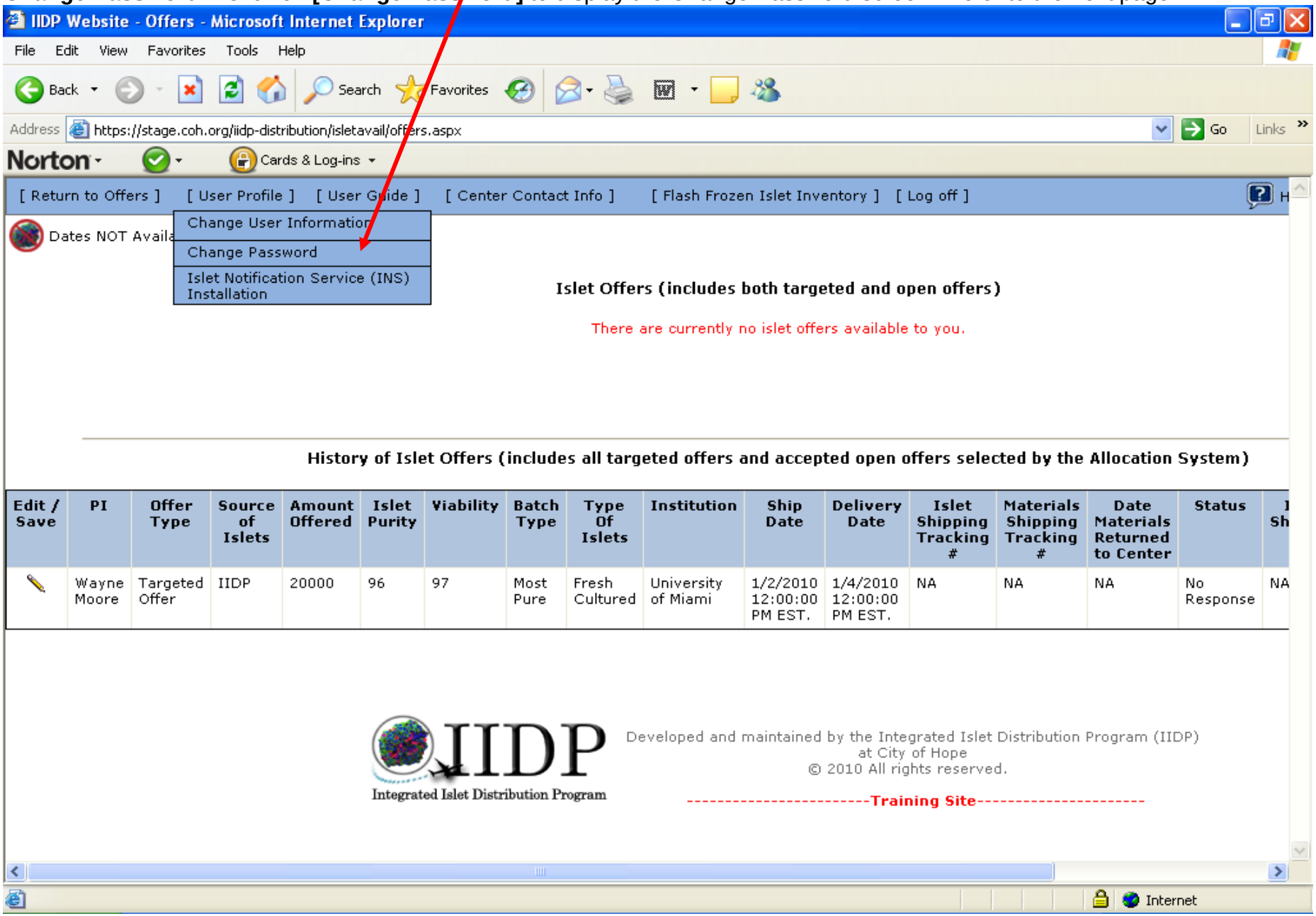
User Information (continued)



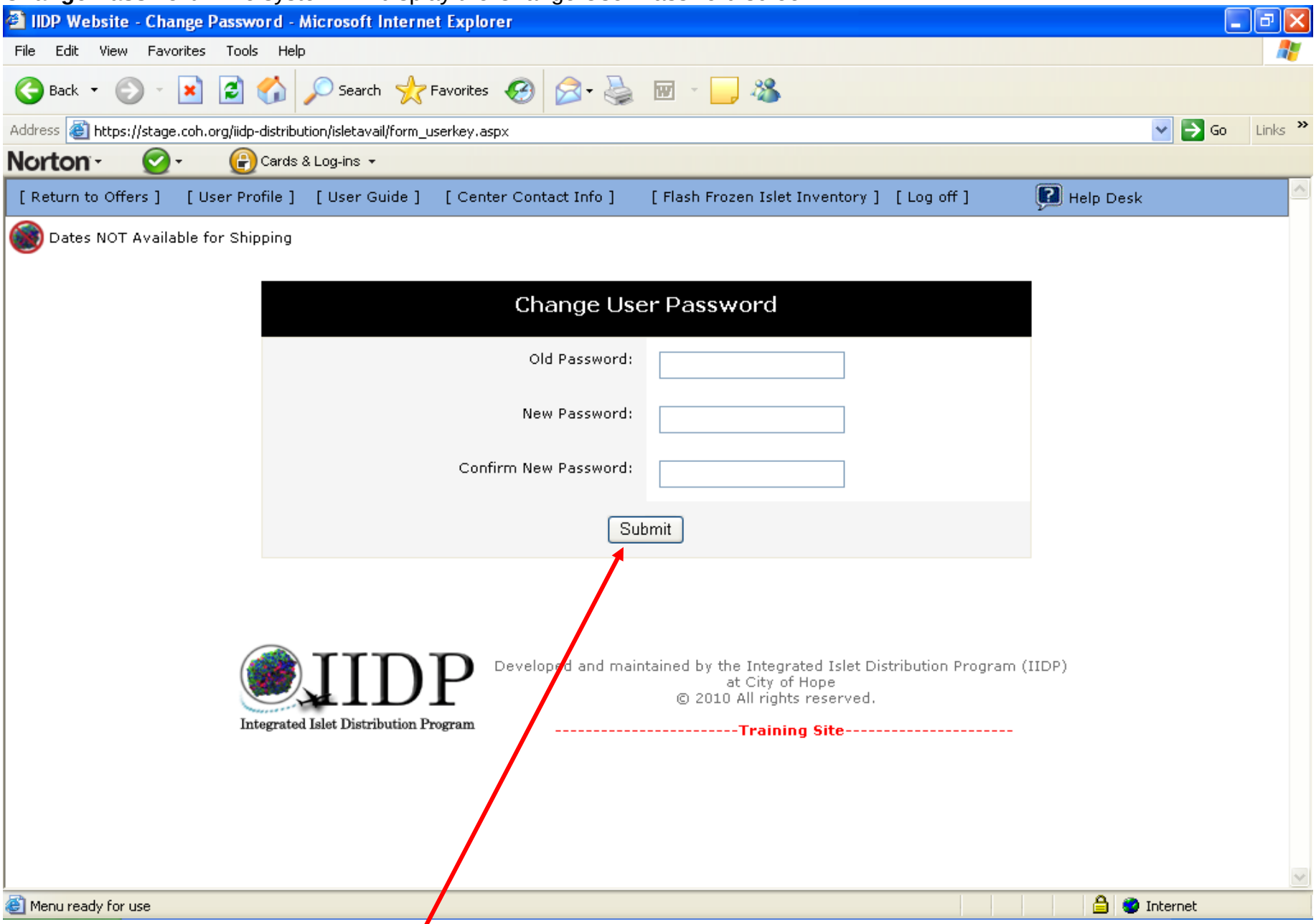
User Information (continued)



Change Password – Click on **[Change Password]** to display the Change Password screen – refer to the next page.

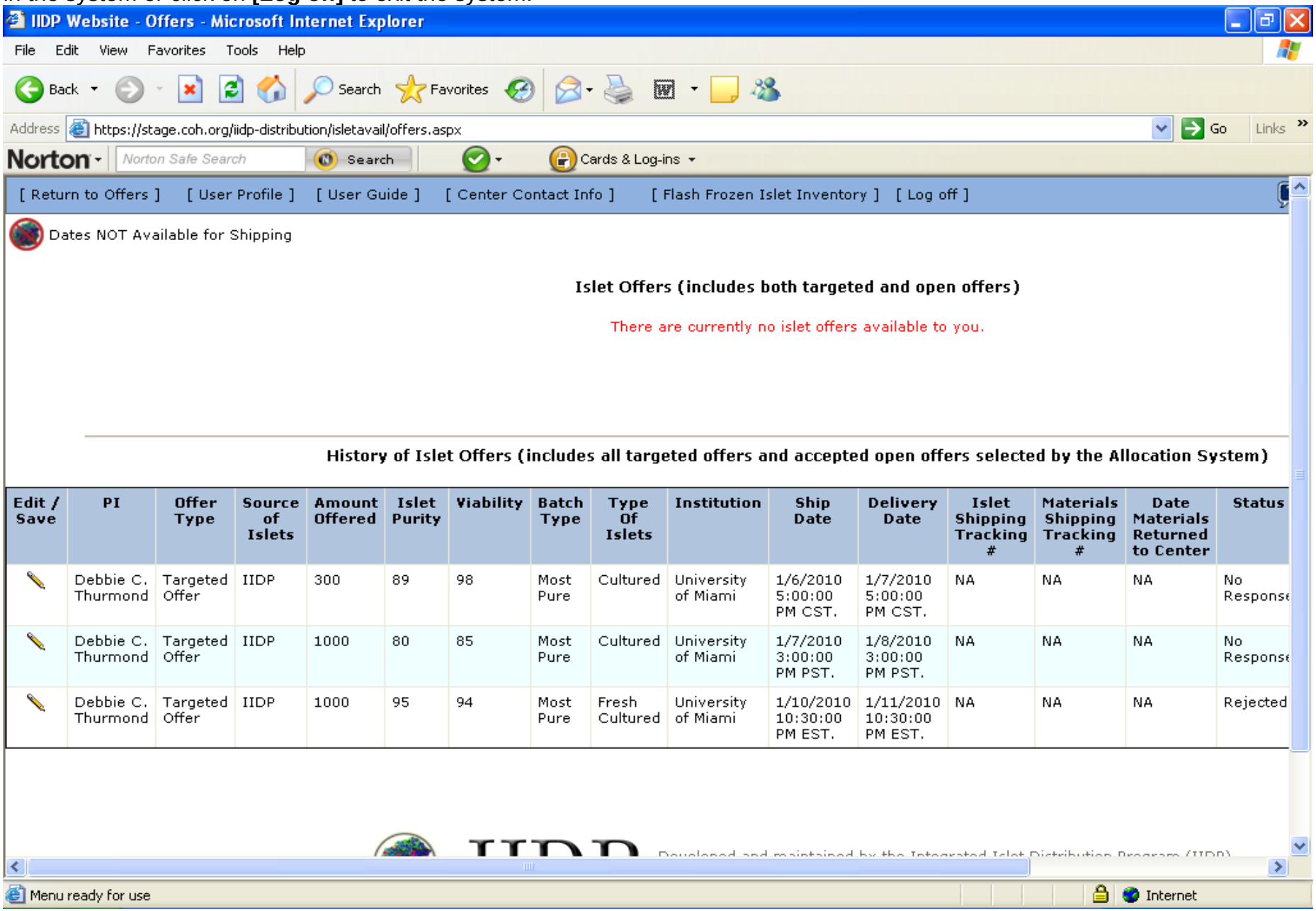


Change Password -The system will display the Change User Password screen.



Change password and then click on **[Submit].** The system will return the user to the Islet Offers screen.

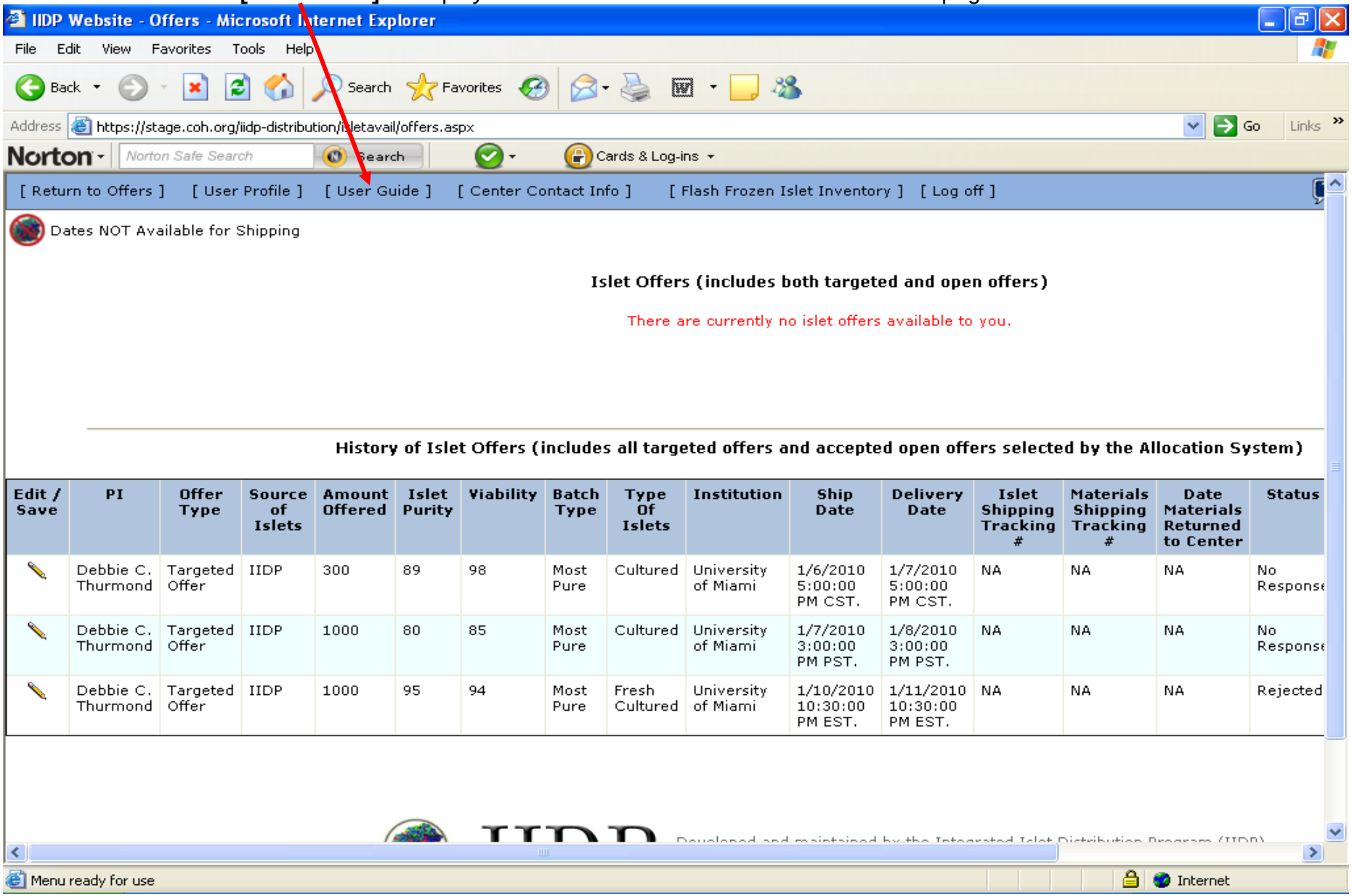
Islet Offers screen - The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.



Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected

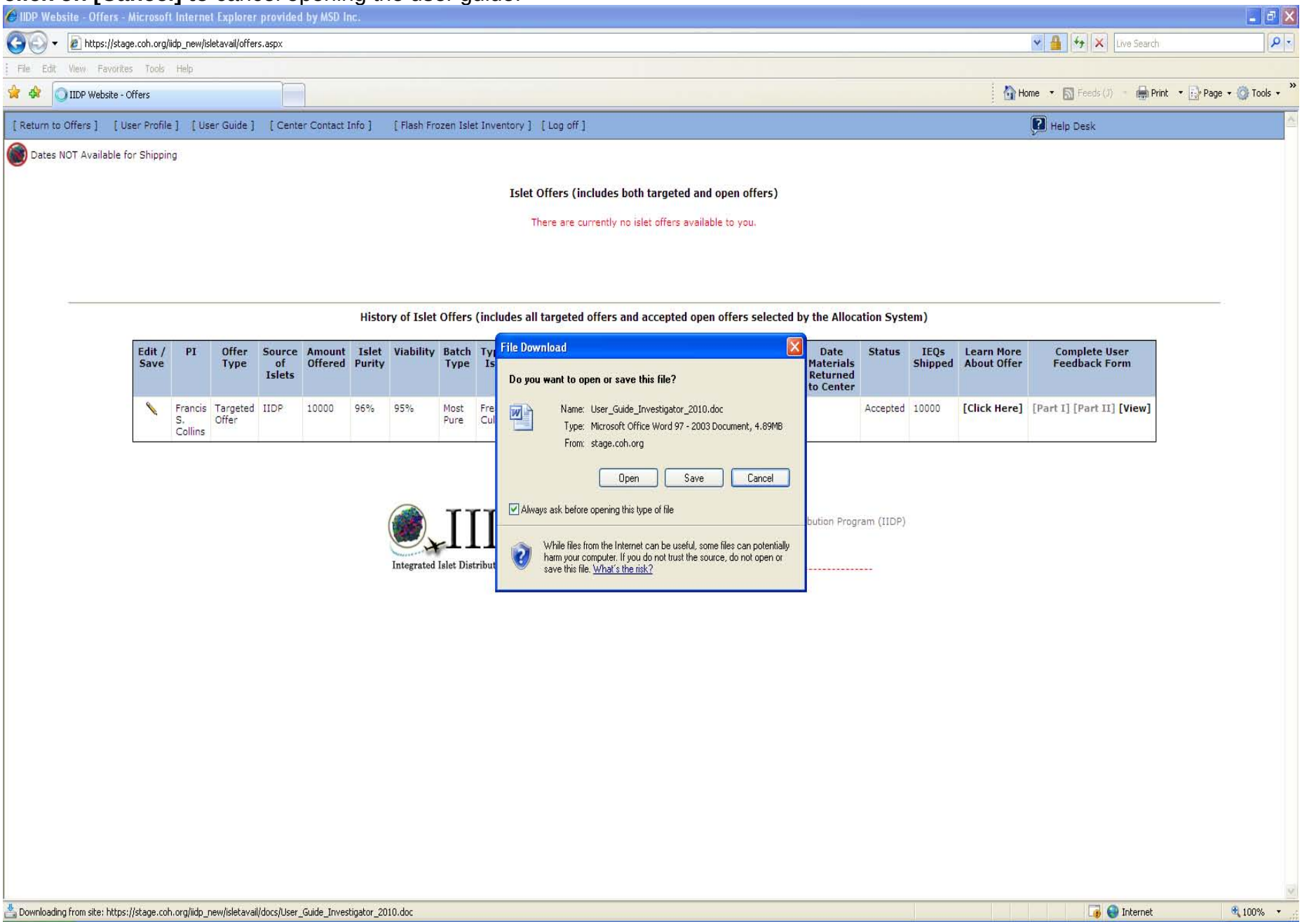
5.0 View the User Guide

User Guide – Click on **[User Guide]** to display the User Guide to review – refer to the next page.

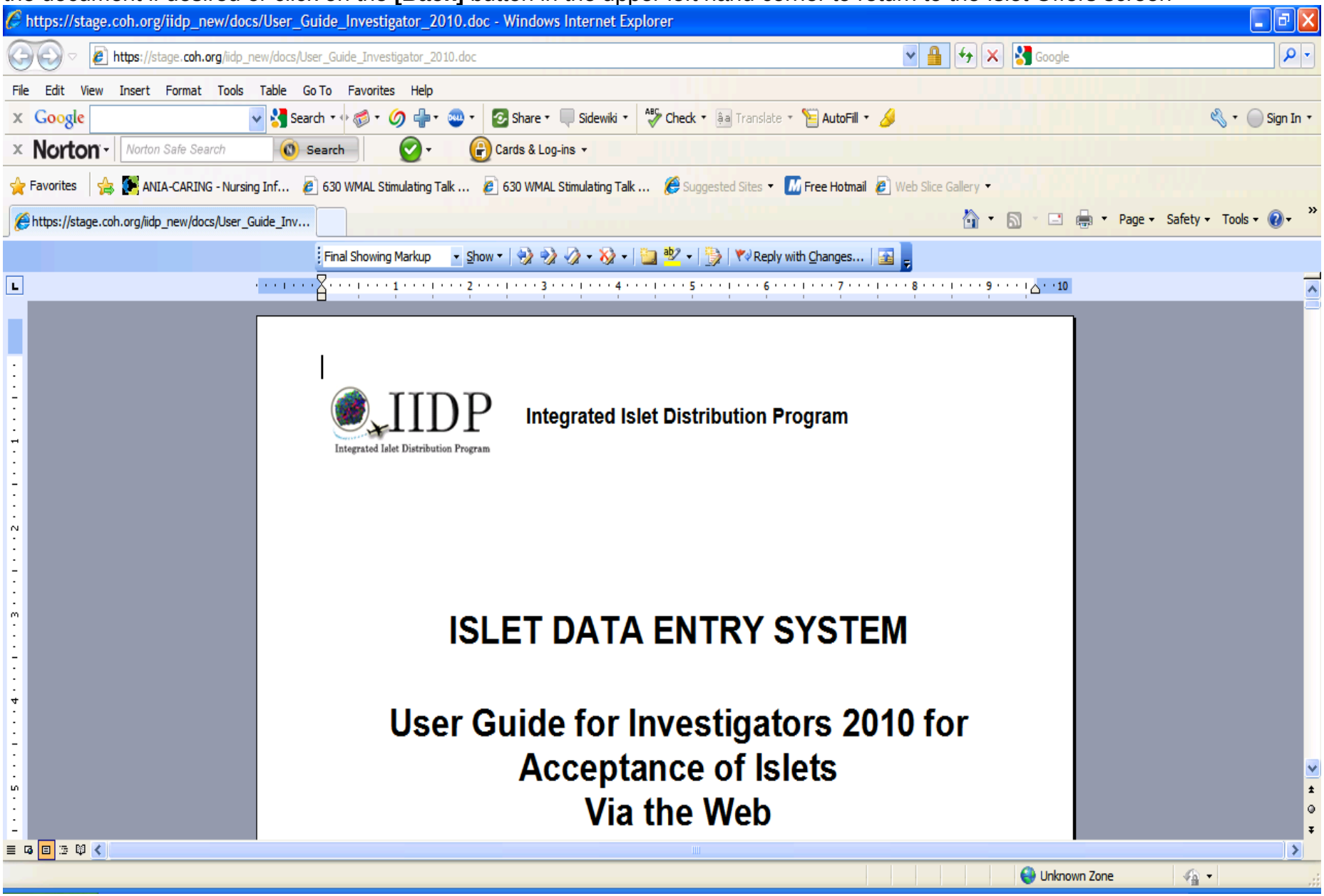


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected

User Guide – Click on [Open] to display the user guide – refer to the next page. Click on [Save] to save the user guide or click on [Cancel] to cancel opening the user guide.



User Guide – The system displays the User Guide. Use the scroll bar on the right to scroll through and view the document. Save the document if desired or click on the **[Back]** button in the upper left hand corner to return to the Islet Offers screen



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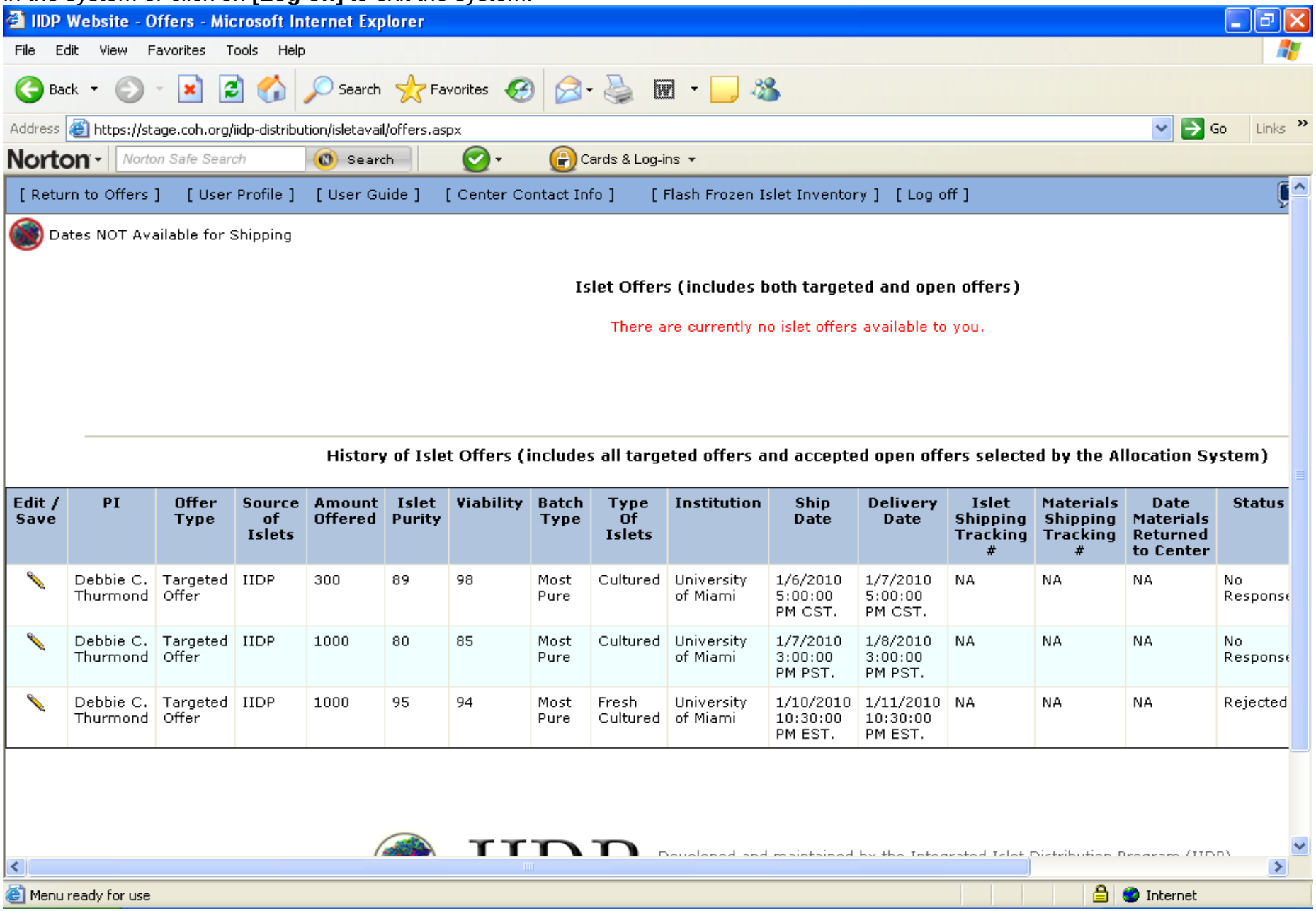
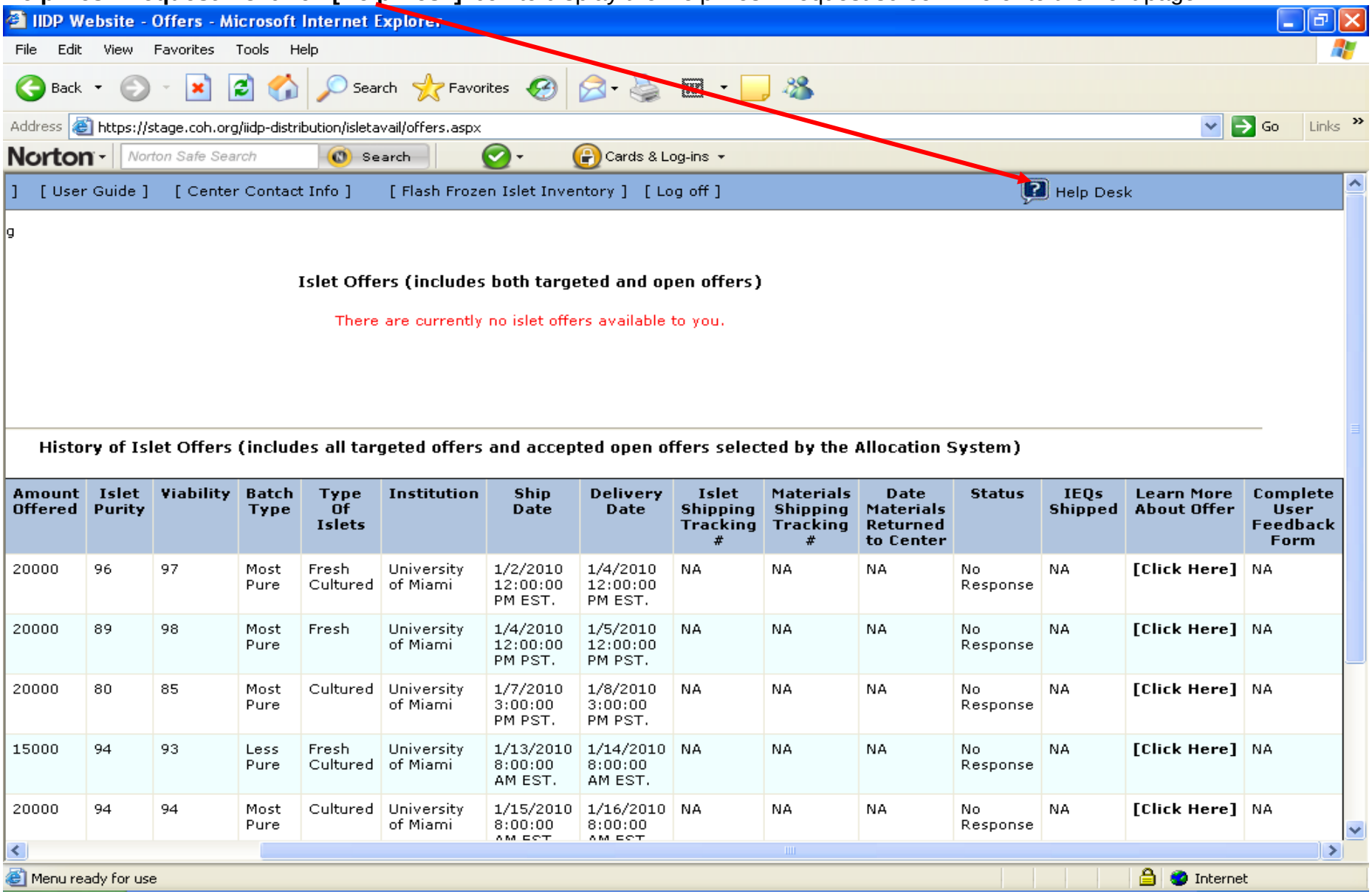
Islet Offers screen - The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.



Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected

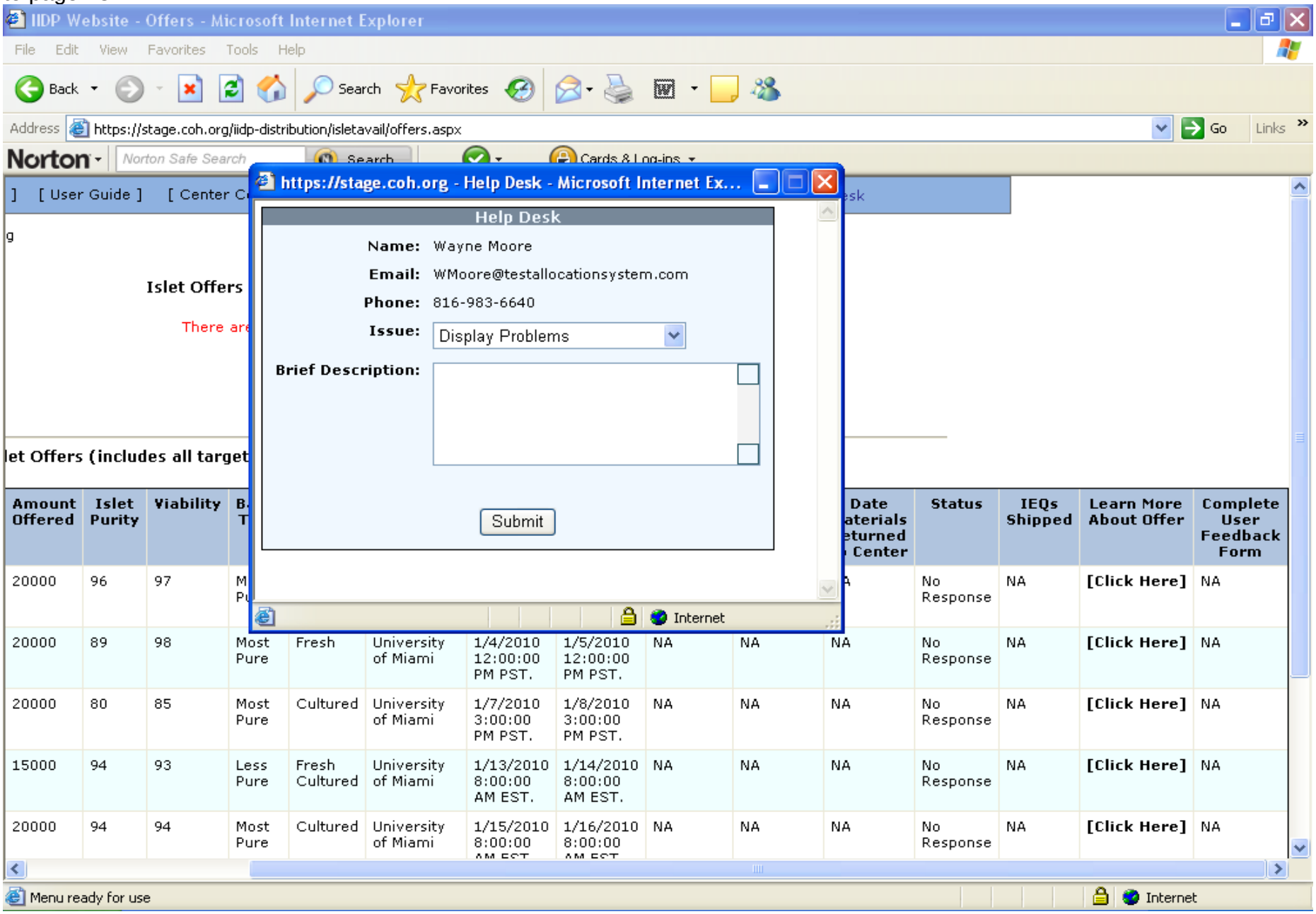
6.0 Submit a Help Desk Request

Help Desk Request – Click on **[Help Desk]** icon to display the Help Desk Request screen – refer to the next page.

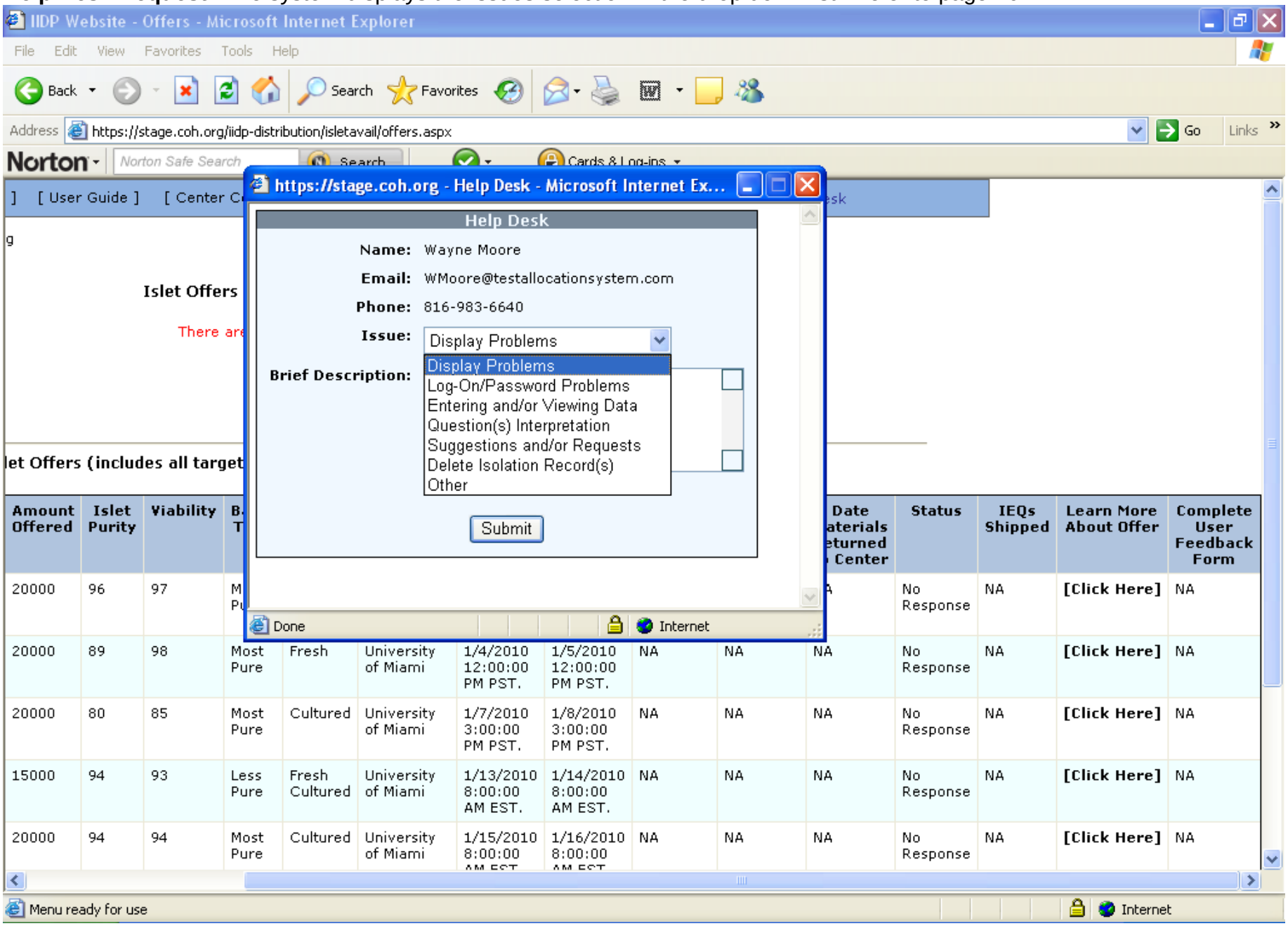


Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
20000	96	97	Most Pure	Fresh Cultured	University of Miami	1/2/2010 12:00:00 PM EST.	1/4/2010 12:00:00 PM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	89	98	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
15000	94	93	Less Pure	Fresh Cultured	University of Miami	1/13/2010 8:00:00 AM EST.	1/14/2010 8:00:00 AM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	94	94	Most Pure	Cultured	University of Miami	1/15/2010 8:00:00 AM EST.	1/16/2010 8:00:00 AM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA

Help Desk Request – The system displays the **[Help Desk]** screen. Select the issue from the drop down list – refer to the next page. Enter a brief description of the issue in the textbox. Click on **[Submit]** to submit the help desk request to the system – refer to page 48.

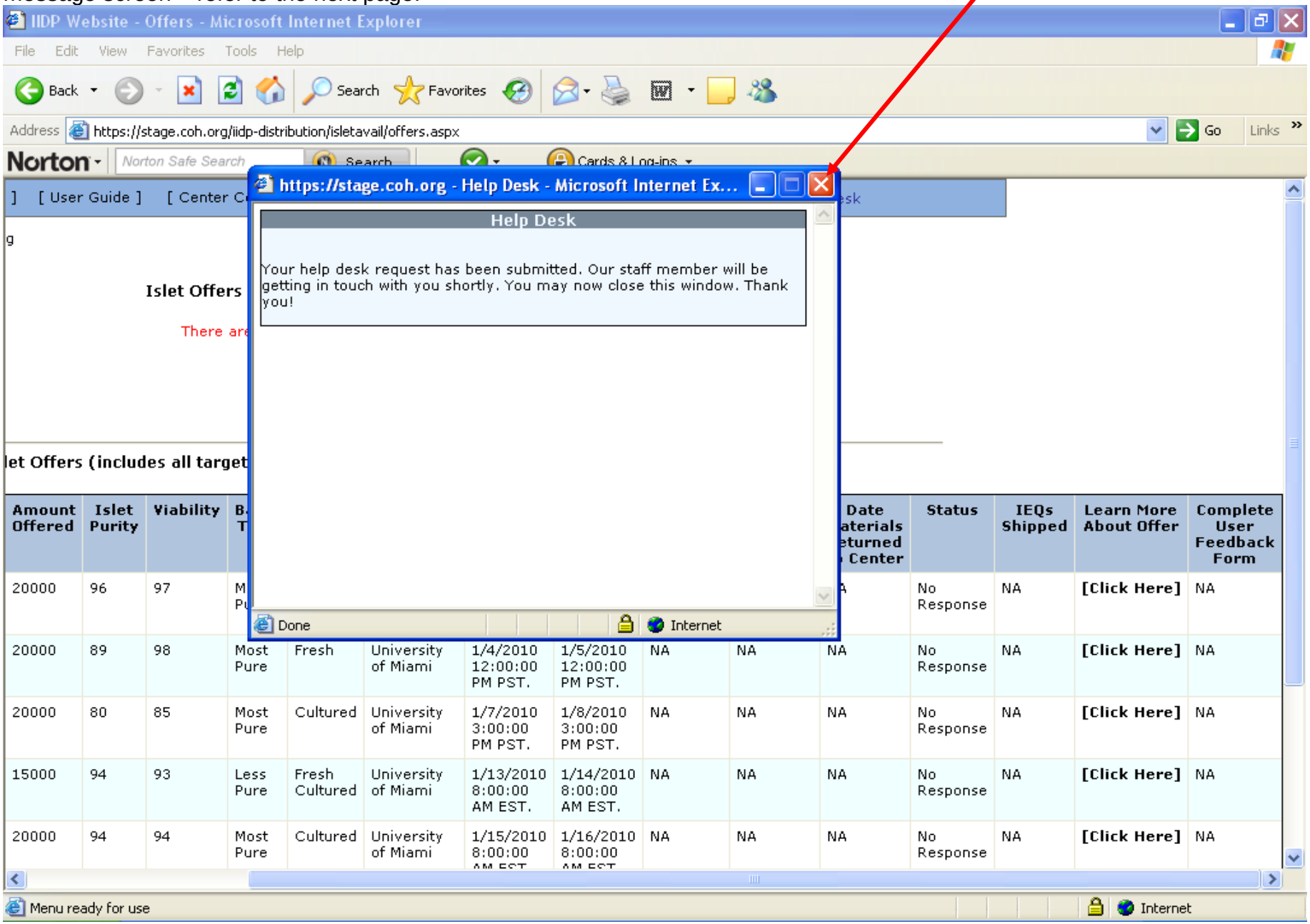


Help Desk Request –The system displays the issues selection in the drop down list – refer to page 46.



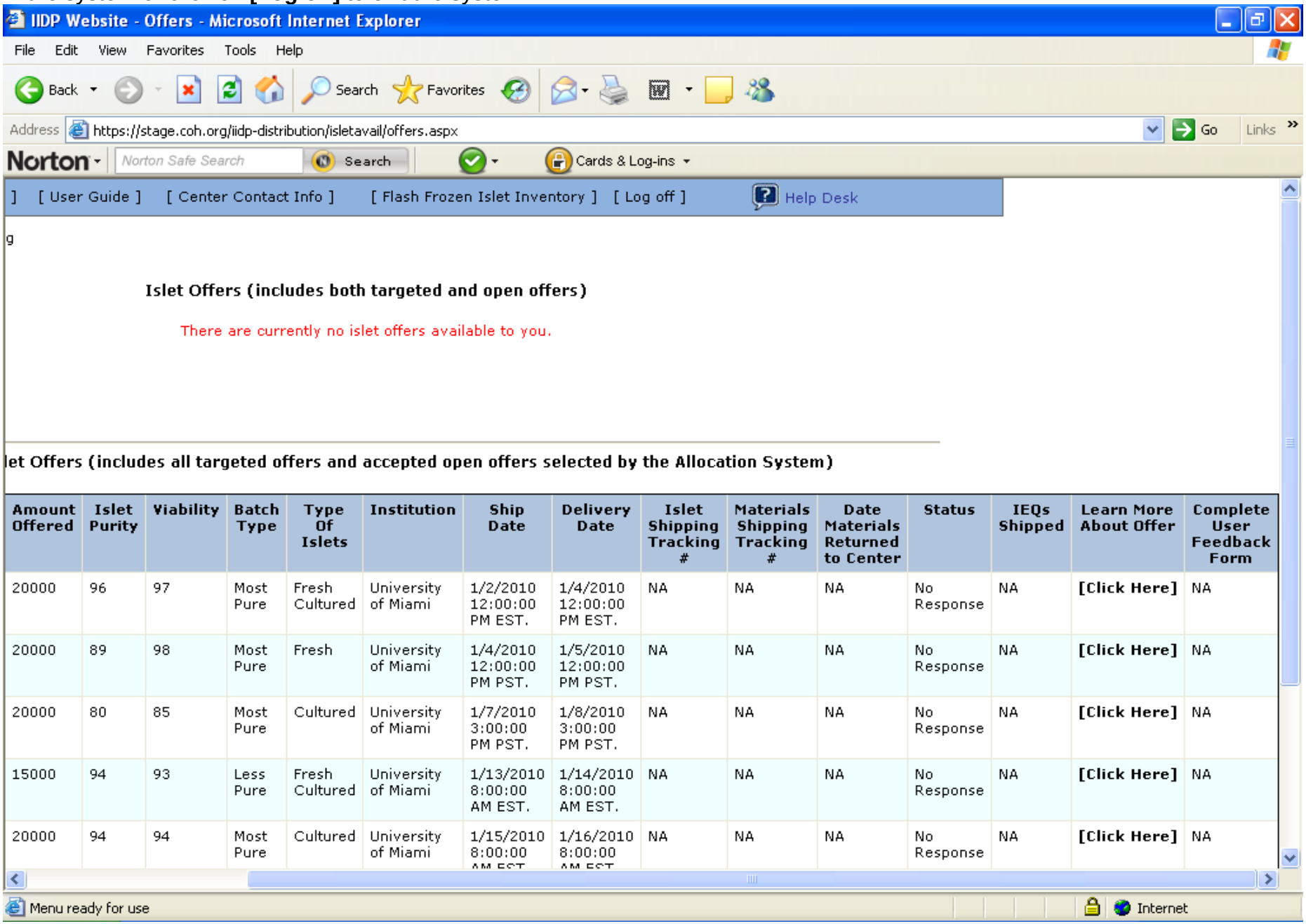
Amount Offered	Islet Purity	Viability	B. T								Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
20000	96	97	M Pu								No Response	NA	[Click Here]	NA
20000	89	98	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
15000	94	93	Less Pure	Fresh Cultured	University of Miami	1/13/2010 8:00:00 AM EST.	1/14/2010 8:00:00 AM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	94	94	Most Pure	Cultured	University of Miami	1/15/2010 8:00:00	1/16/2010 8:00:00	NA	NA	NA	No Response	NA	[Click Here]	NA

Help Desk Request – The system displays the help desk request confirmation message. Click on **[X]** to close the confirmation message screen – refer to the next page.



Amount Offered	Islet Purity	Viability								Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
20000	96	97								No Response	NA	[Click Here]	NA
20000	89	98	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA	No Response	NA	[Click Here]	NA
20000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	No Response	NA	[Click Here]	NA
15000	94	93	Less Pure	Fresh Cultured	University of Miami	1/13/2010 8:00:00 AM EST.	1/14/2010 8:00:00 AM EST.	NA	NA	No Response	NA	[Click Here]	NA
20000	94	94	Most Pure	Cultured	University of Miami	1/15/2010 8:00:00	1/16/2010 8:00:00	NA	NA	No Response	NA	[Click Here]	NA

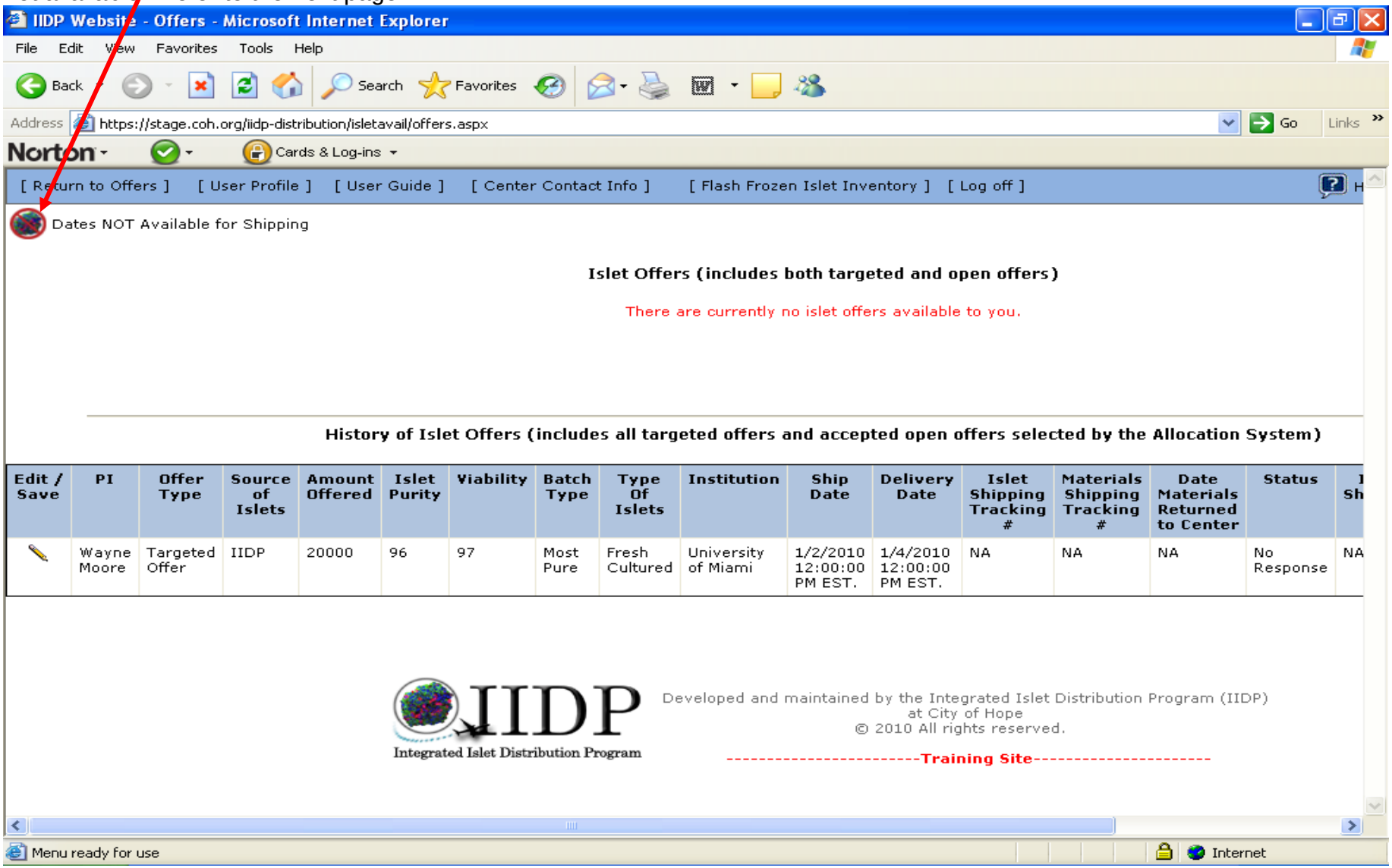
Help Desk Request – The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.



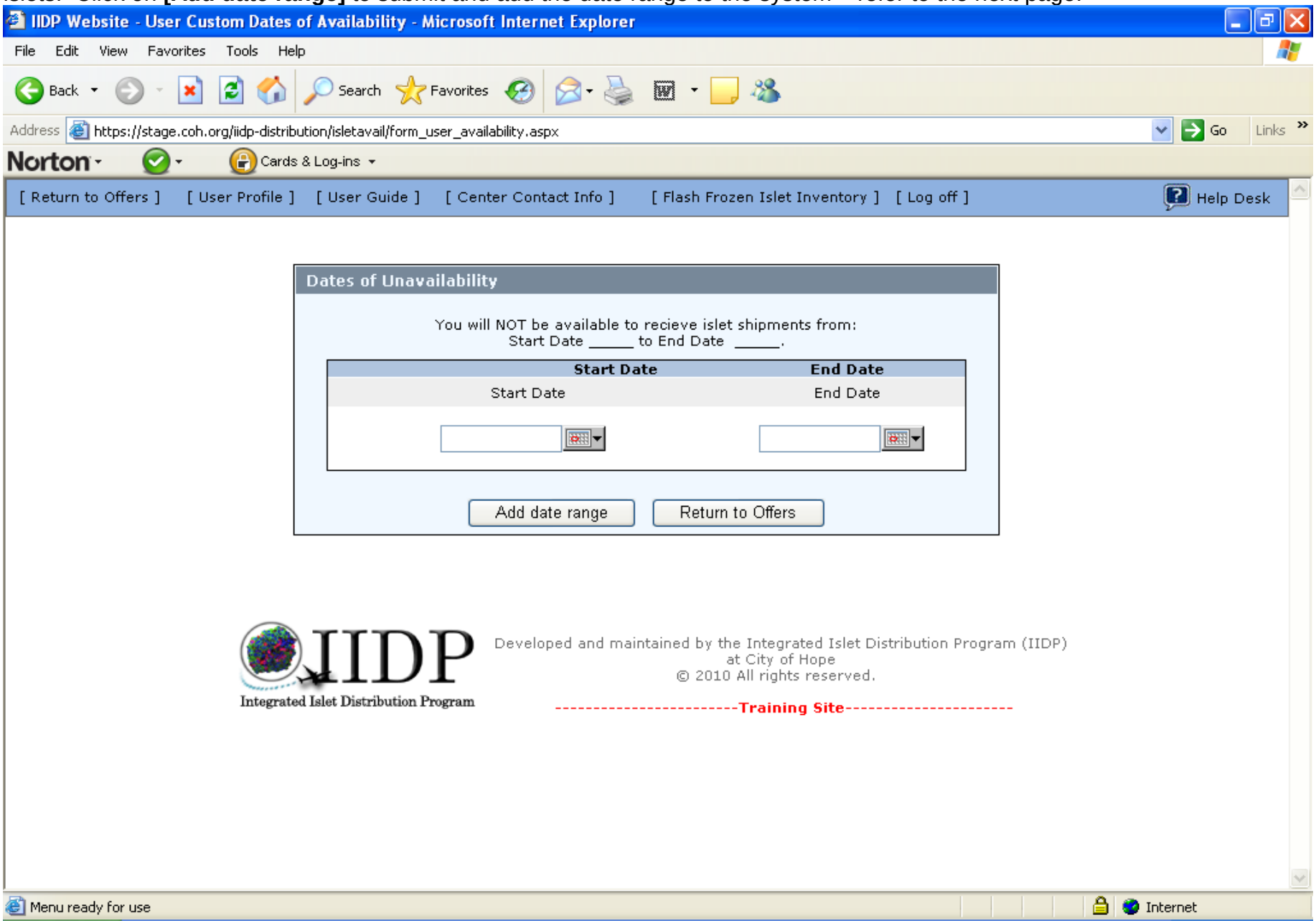
Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
20000	96	97	Most Pure	Fresh Cultured	University of Miami	1/2/2010 12:00:00 PM EST.	1/4/2010 12:00:00 PM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	89	98	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
15000	94	93	Less Pure	Fresh Cultured	University of Miami	1/13/2010 8:00:00 AM EST.	1/14/2010 8:00:00 AM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA
20000	94	94	Most Pure	Cultured	University of Miami	1/15/2010 8:00:00	1/16/2010 8:00:00	NA	NA	NA	No Response	NA	[Click Here]	NA

7.0 Dates Not Available for Shipping

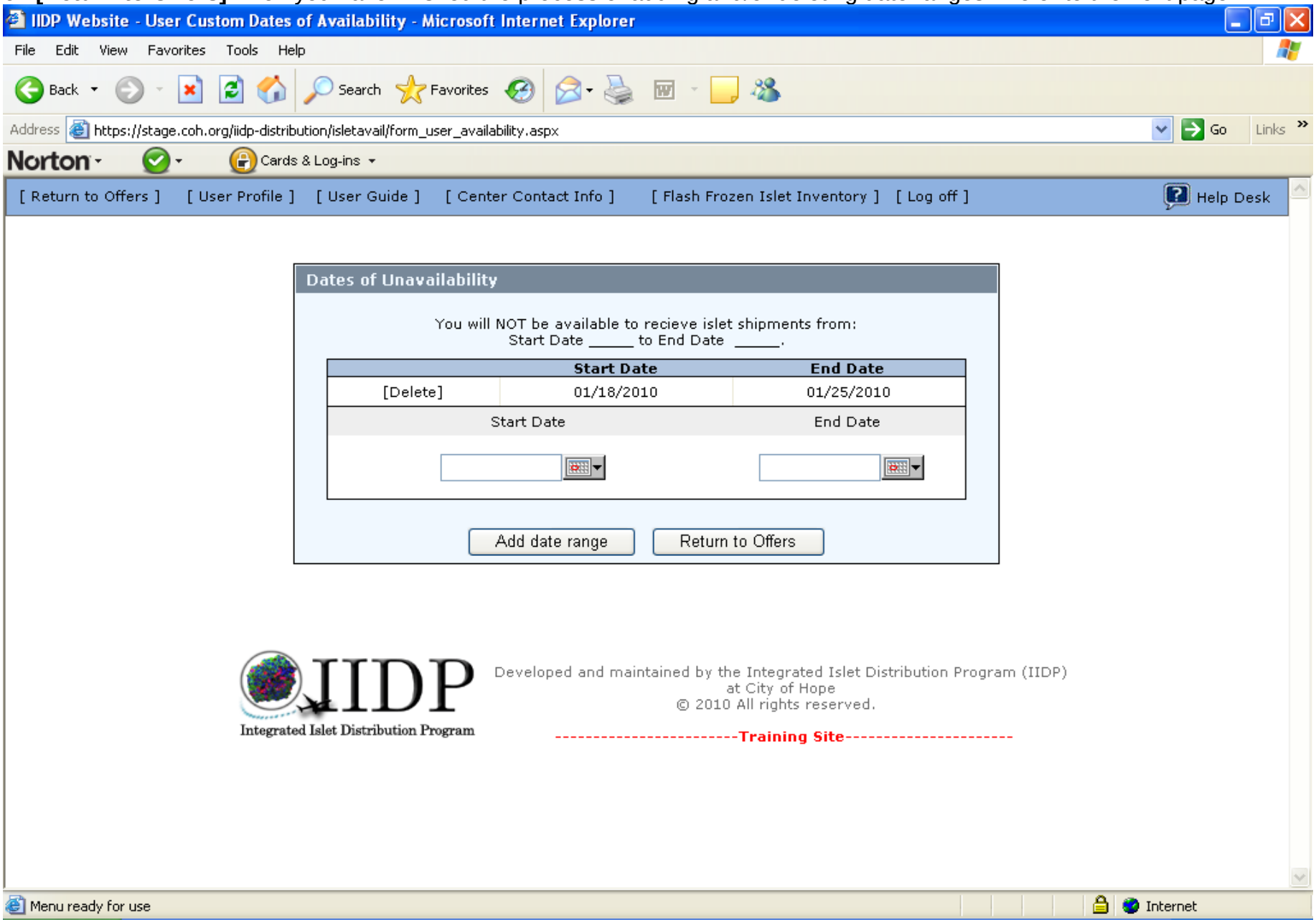
Dates Not Available for Shipping – Click on **[Dates NOT Available for Shipping]** icon to display the screen to enter dates when not available – refer to the next page



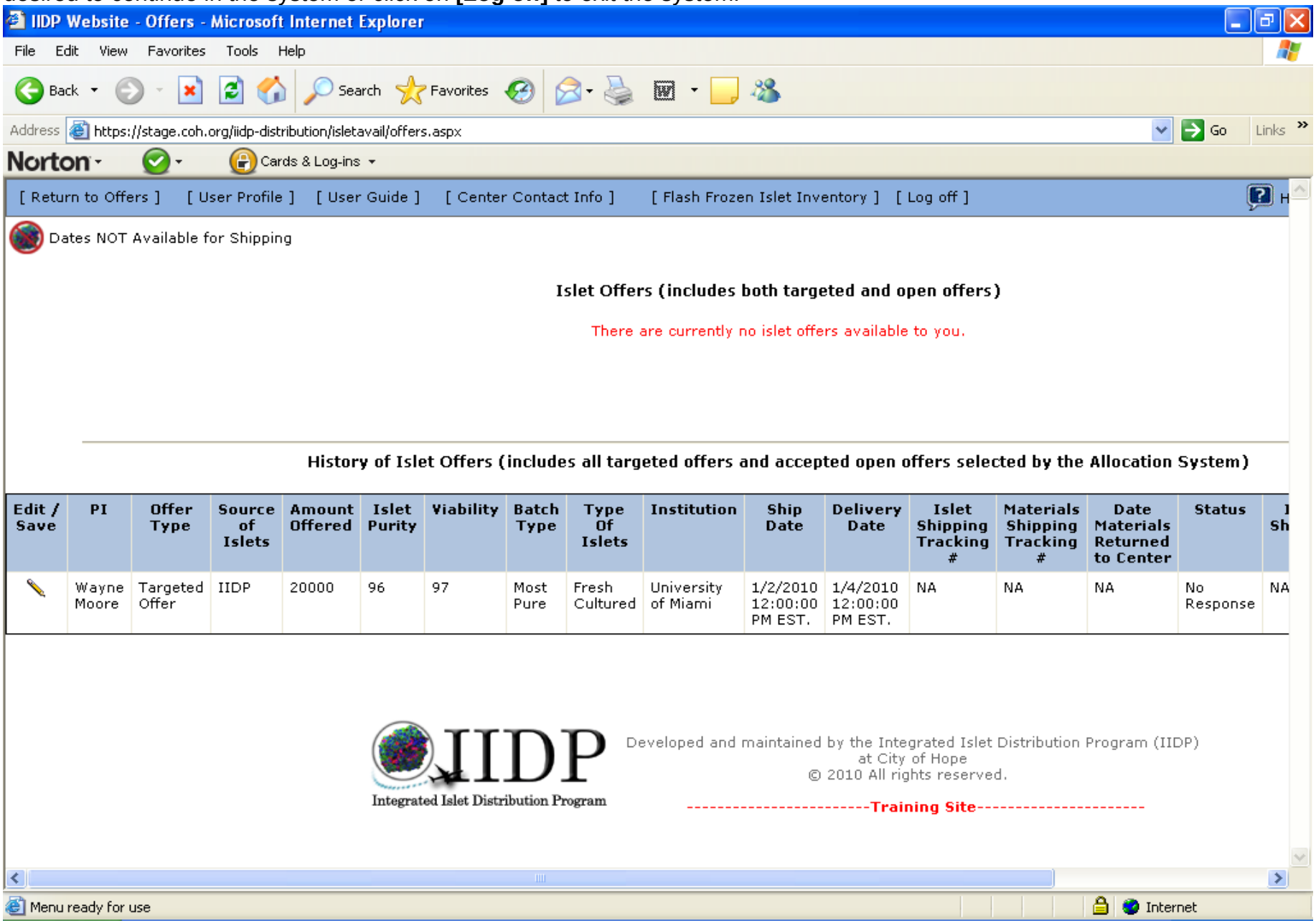
Dates Not Available for Shipping – Enter the **[Start Date]** and **[End Date]** for the time when you will not be available to receive islets. Click on **[Add date range]** to submit and add the date range to the system – refer to the next page.



Dates Not Available for Shipping – The system displays the date range that has been entered. Click on **[Delete]** to delete a date range from the system. Repeat the process as needed for adding and/or deleting other date ranges of unavailability. Click on **[Return to Offers]** when you have finished the process of adding and/or deleting date ranges – refer to the next page.

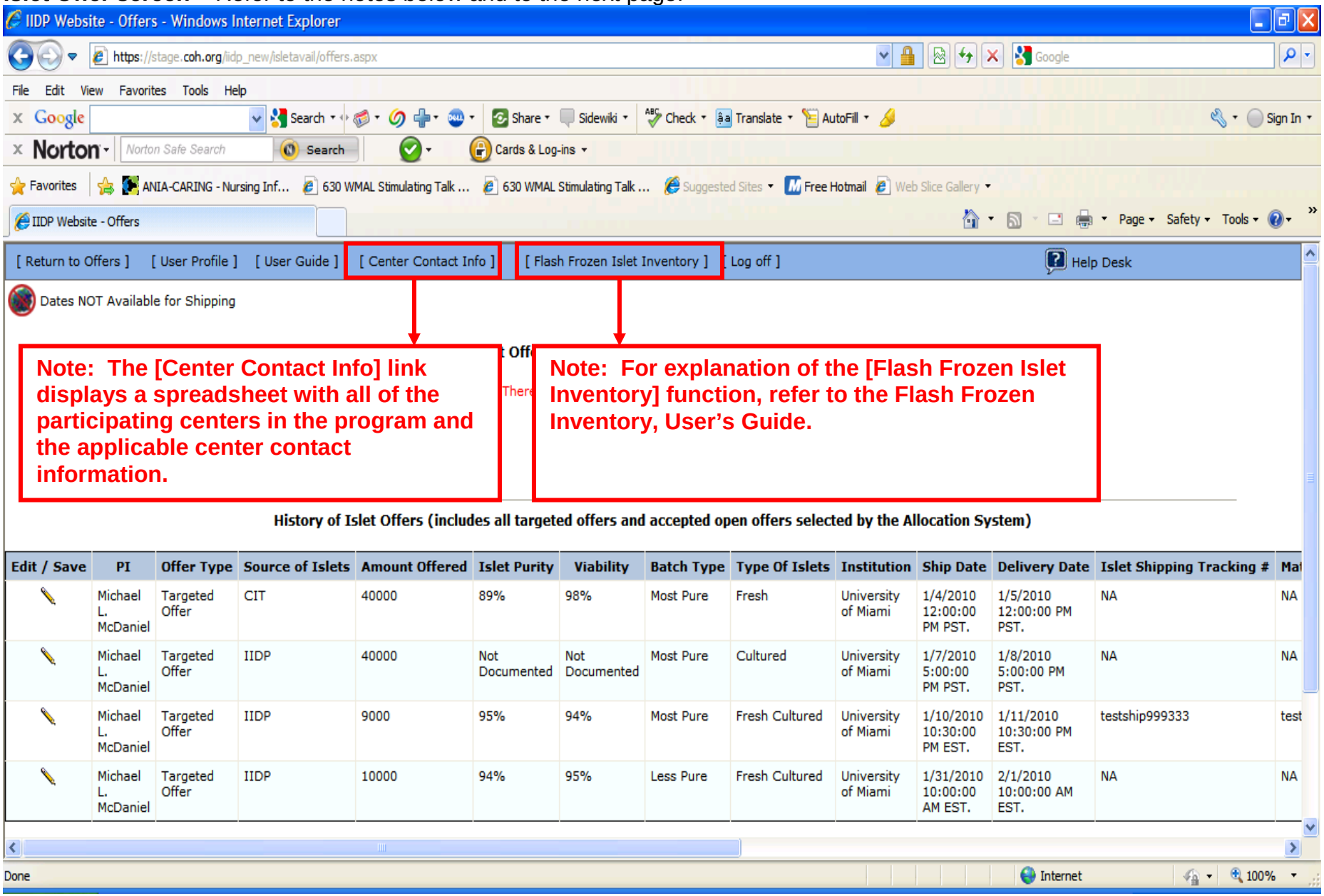


Dates Not Available for Shipping – The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.



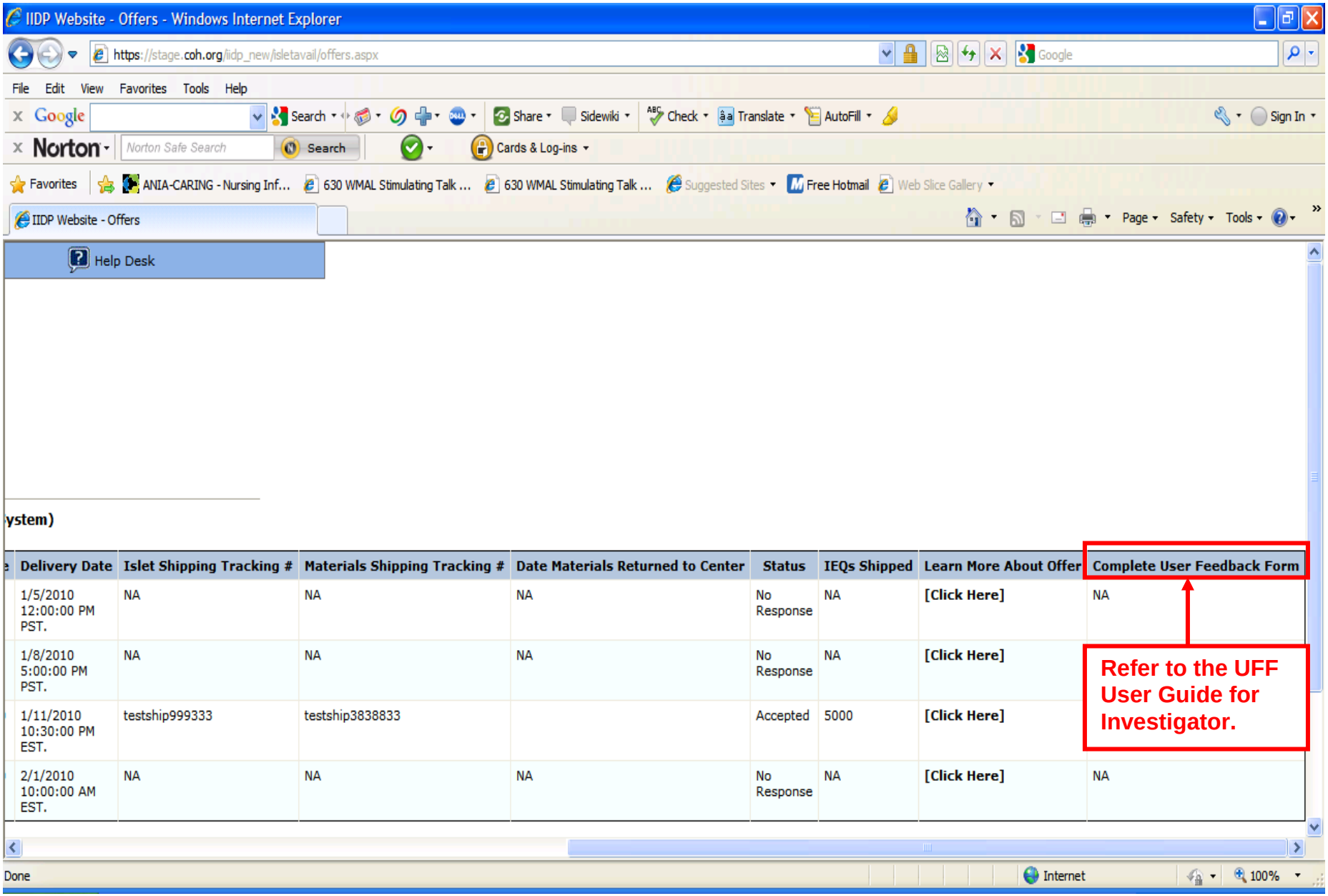
8.0 Other Functions

Islet Offer screen – Refer to the notes below and to the next page.



Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mat
	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	40000	Not Documented	Not Documented	Most Pure	Cultured	University of Miami	1/7/2010 5:00:00 PM PST.	1/8/2010 5:00:00 PM PST.	NA	NA
	Michael L. McDaniel	Targeted Offer	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	testship999333	test
	Michael L. McDaniel	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010 10:00:00 AM EST.	2/1/2010 10:00:00 AM EST.	NA	NA

Islet Offer screen – Refer to the note below.



Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA
1/8/2010 5:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	
1/11/2010 10:30:00 PM EST.	testship999333	testship3838833		Accepted	5000	[Click Here]	
2/1/2010 10:00:00 AM EST.	NA	NA	NA	No Response	NA	[Click Here]	NA

User Feedback Form User Guide for Broadcasting Staff

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1.0 General Guidelines

1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Main Menu (e.g. access the Enter New Isolation data form, View Islet Offers, etc.). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for viewing completed User Feedback Forms (UFFs) are presented in the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the User Feedback Form (UFF) data entry screens are designed to be a 'single page' in which the data for each section of the User Feedback Form (UFF) are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the User Feedback Form (UFF) to capture the data.

1.2.2.1 Text Boxes

- Data must be typed in
- Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen – e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

(mm/dd/yy)

The system will automatically enter the forward slashes **(/)** as you enter the date.

1.3.1.2 Time Field Formats

(hh:mm)

The system will automatically enter the colon **(:)** as you enter the time.

1.3.1.3 Date Field Ranges

06/04/2010 (mm/dd/yy)

The system will display a message that the date is out of range and that the latest date that may be entered is the current date.

1.3.1.4 Numeric Field Formats

Percent of Trapped Islets (xxx.xxx)

This is one example of a numeric field format within the Batch Record Data Form.

1.3.1.5 Numeric Field Ranges

Acceptable Numeric Value

Percent of Trapped Islets 75.34 % (xxx.xxx)

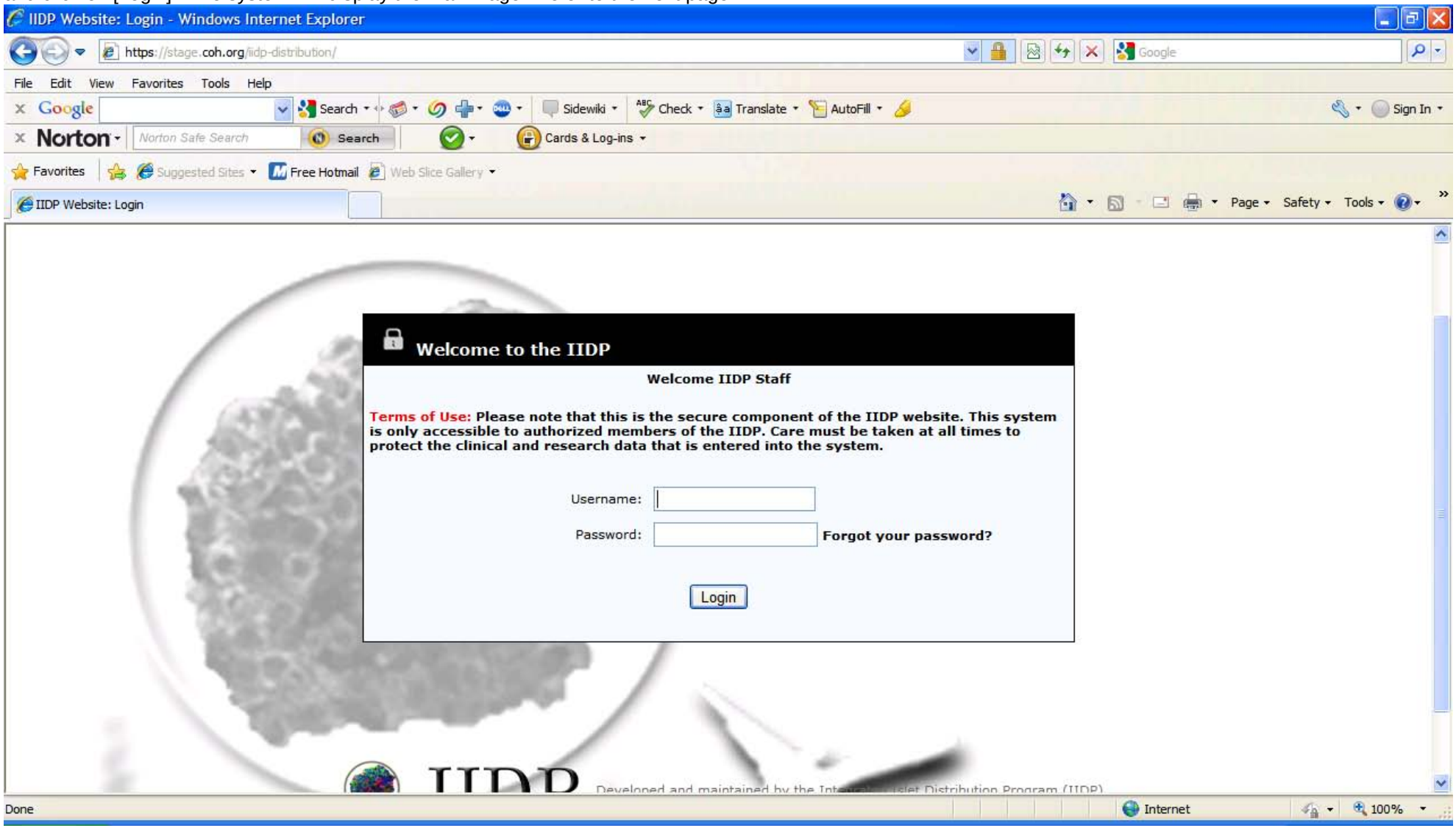
Numeric Value Out of Range

Percent of Trapped Islets 110.93 % (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

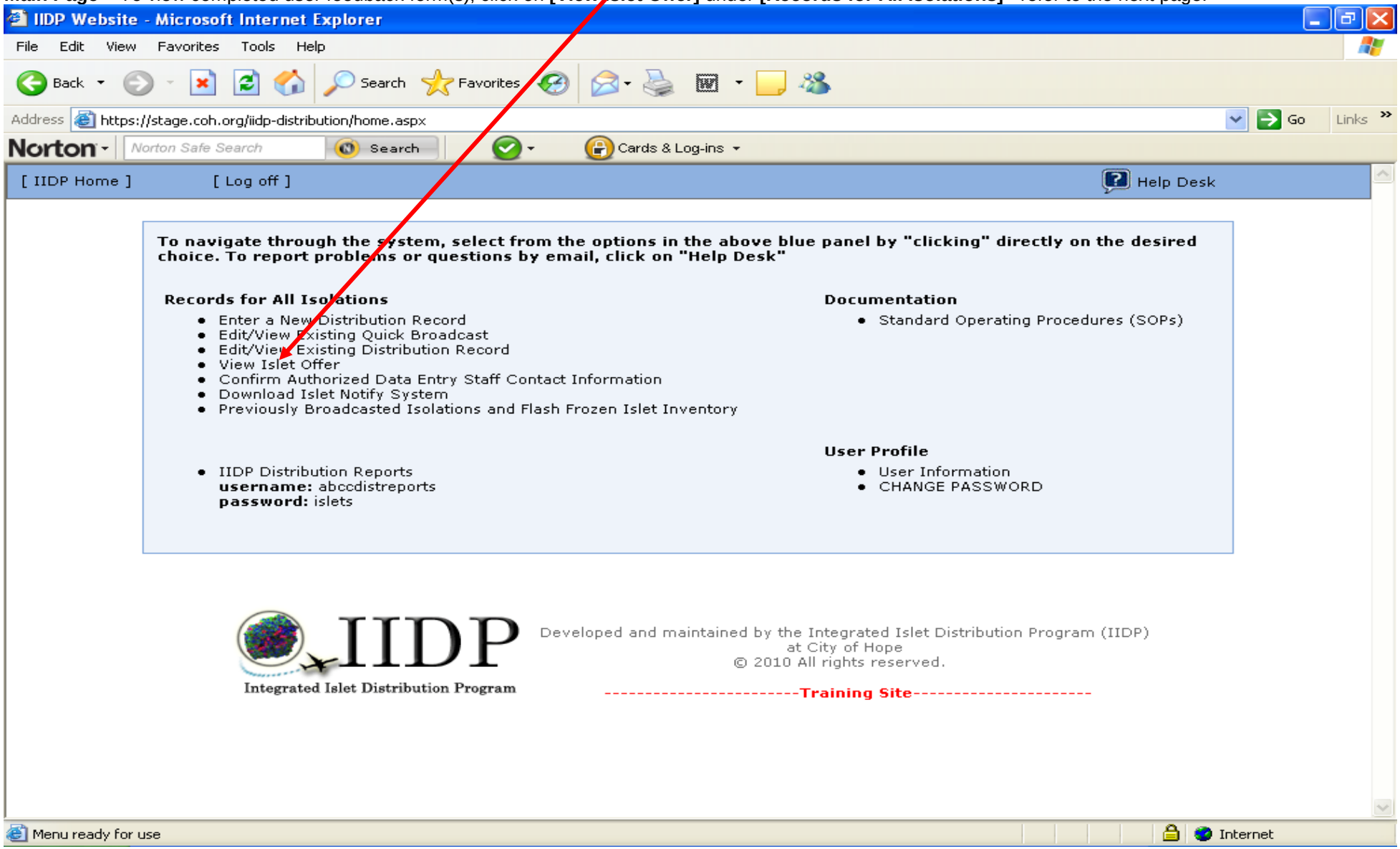
2.0 Login to the Islet Data Entry System (IDES)

This is the **Login Screen** to access the Islet Data Entry System (IDES). IIDP will issue each user a Username and Password. Enter your username and password and click on [Login]. The system will display the Main Page – refer to the next page.

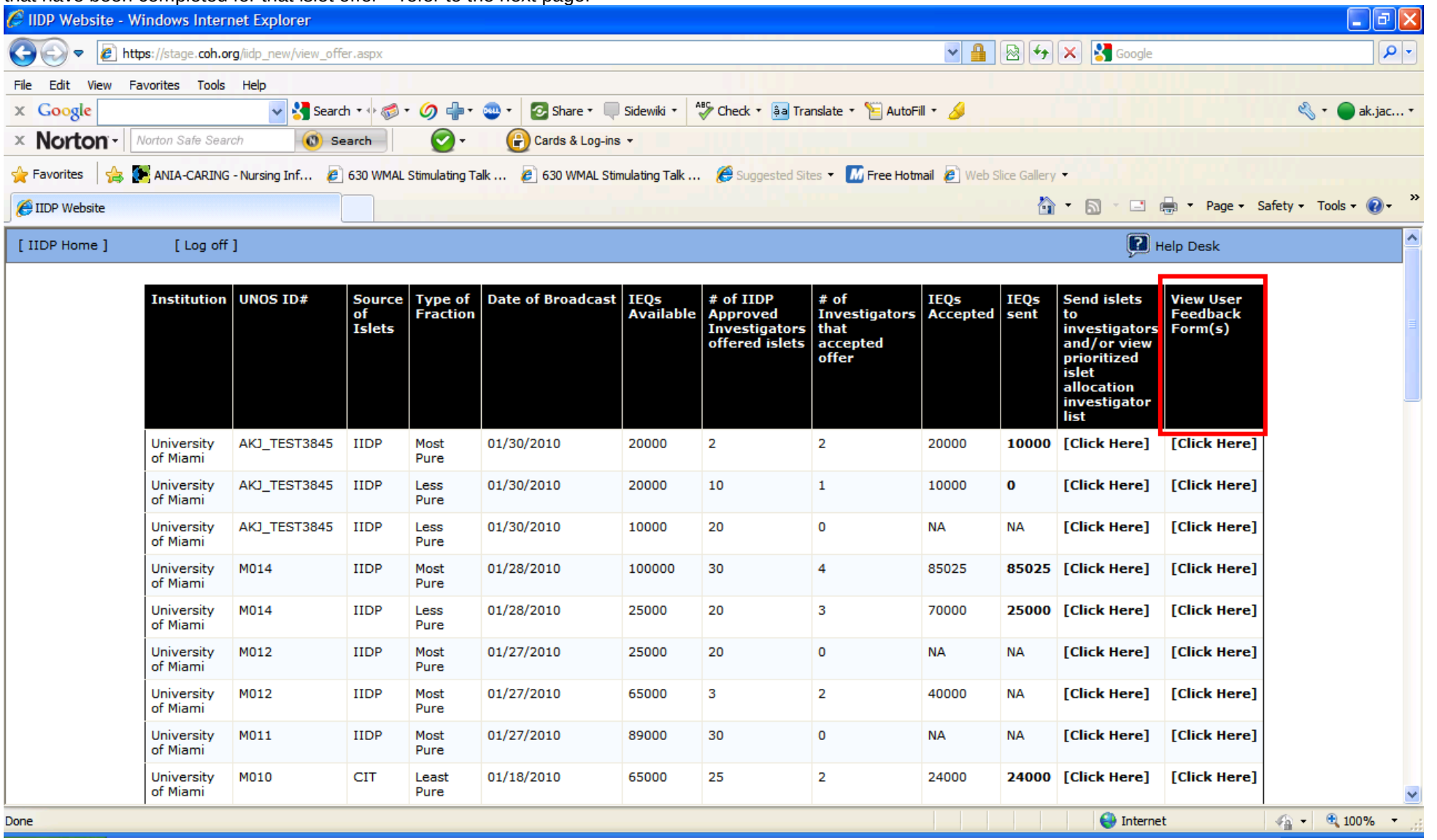


3.0 View Completed User Feedback Form (UFF)

Main Page – To view completed user feedback form(s), click on **[View Islet Offer]** under **[Records for All Isolations]** - refer to the next page.

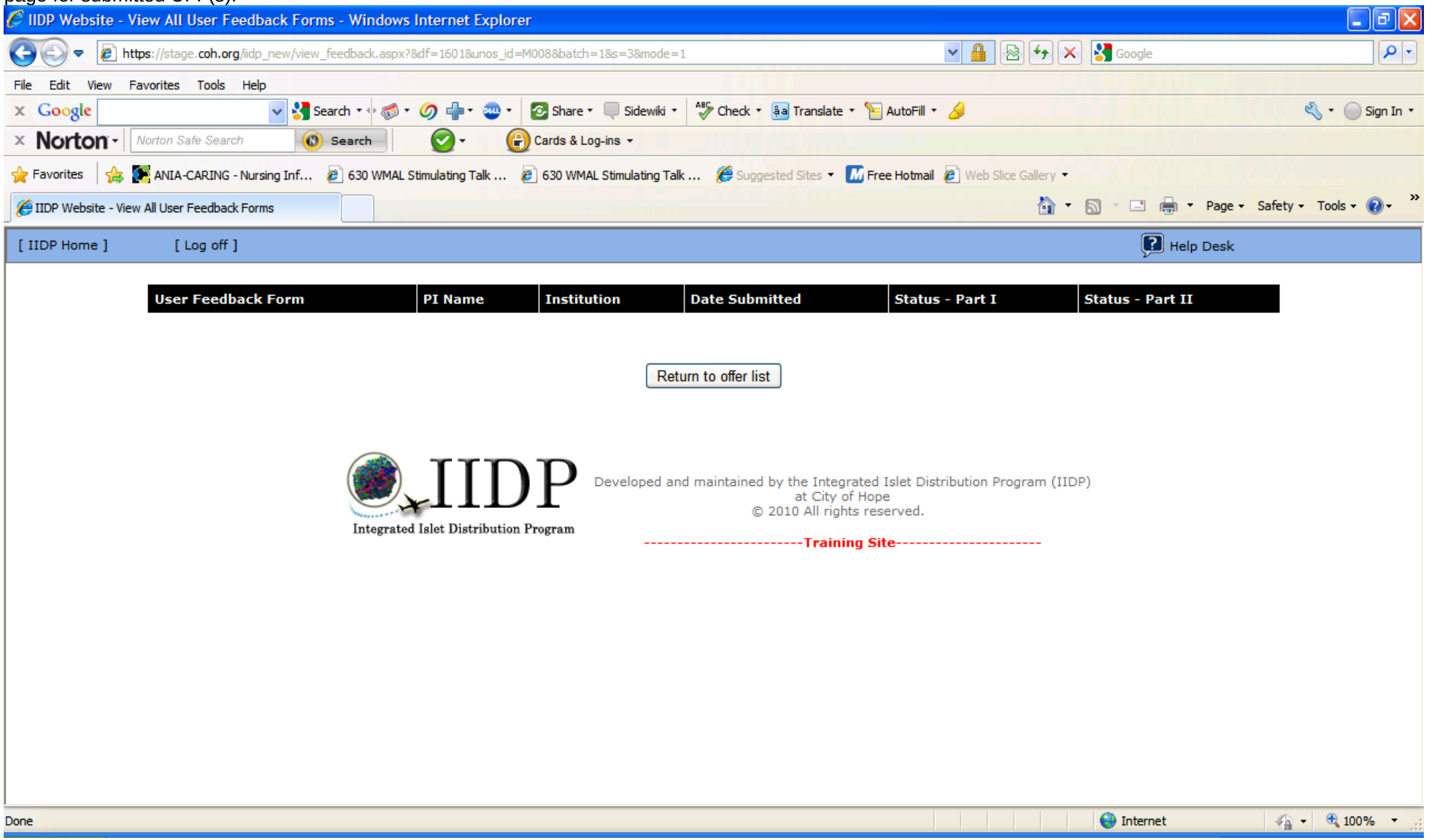


Islet Offer screen - Click on **[Click Here]** under the **[View User Feedback Form(s)]** column of the designated islet offer to view the completed user feedback form(s) that have been completed for that islet offer – refer to the next page.

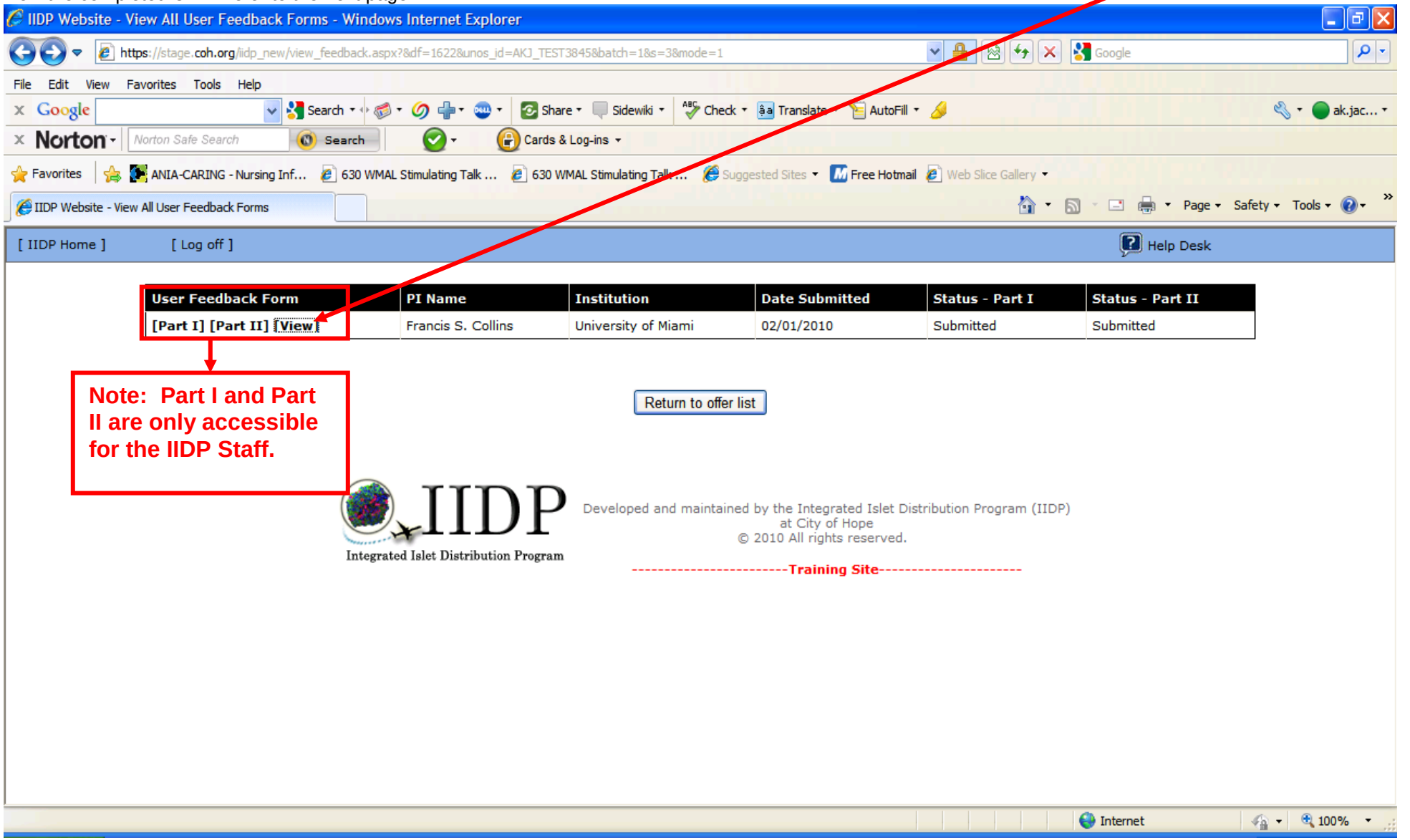


Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	View User Feedback Form(s)
University of Miami	AKJ_TEST3845	IIDP	Most Pure	01/30/2010	20000	2	2	20000	**10000**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	20000	10	1	10000	**0**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	10000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Most Pure	01/28/2010	100000	30	4	85025	**85025**	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Less Pure	01/28/2010	25000	20	3	70000	**25000**	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	25000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	65000	3	2	40000	NA	**[Click Here]**	**[Click Here]**
University of Miami	M011	IIDP	Most Pure	01/27/2010	89000	30	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M010	CIT	Least Pure	01/18/2010	65000	25	2	24000	**24000**	**[Click Here]**	**[Click Here]**

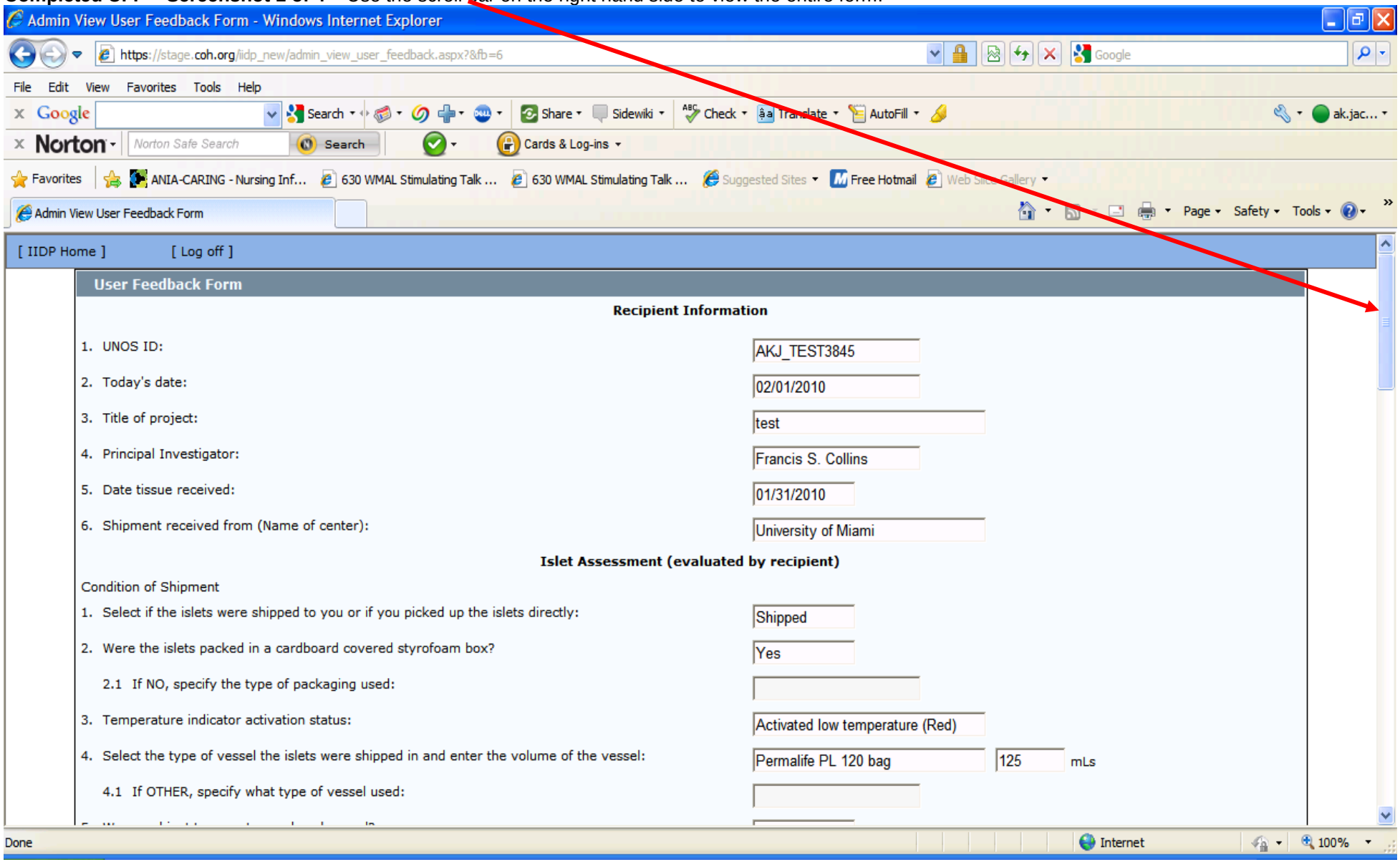
View User Feedback Form screen – If no User Feedback Form(s) (UFF(s)) has/have been submitted for an offer, this is what will be displayed. Refer to the next page for submitted UFF(s).



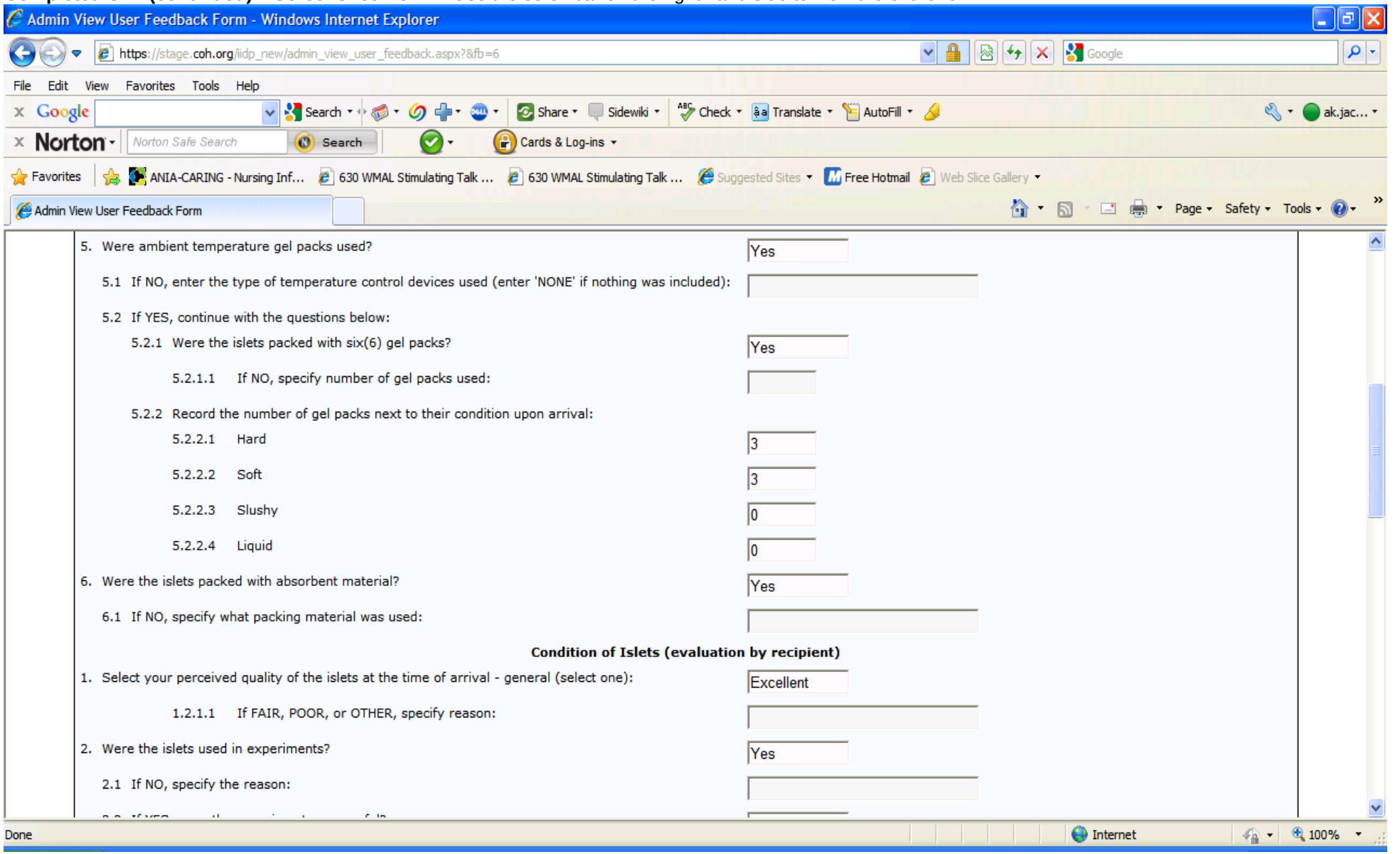
View User Feedback Form screen - User feedback form(s) (UFF) that have been completed for the designated islet offer – Click on **[View]** of the designated UFF to view the completed UFF - refer to the next page.



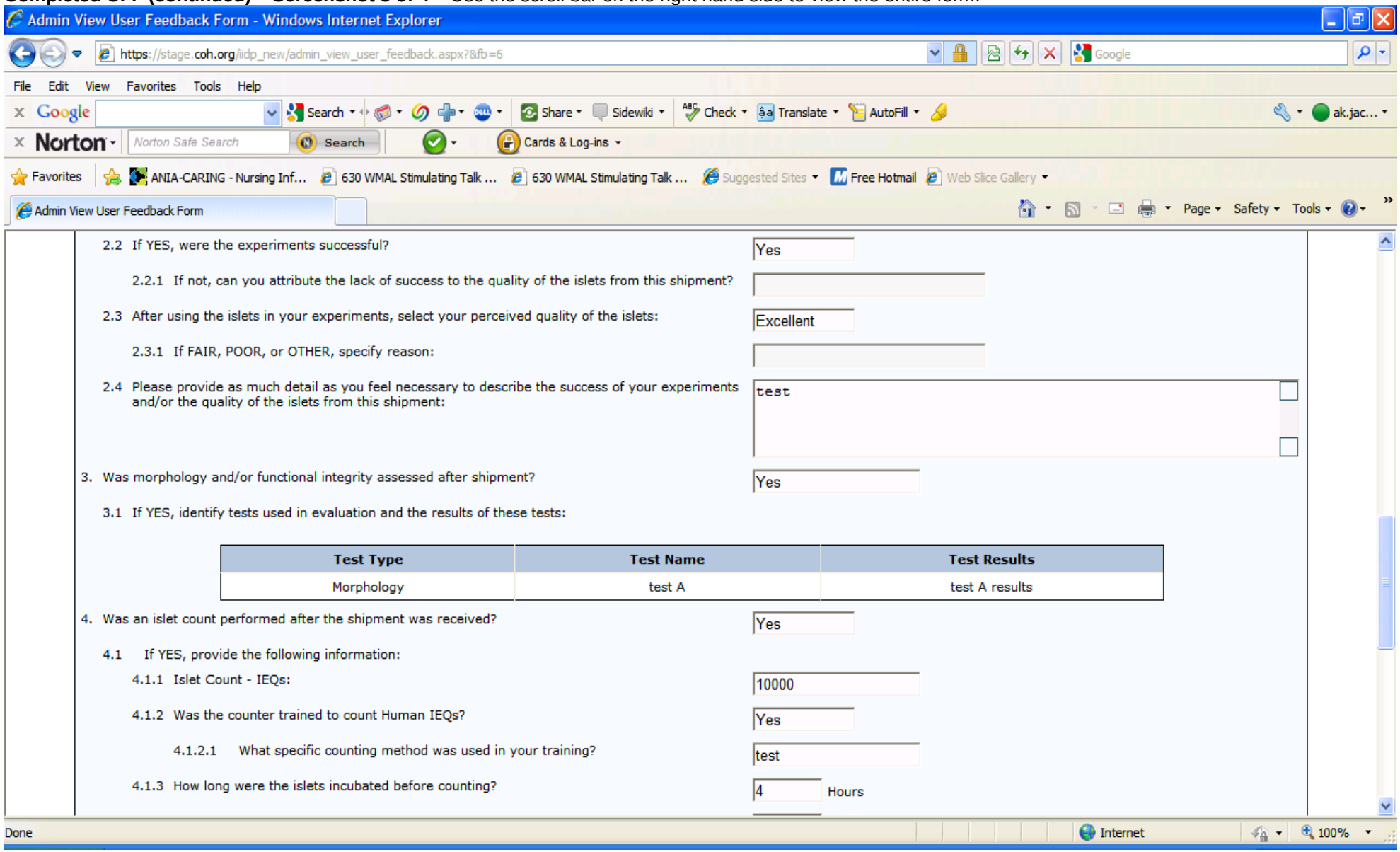
Completed UFF – Screenshot 1 of 4 – Use the scroll bar on the right hand side to view the entire form.



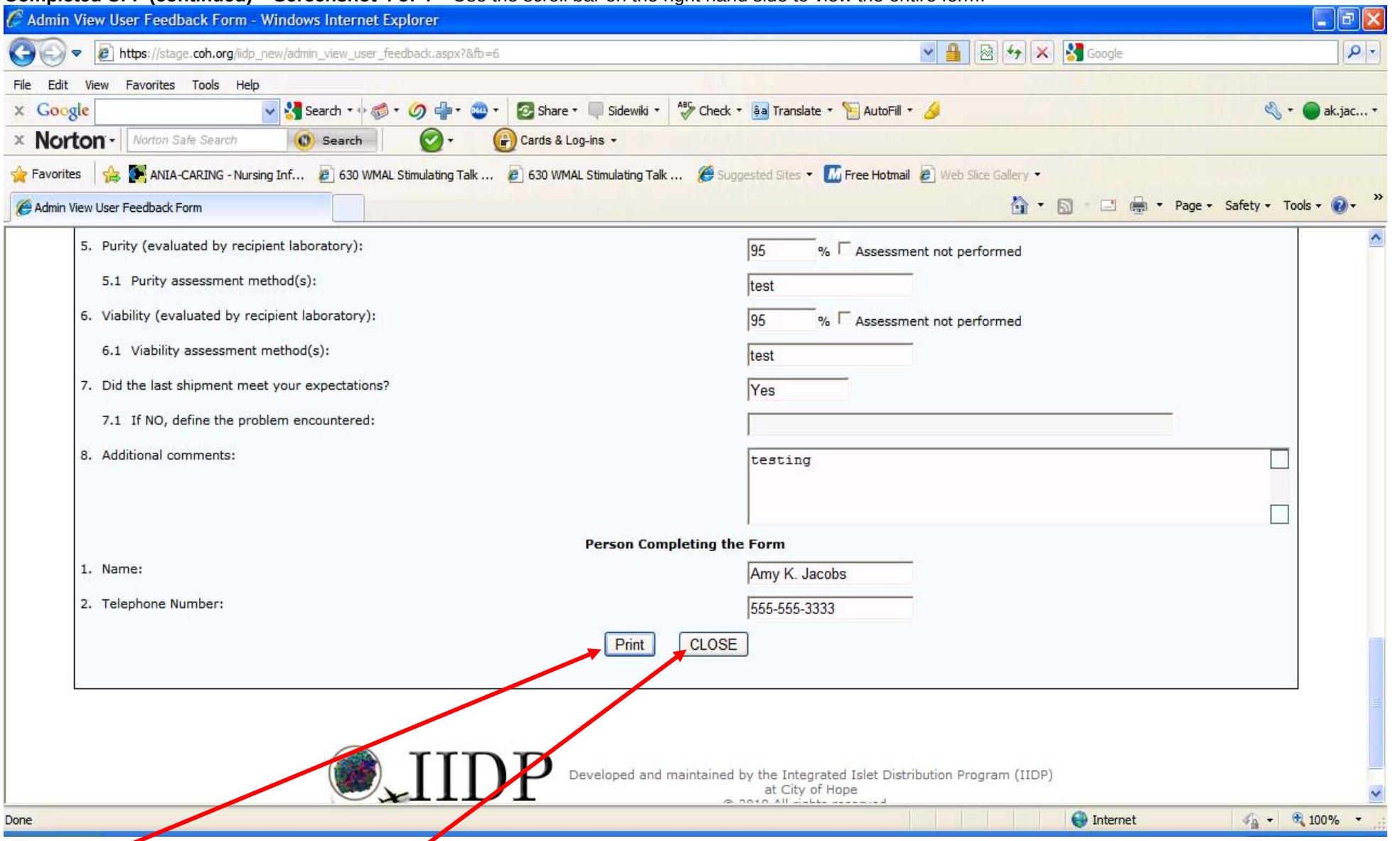
Completed UFF (continued) – Screenshot 2 of 4 – Use the scroll bar on the right hand side to view the entire form.



Completed UFF (continued) – Screenshot 3 of 4 – Use the scroll bar on the right hand side to view the entire form.

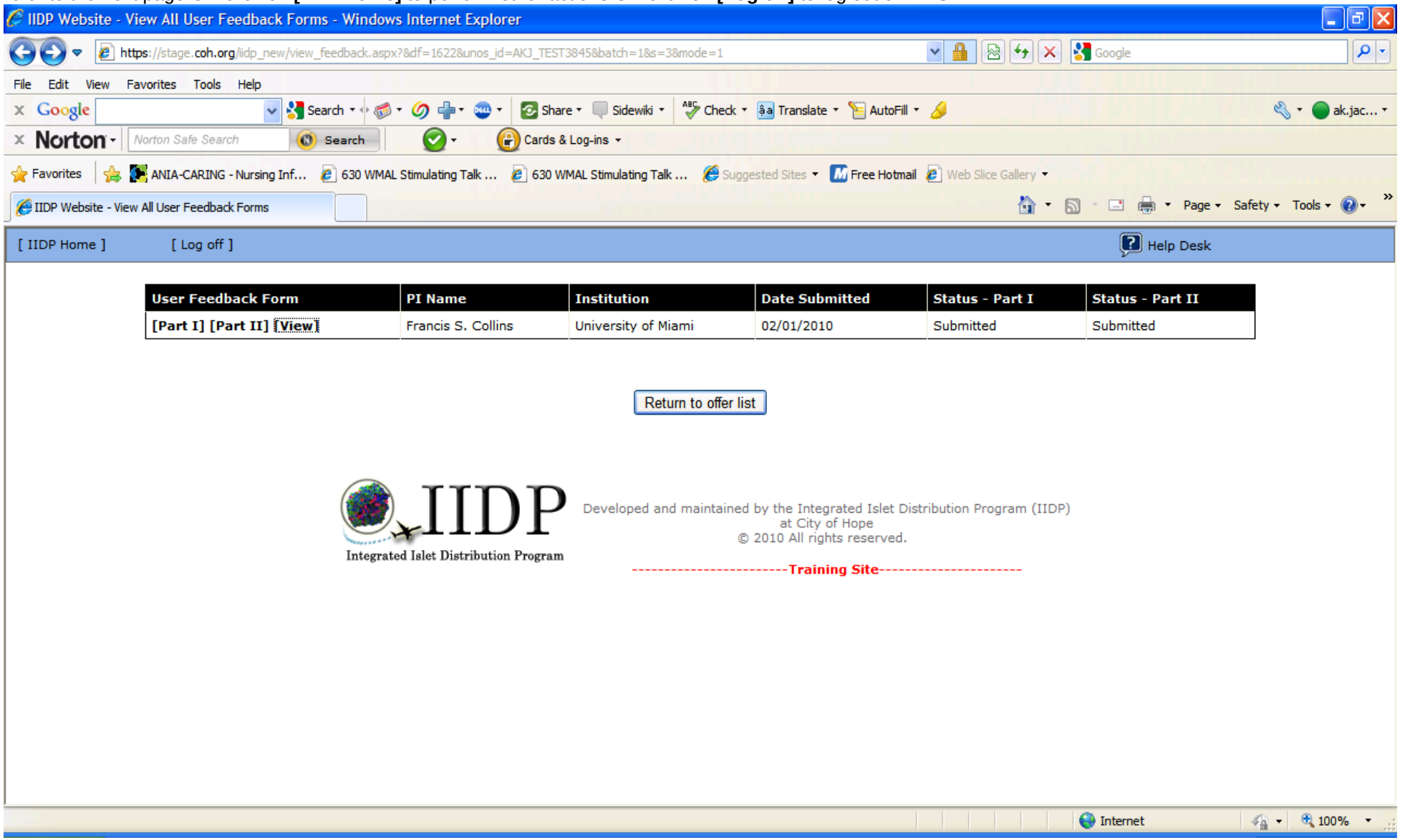


Completed UFF (continued) – Screenshot 4 of 4 – Use the scroll bar on the right hand side to view the entire form.

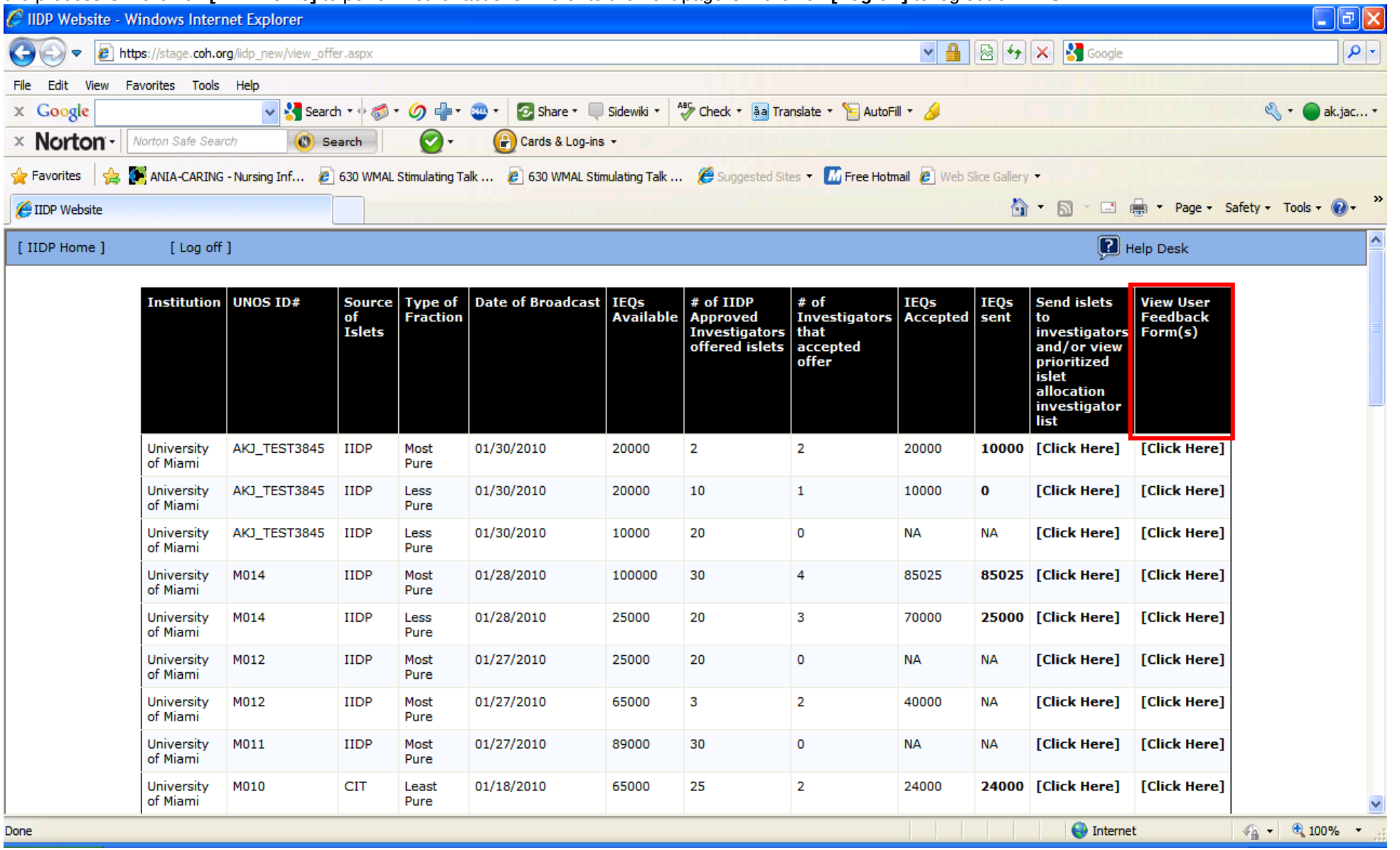


Click on **[Print]** to print the UFF OR click on **[Close]** to close the UFF and return to the **View User Feedback Form screen** – refer to the next page.

View User Feedback Form screen – Click on **[View]** to view another completed UFF OR click on **[Return to offer list]** to return to the **View Islet Offer screen** – refer to the next page OR click on **[IIDP Home]** to perform other actions OR click on **[Log off]** to log out of IDES.



Islet Offer screen - Click on **[Click Here]** under the **[View User Feedback Form(s)]** column of the designated islet offer to view another completed UFF and repeat the process OR click on **[IIDP Home]** to perform other actions – refer to the next page OR click on **[Log off]** to log out of IDES.



Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	View User Feedback Form(s)
University of Miami	AKJ_TEST3845	IIDP	Most Pure	01/30/2010	20000	2	2	20000	**10000**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	20000	10	1	10000	**0**	**[Click Here]**	**[Click Here]**
University of Miami	AKJ_TEST3845	IIDP	Less Pure	01/30/2010	10000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Most Pure	01/28/2010	100000	30	4	85025	**85025**	**[Click Here]**	**[Click Here]**
University of Miami	M014	IIDP	Less Pure	01/28/2010	25000	20	3	70000	**25000**	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	25000	20	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M012	IIDP	Most Pure	01/27/2010	65000	3	2	40000	NA	**[Click Here]**	**[Click Here]**
University of Miami	M011	IIDP	Most Pure	01/27/2010	89000	30	0	NA	NA	**[Click Here]**	**[Click Here]**
University of Miami	M010	CIT	Least Pure	01/18/2010	65000	25	2	24000	**24000**	**[Click Here]**	**[Click Here]**

Main Page – Click on another action as applicable OR click on **[Log off]** to log out of IDES.

Electronic User Feedback Form
User Guide for Investigator

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1.0 General Guidelines

1.1. Navigation

The Principal Investigator (PI) section of the Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Islet Offer Screen (e.g. access the User Feedback Form (UFF)). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for completing each section of Part I and Part II of the User Feedback Form (UFF) are presented in the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the User Feedback Form (UFF) data entry screens are designed to be a 'single page' in which the data for each section of the User Feedback Form (UFF) are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the User Feedback Form (UFF) to capture the data.

1.2.2.1 Text Boxes

- Data must be typed in
- Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen – e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

(mm/dd/yy)

The system will automatically enter the forward slashes **(/)** as you enter the date.

1.3.1.2 Time Field Formats

(hh:mm)

The system will automatically enter the colon **(:)** as you enter the time.

1.3.1.3 Date Field Ranges

06/04/2010 (mm/dd/yy)

The system will display a message that the date is out of range and that the latest date that may be entered is the current date.

1.3.1.4 Numeric Field Formats

Percent of Trapped Islets (xxx.xxx)

This is one example of a numeric field format within the Batch Record Data Form.

1.3.1.5 Numeric Field Ranges

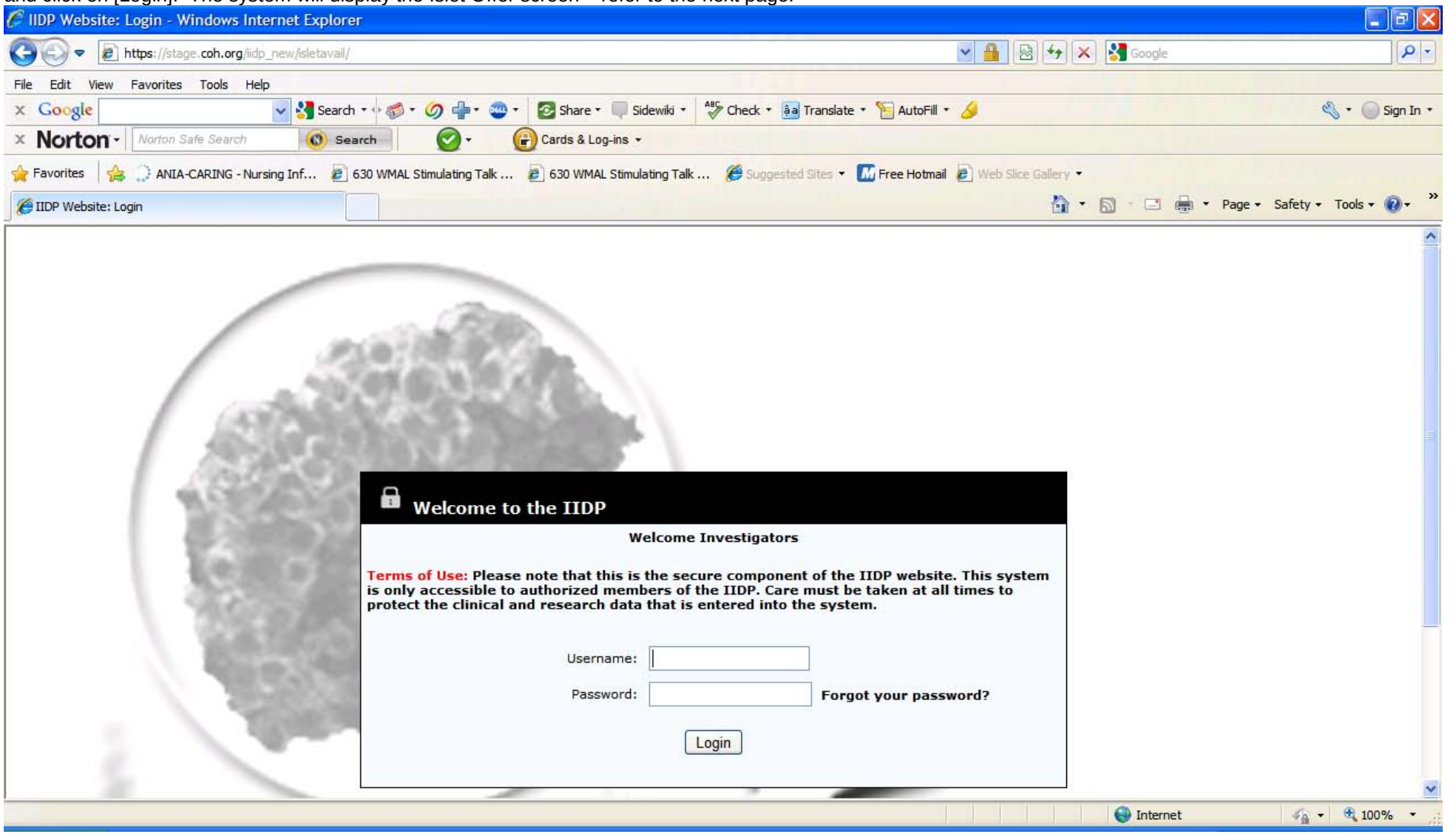
Acceptable Numeric Value → Percent of Trapped Islets 75.34 % (xxx.xxx)

Numeric Value Out of Range → Percent of Trapped Islets 110.93 % (xxx.xxx)

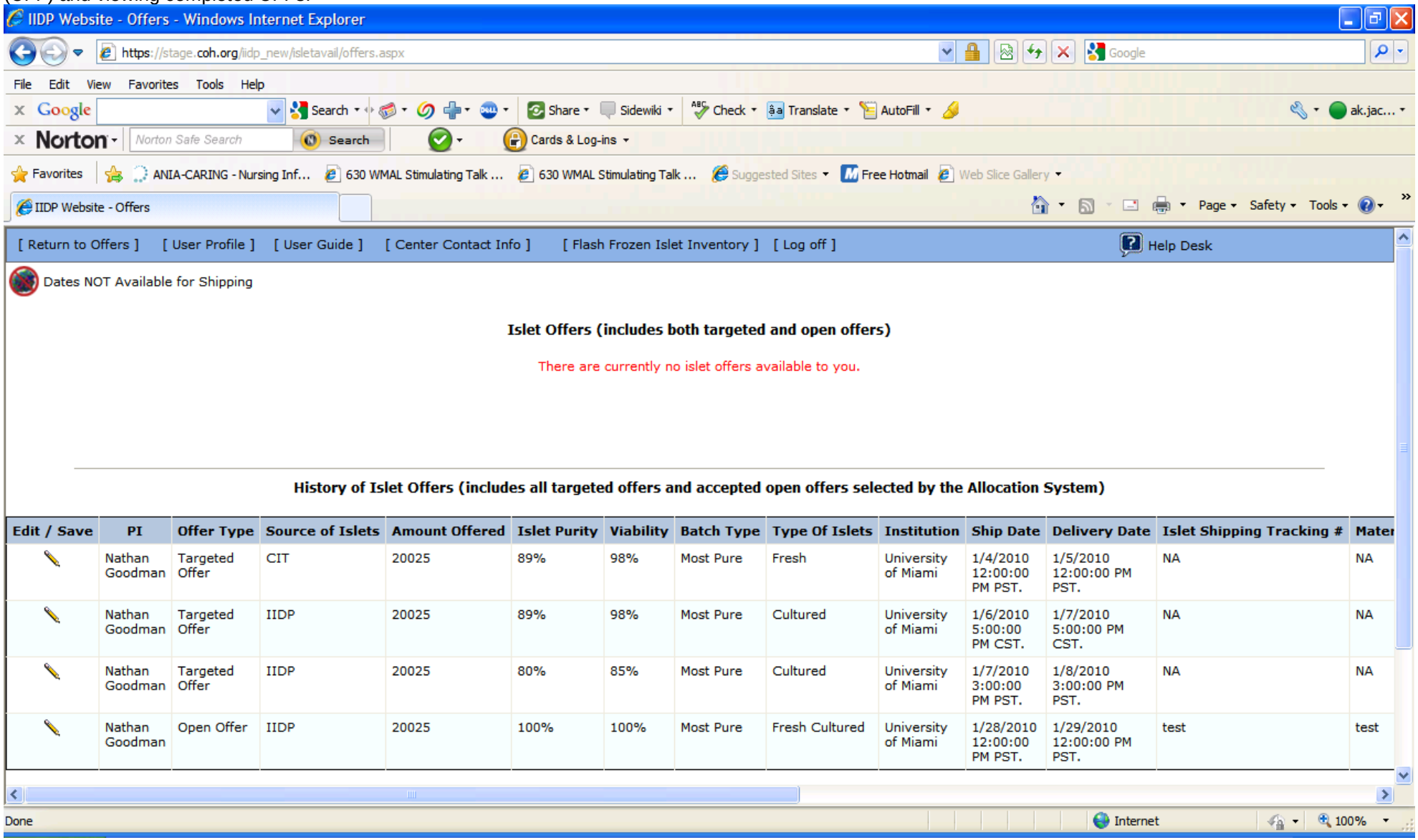
The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

2.0 Login to the Islet Data Entry System (IDES)

This is the **Login Screen** to access the Islet Data Entry System (IDES). IIDP will issue each user a Username and Password. Enter your username and password and click on [Login]. The system will display the Islet Offer screen – refer to the next page.



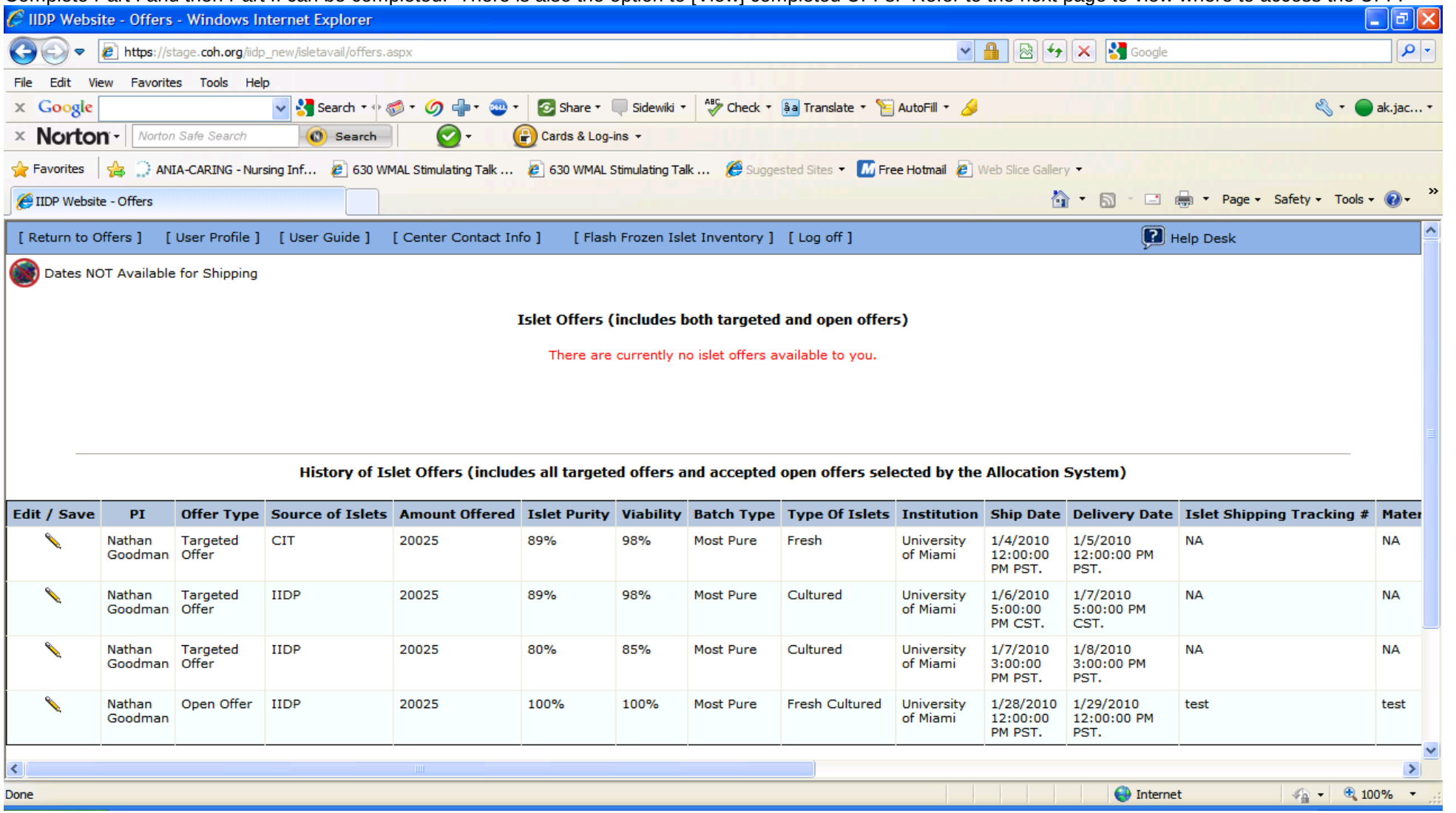
Islet Offers screen – The system displays the Islet Offers screen. Refer to the next sections regarding completing Part I and Part II of the User Feedback Form (UFF) and viewing completed UFFs.



Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mater
	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
	Nathan Goodman	Open Offer	IIDP	20025	100%	100%	Most Pure	Fresh Cultured	University of Miami	1/28/2010 12:00:00 PM PST.	1/29/2010 12:00:00 PM PST.	test	test

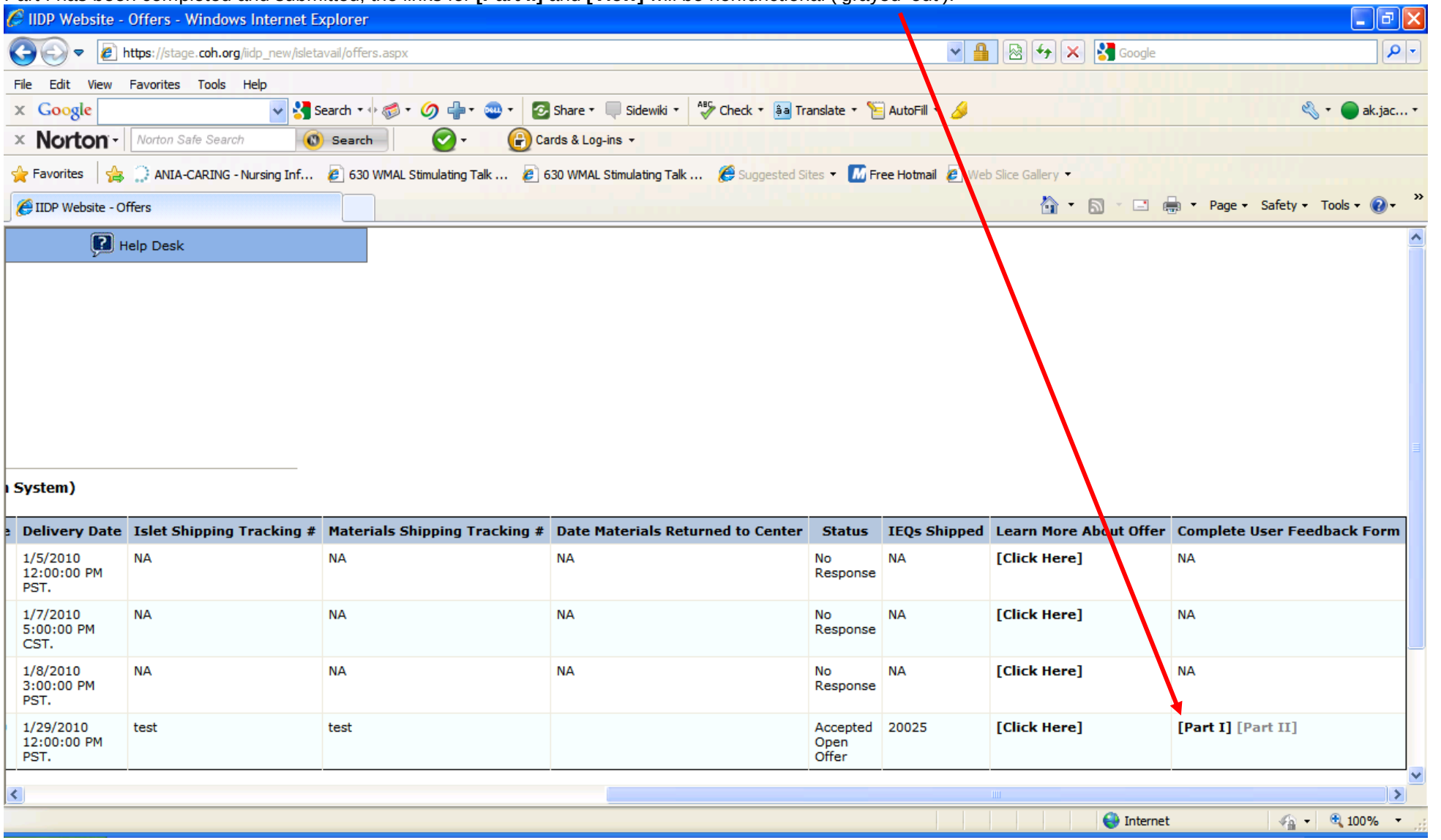
3.0 Complete Part I of the User Feedback Form (UFF)

Islet Offers screen – Under the History of Islet Offers, select the designated Islet Offer to complete the User Feedback Form (UFF). There are two parts of the UFF. Complete Part I and then Part II can be completed. There is also the option to [View] completed UFFs. Refer to the next page to view where to access the UFF.



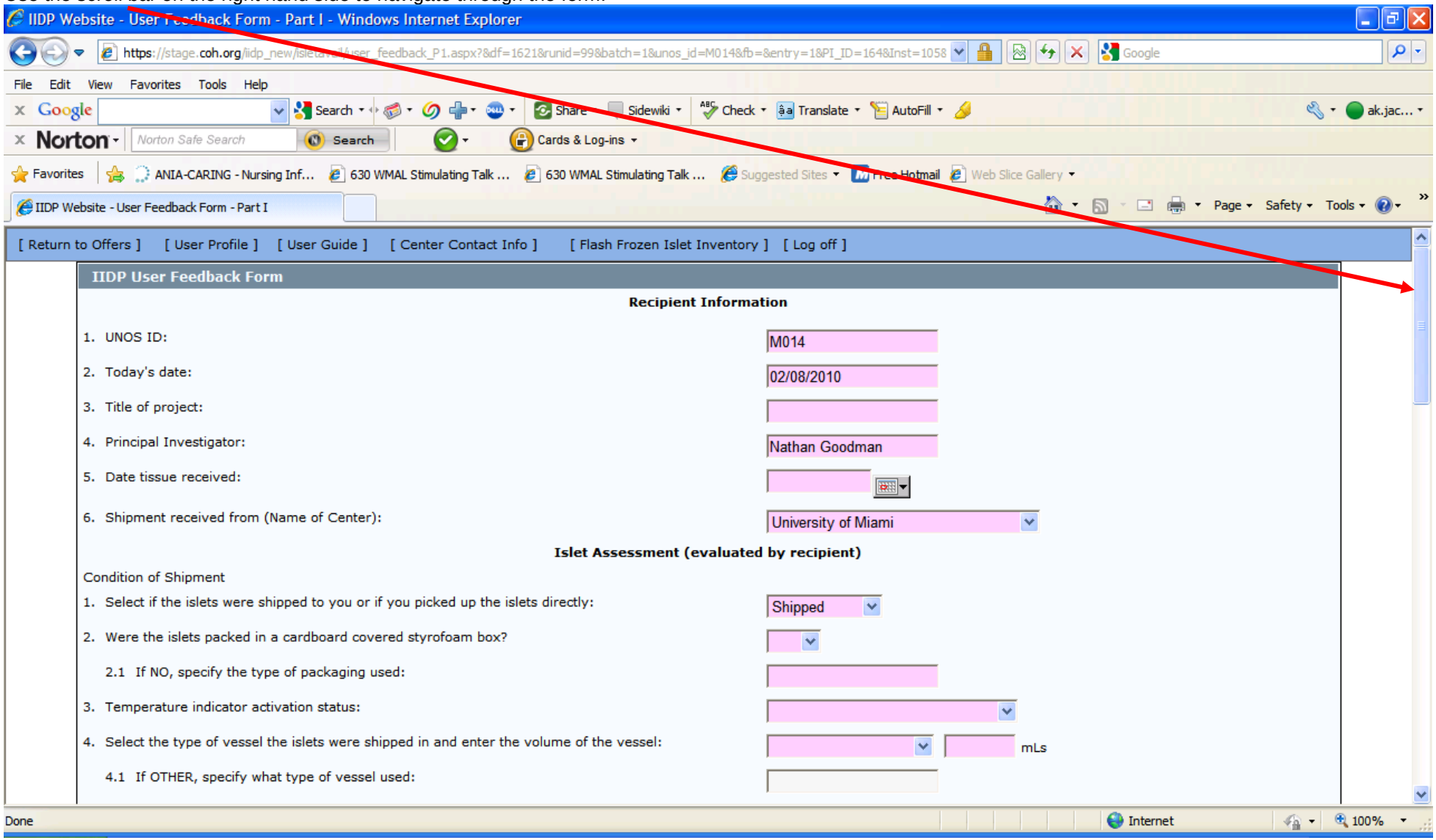
Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mater
	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
	Nathan Goodman	Open Offer	IIDP	20025	100%	100%	Most Pure	Fresh Cultured	University of Miami	1/28/2010 12:00:00 PM PST.	1/29/2010 12:00:00 PM PST.	test	test

Islet Offer screen (continued) – Under the column **[Complete User Feedback Form],** click on **[Part I]** to complete Part I of the UFF – refer to the next page. Until Part I has been completed and submitted, the links for **[Part II]** and **[View]** will be nonfunctional ('grayed' out').

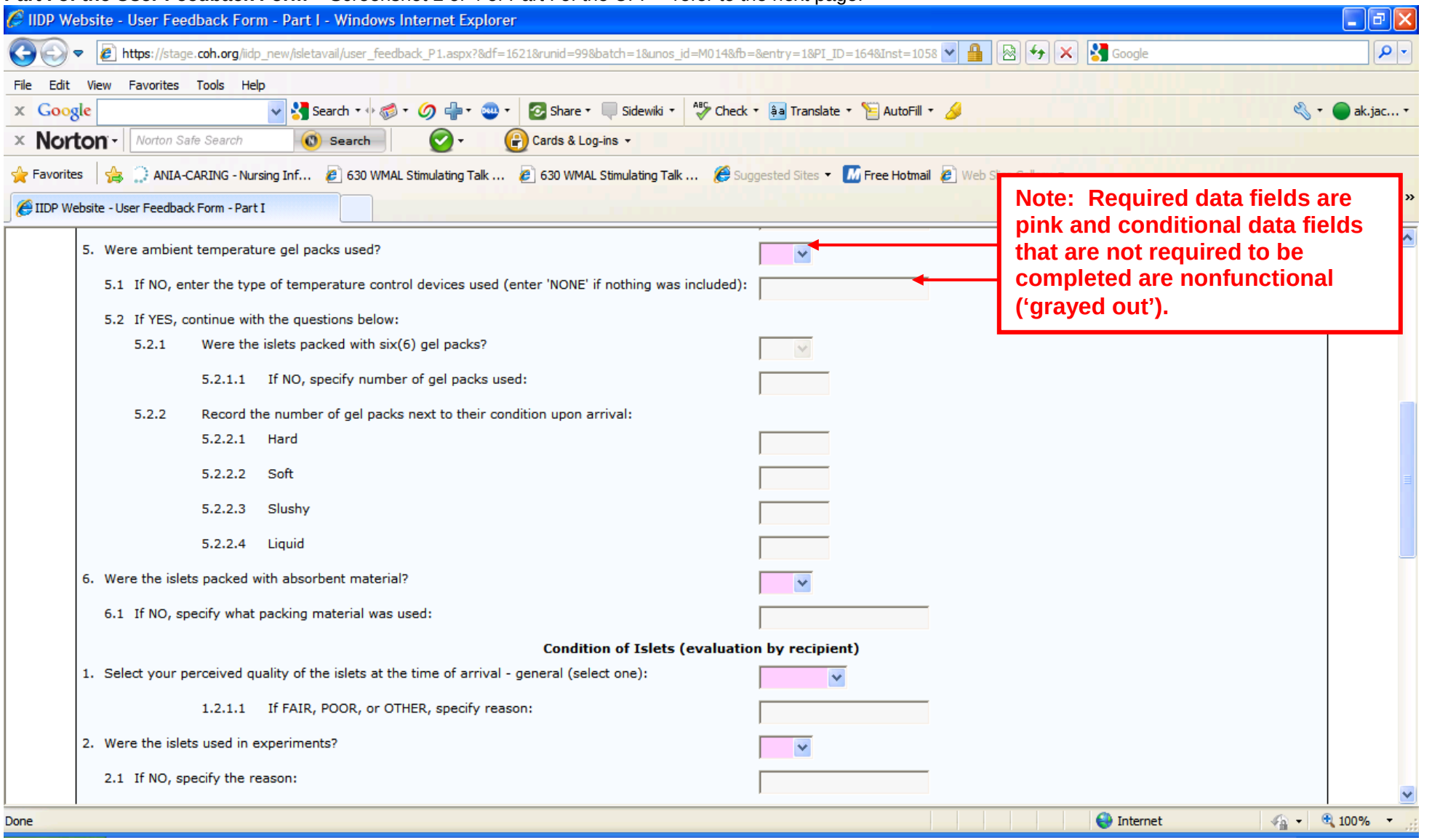


Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	**[Click Here]**	NA
1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response	NA	**[Click Here]**	NA
1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response	NA	**[Click Here]**	NA
1/29/2010 12:00:00 PM PST.	test	test		Accepted Open Offer	20025	**[Click Here]**	**[Part I]** [Part II]

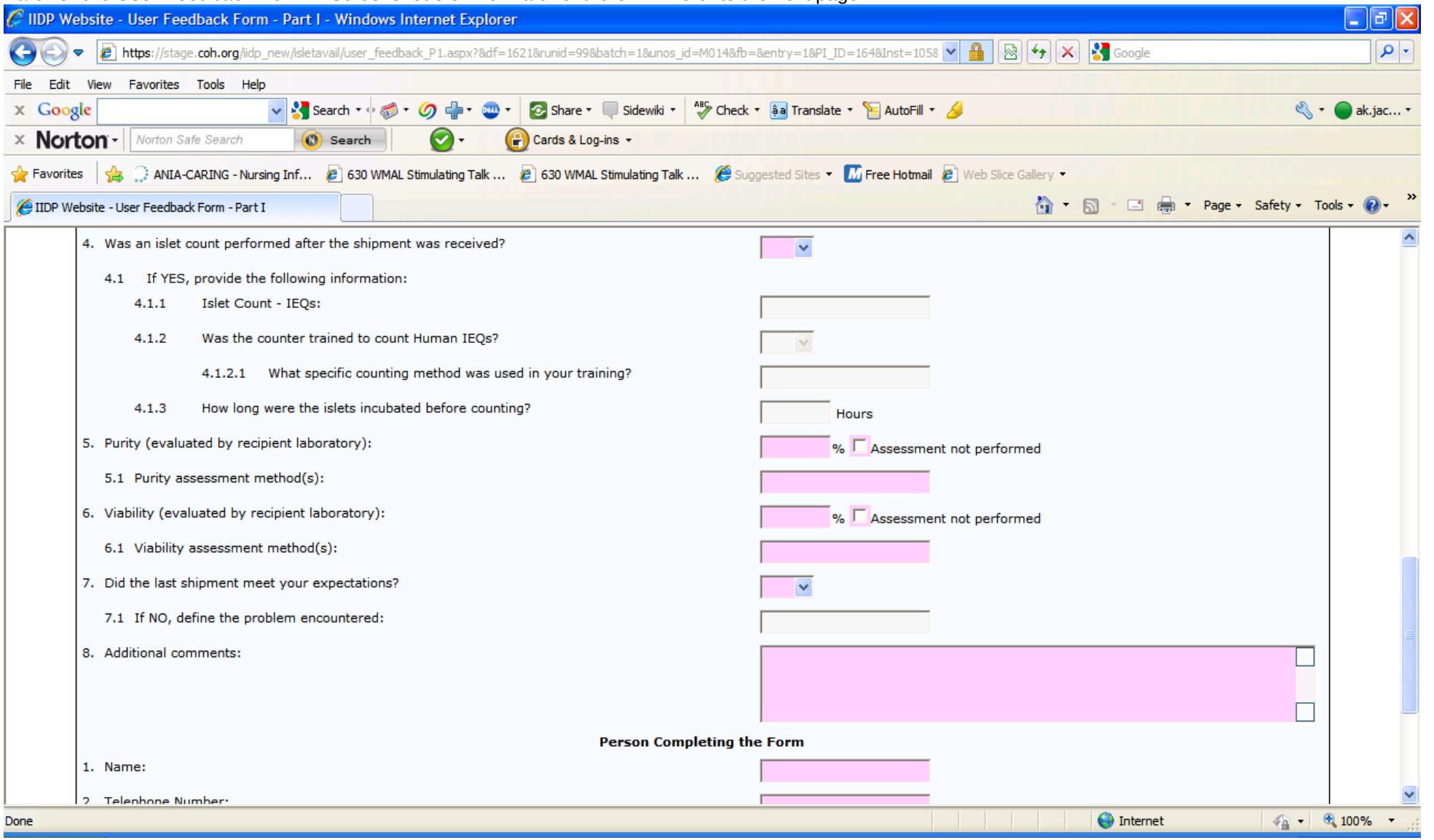
Part I of the User Feedback Form – Screenshot 1 of 4 of Part I of the UFF – Complete the data fields of the form. All data fields are required except for the 'Comments' data field at the end of the form and the conditional fields of 'If NO,……' or 'If YES,…..' Refer to screenshots 2, 3, and 4 on the following pages. Use the scroll bar on the right hand side to navigate through the form.



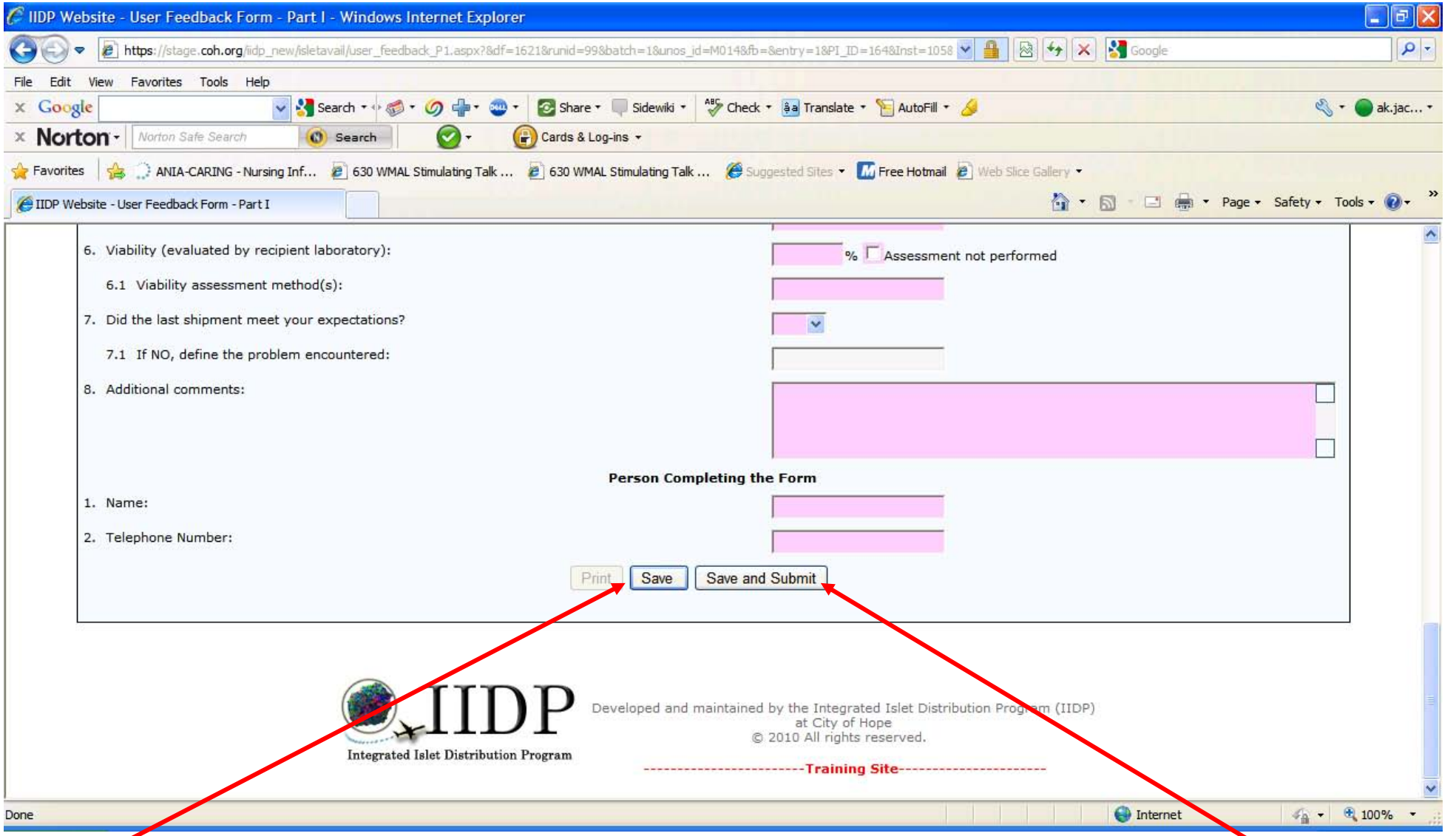
Part I of the User Feedback Form – Screenshot 2 of 4 of Part I of the UFF – refer to the next page.



Part I of the User Feedback Form – Screenshot 3 of 4 of Part I of the UFF – refer to the next page.



Part I of the User Feedback Form – Screenshot 4 of 4 of Part I of the UFF.



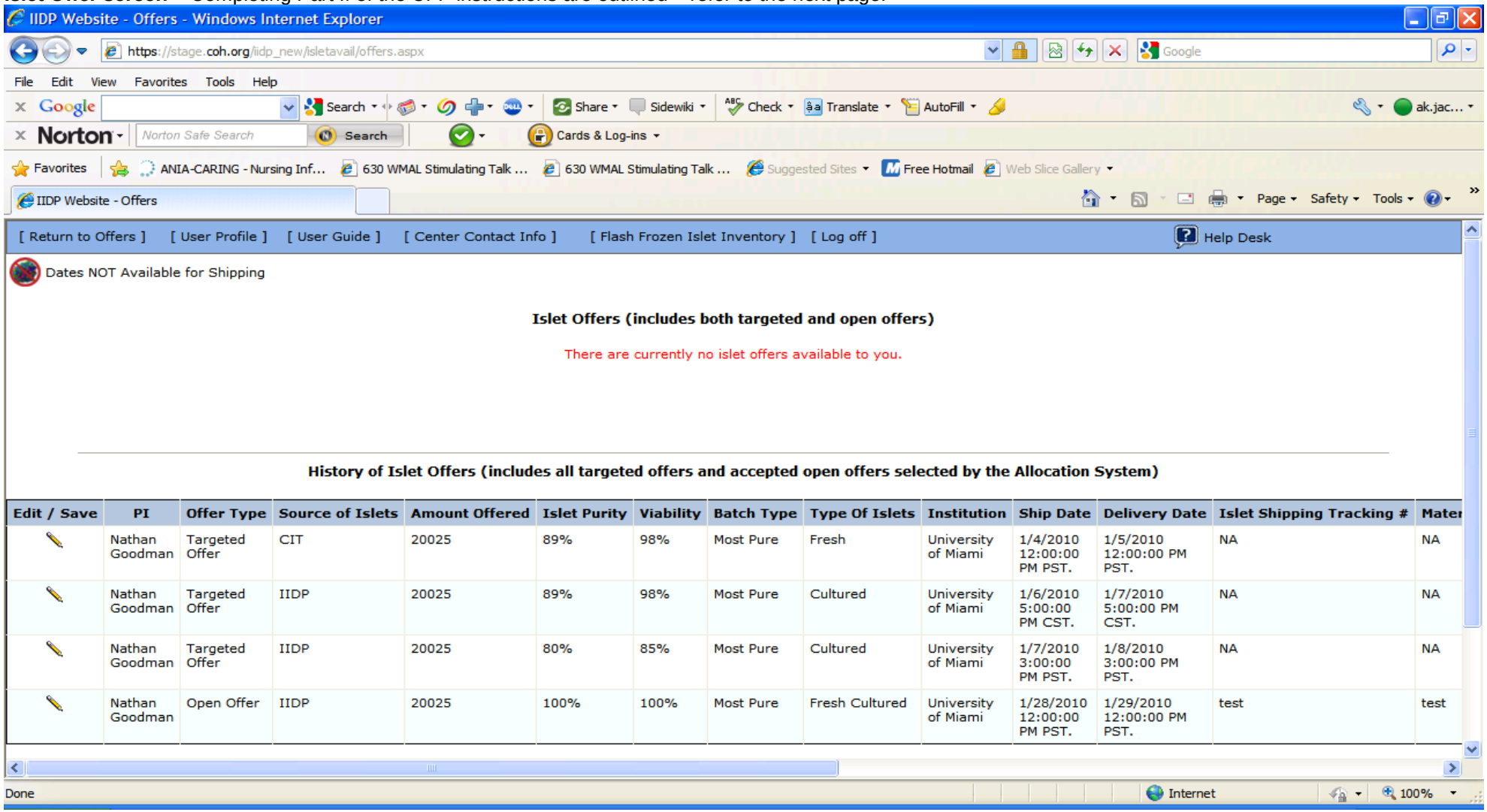
Click on **[Save]** to save Part I of the UFF and complete at a later time - refer to the confirmation message on the next page OR click on **[Save and Submit]** to save and submit the completed Part I of the UFF - refer to the confirmation message on page 14.

Confirmation message - Part I of the UFF has been saved in the system and is incomplete. Click on **[Close]** to return to the **Islet Offers** screen – refer to page 7.

Confirmation message - Part I of the UFF has been saved and submitted in the system. Click on **[Close]** to return to the **[Islet Offers]** screen – refer to page 7.

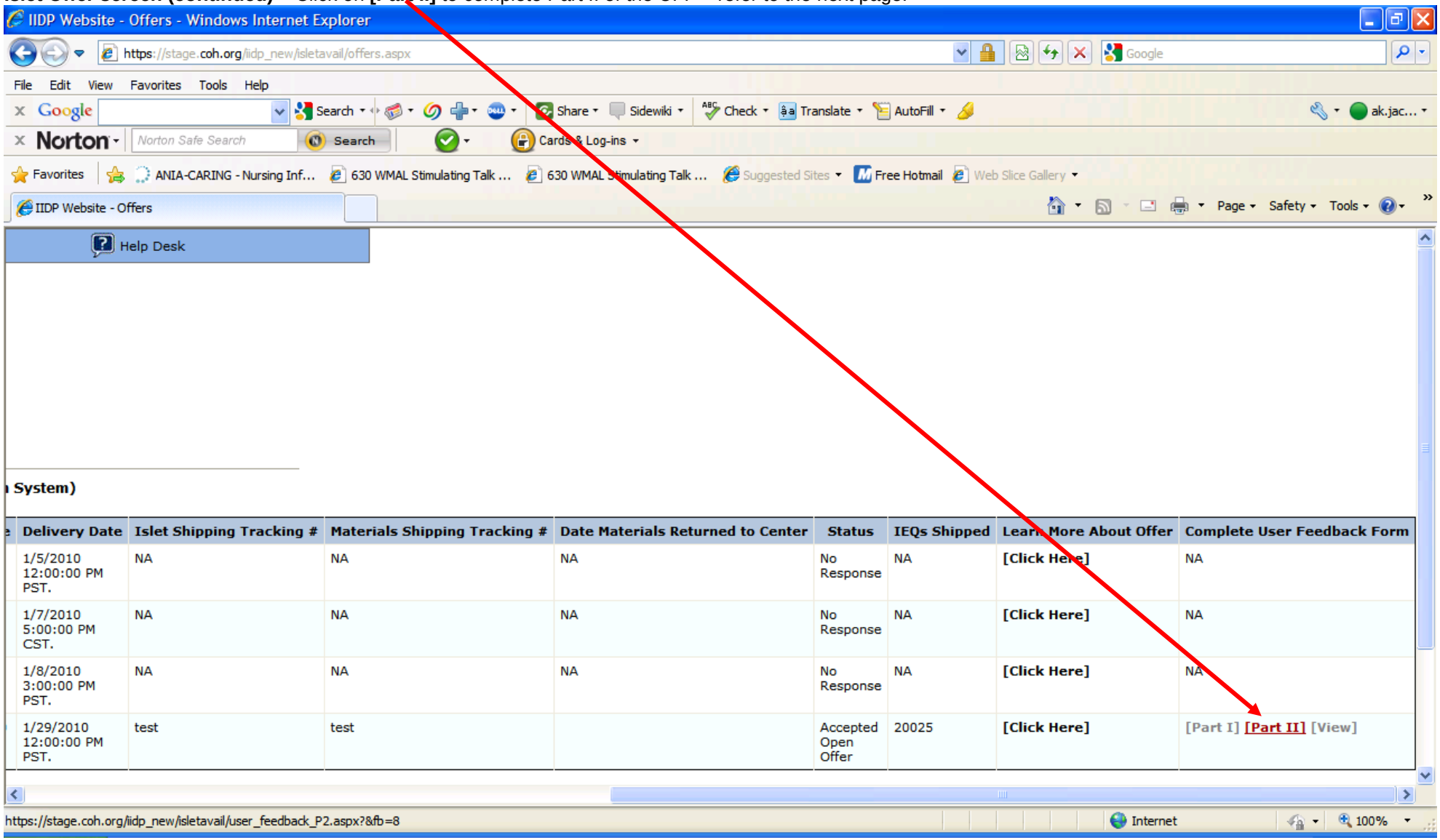
4.0 Complete Part II of the User Feedback Form (UFF)

Islet Offer screen – Completing Part II of the UFF instructions are outlined – refer to the next page.

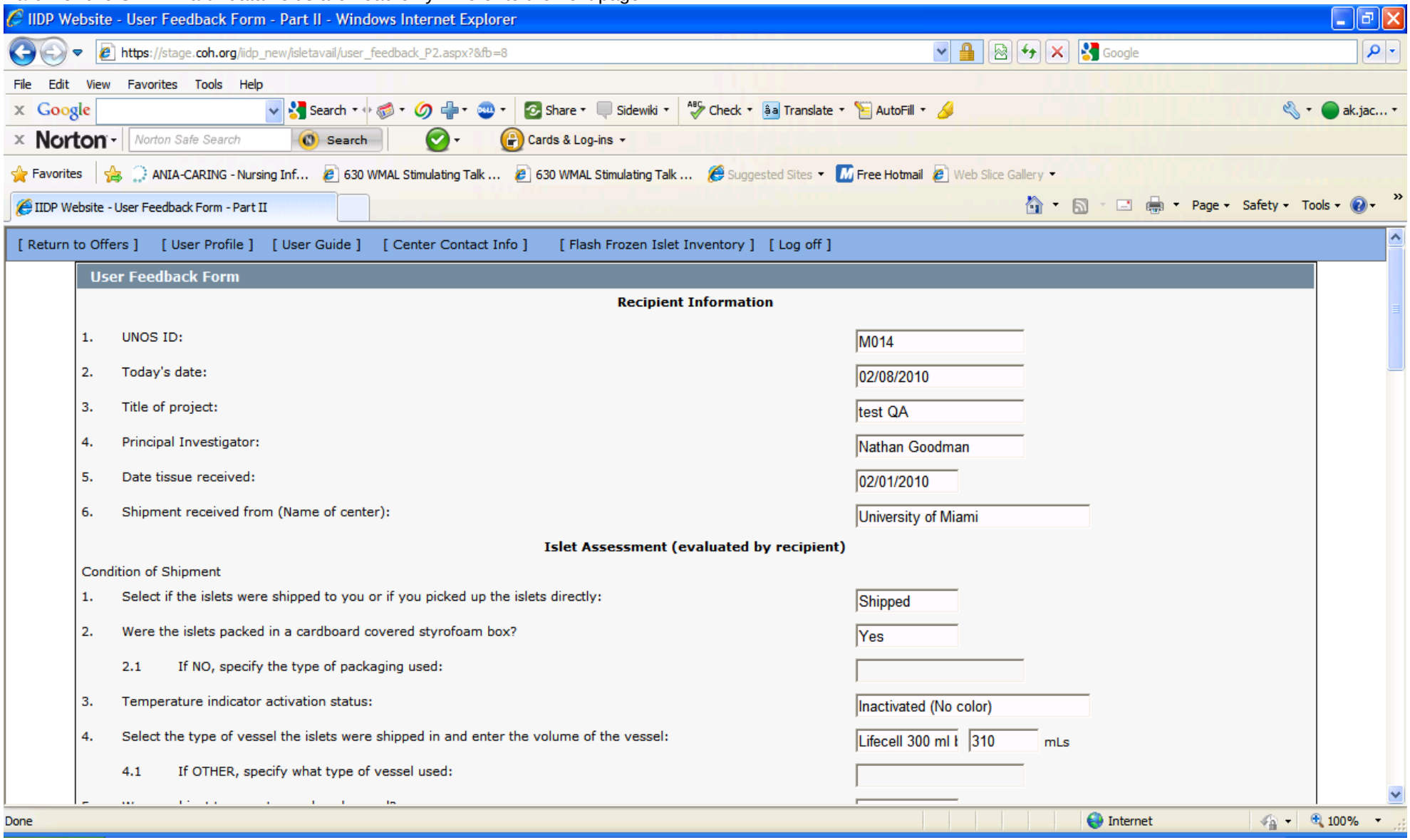


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mater
	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
	Nathan Goodman	Open Offer	IIDP	20025	100%	100%	Most Pure	Fresh Cultured	University of Miami	1/28/2010 12:00:00 PM PST.	1/29/2010 12:00:00 PM PST.	test	test

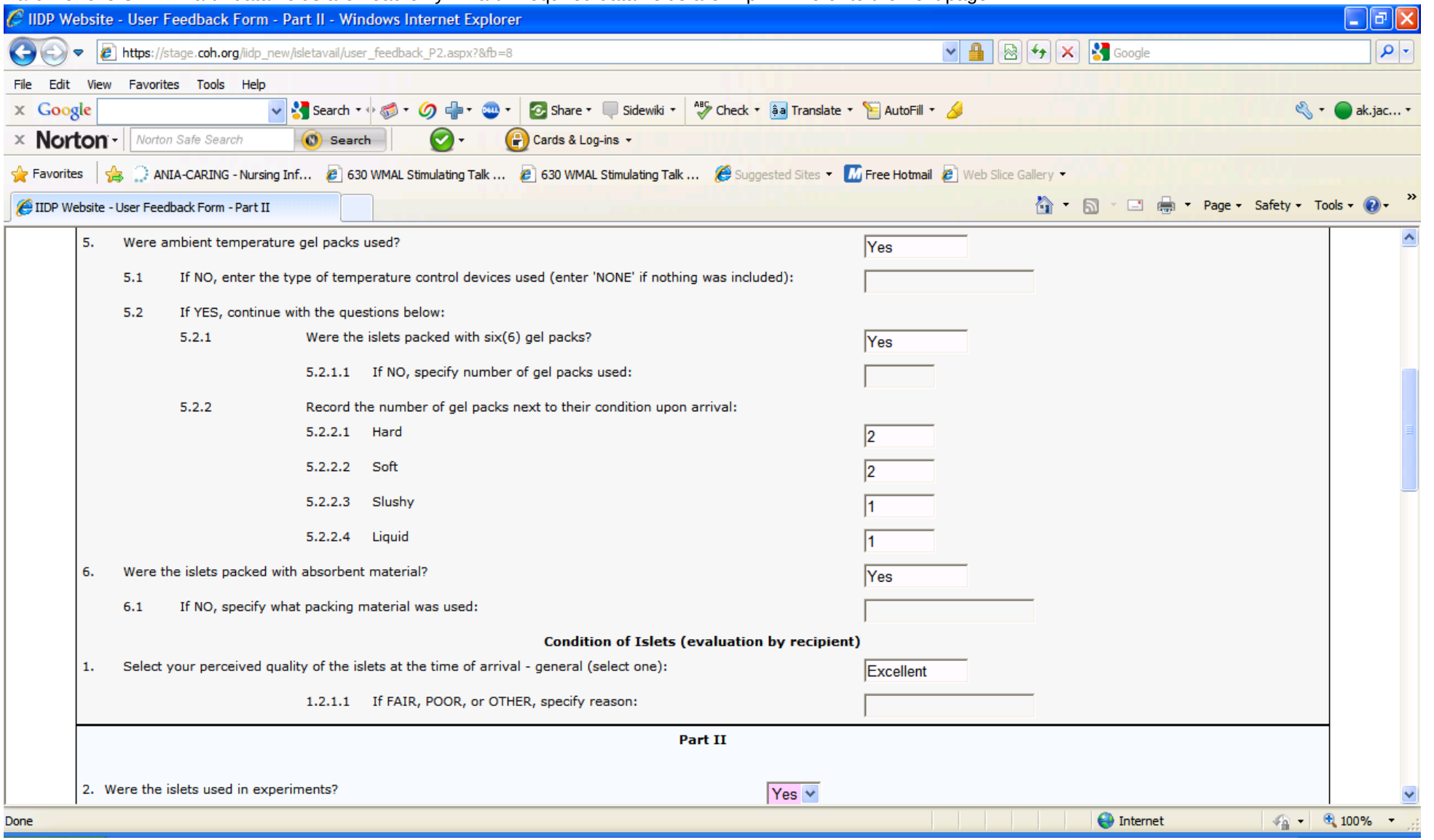
Islet Offer screen (continued) – Click on **[Part II]** to complete Part II of the UFF – refer to the next page.



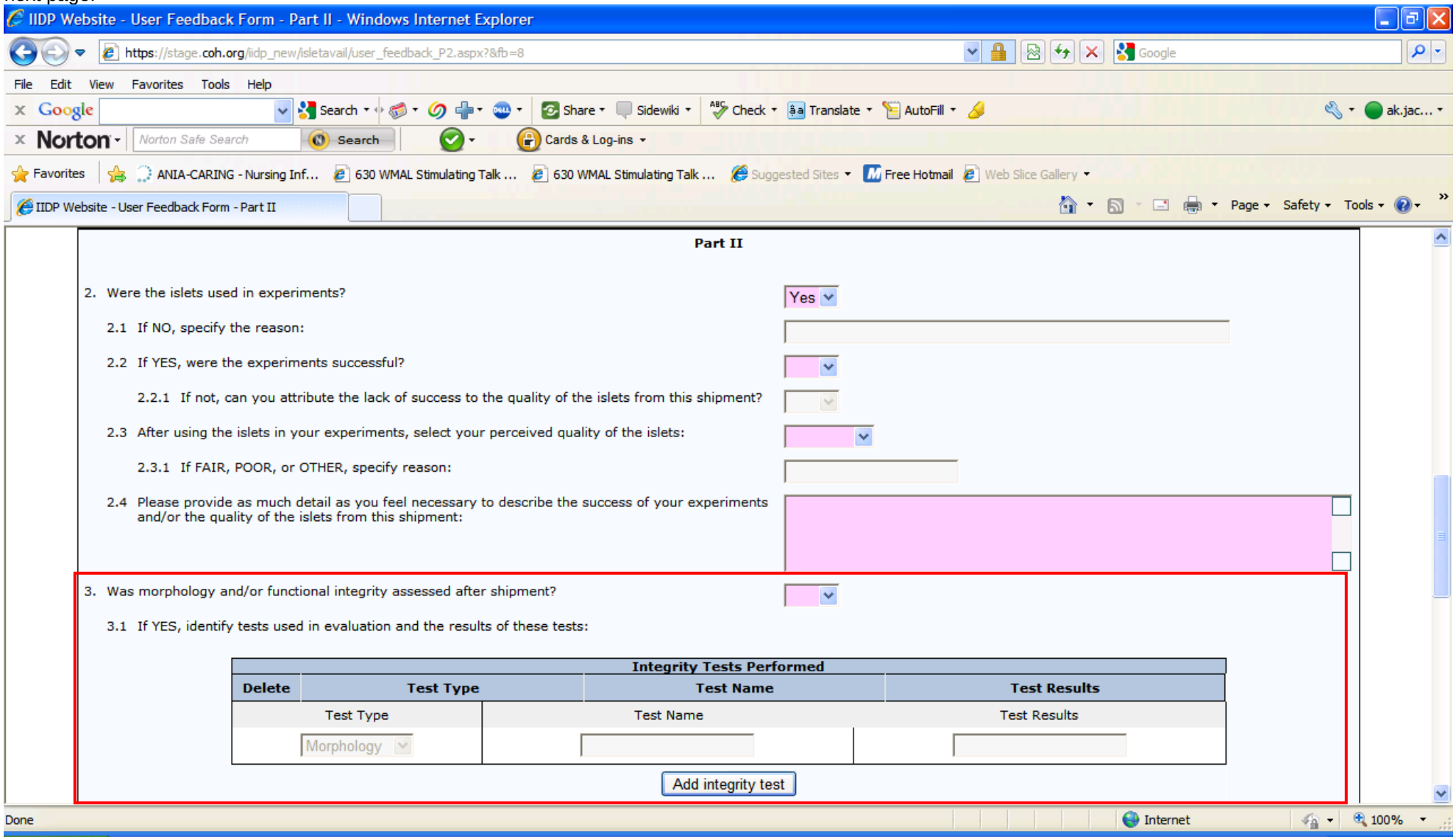
Part II of the UFF – Part I data fields are 'read only' – refer to the next page.



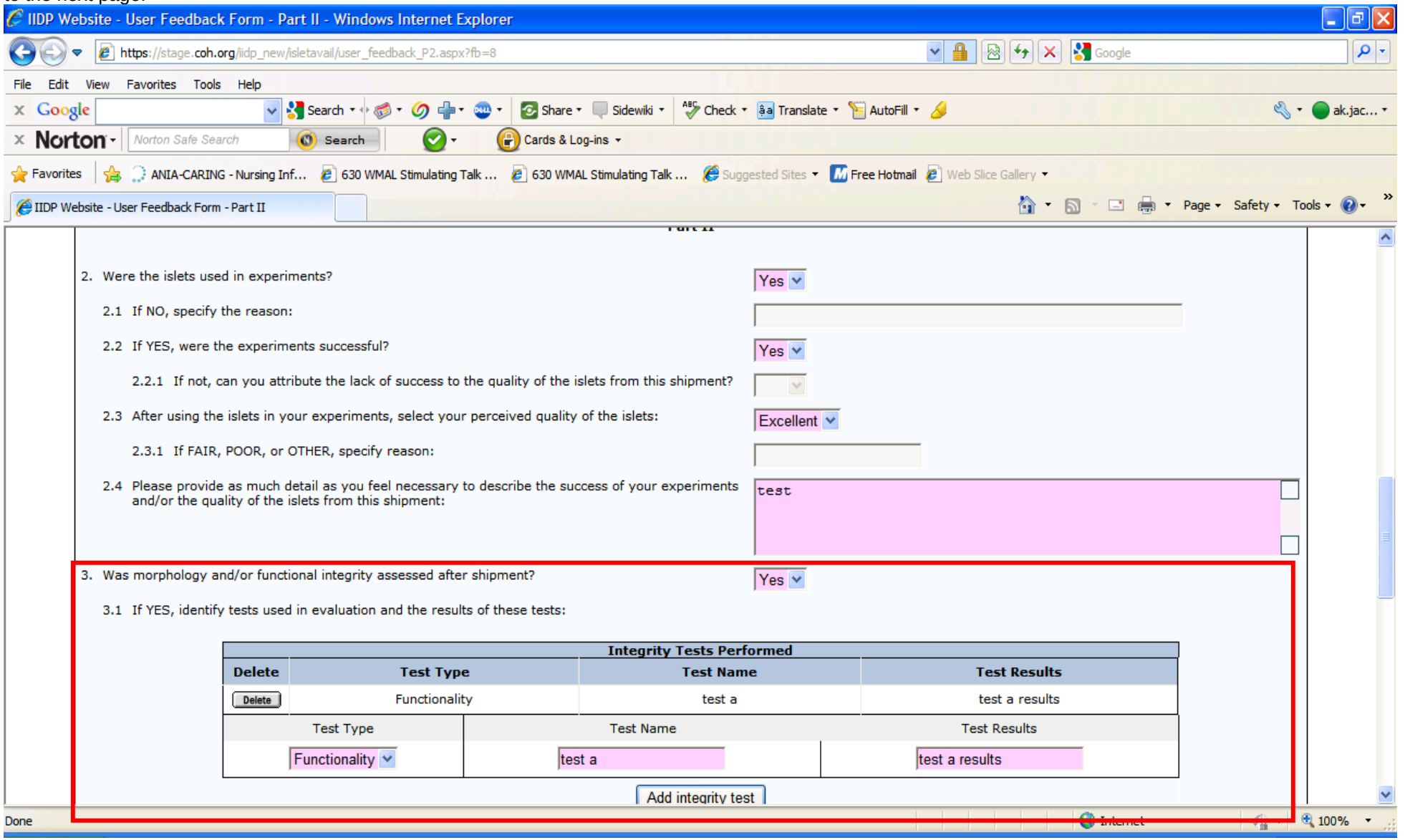
Part II of the UFF – Part I data fields are 'read only'. Part II required data fields are in pink – refer to the next page.



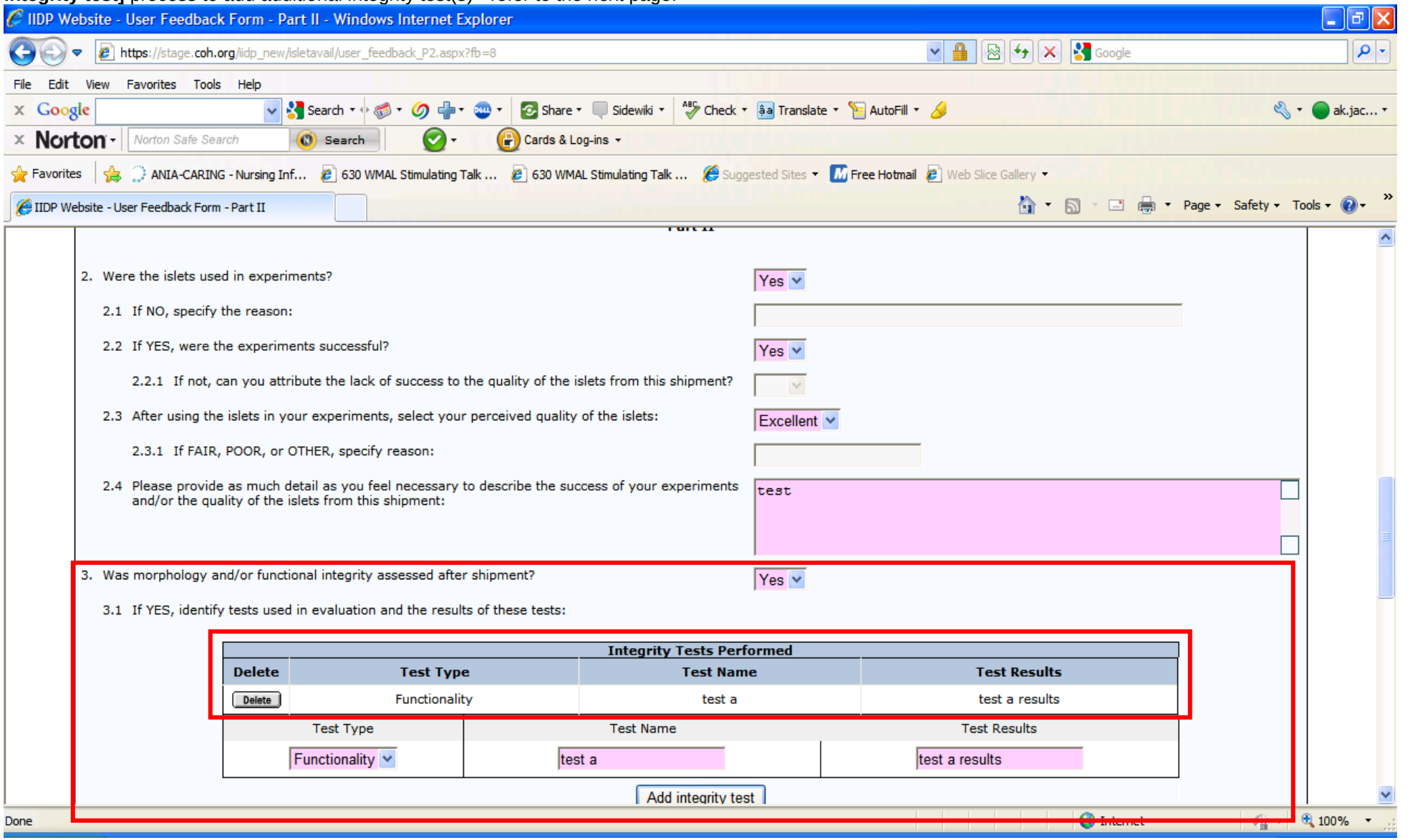
Part II of the UFF – Part II required data fields are in pink and conditional data fields are nonfunctional ('grayed out'). If 'Yes' is selected for Question 3 of Part II, then Question 3.1 will become functional. Then click on **[Add integrity test]** to add an integrity test. Repeat the process as needed for each integrity test – refer to the next page.



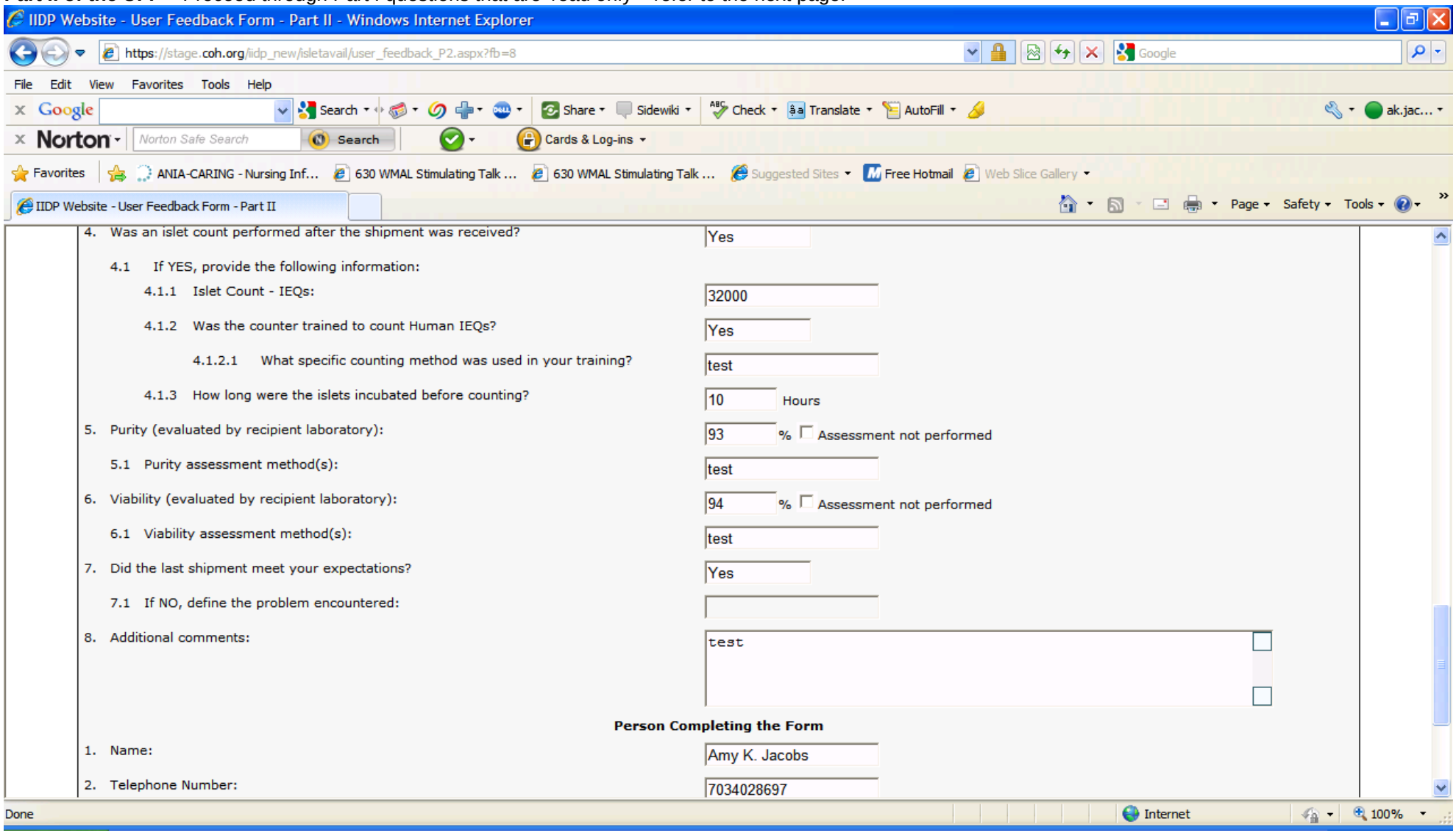
Part II of the UFF – Refer to Questions 3 and 3.1 - click on **[Add integrity test]** to add an integrity test. Repeat the process as needed for each integrity test – refer to the next page.



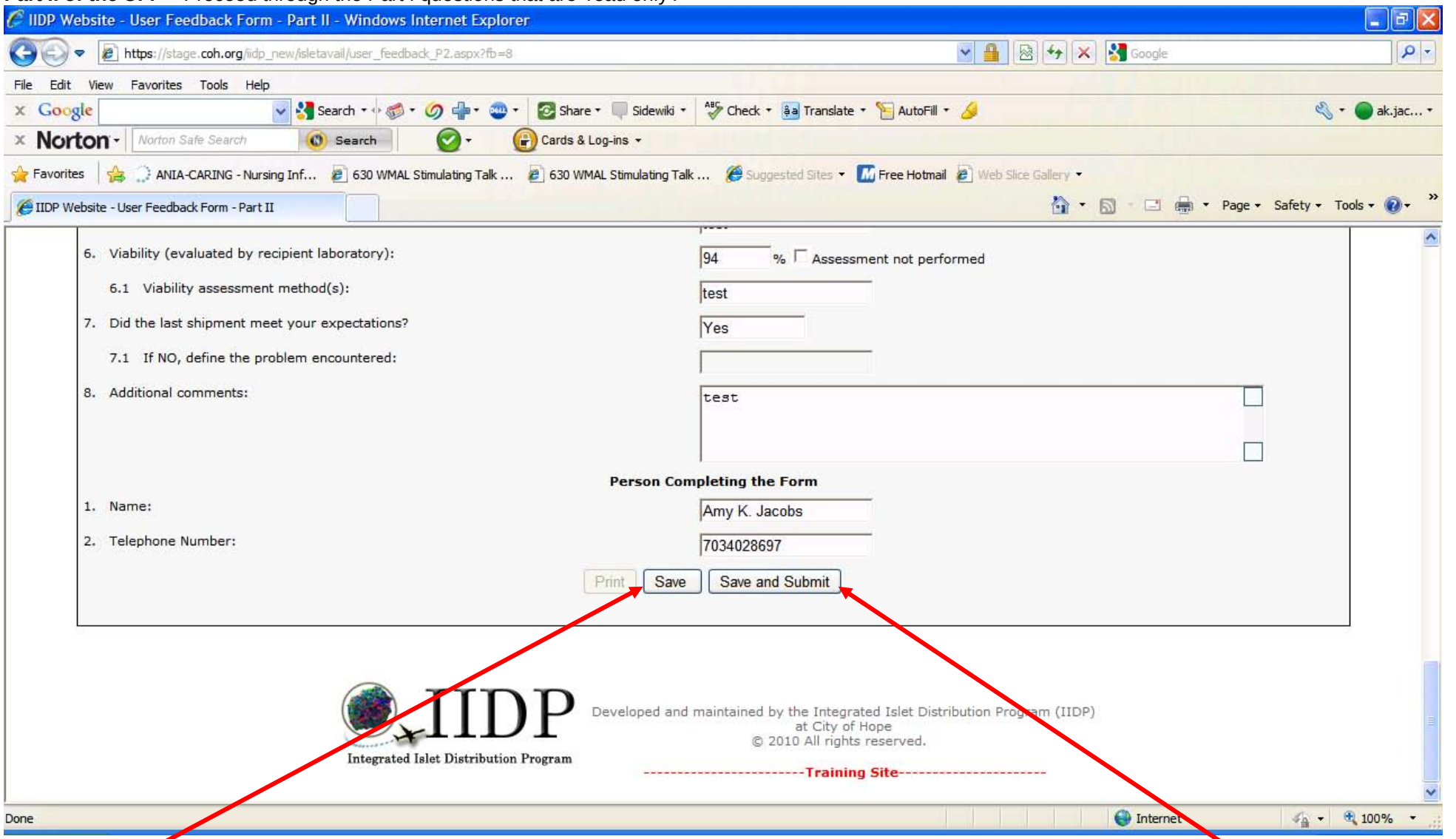
Part II of the UFF – Refer to Questions 3 and 3.1 – Click on **[Delete]** of an integrity test if an integrity test that was entered needs to be deleted. Repeat the **[Add integrity test]** process to add additional integrity test(s) - refer to the next page.



Part II of the UFF – Proceed through Part I questions that are 'read only' - refer to the next page.



Part II of the UFF – Proceed through the Part I questions that are 'read only'.



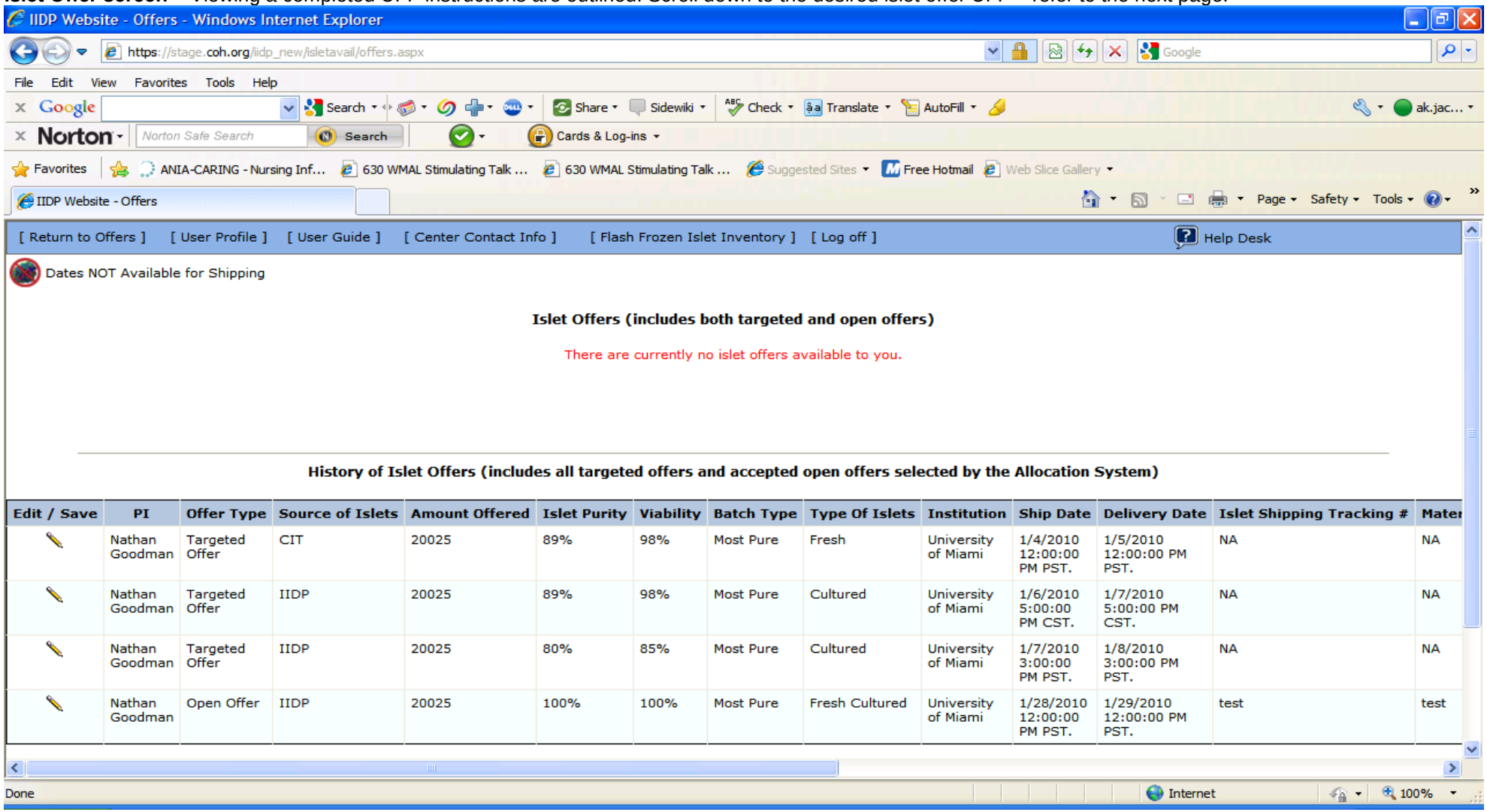
Click on **[Save]** to save Part II of the UFF and complete at a later time - refer to the confirmation message on the next page OR click on **[Save and Submit]** to save and submit the completed Part II of the UFF - refer to the confirmation message on page 25.

Confirmation message - Part II of the UFF has been saved in the system and is incomplete. Click on **[Close]** to return to the **Islet Offers** screen – refer to page 15.

Confirmation message - Part II of the UFF has been saved and submitted in the system. Click on **[Close]** to return to the **Islet Offers** screen – refer to page 15.

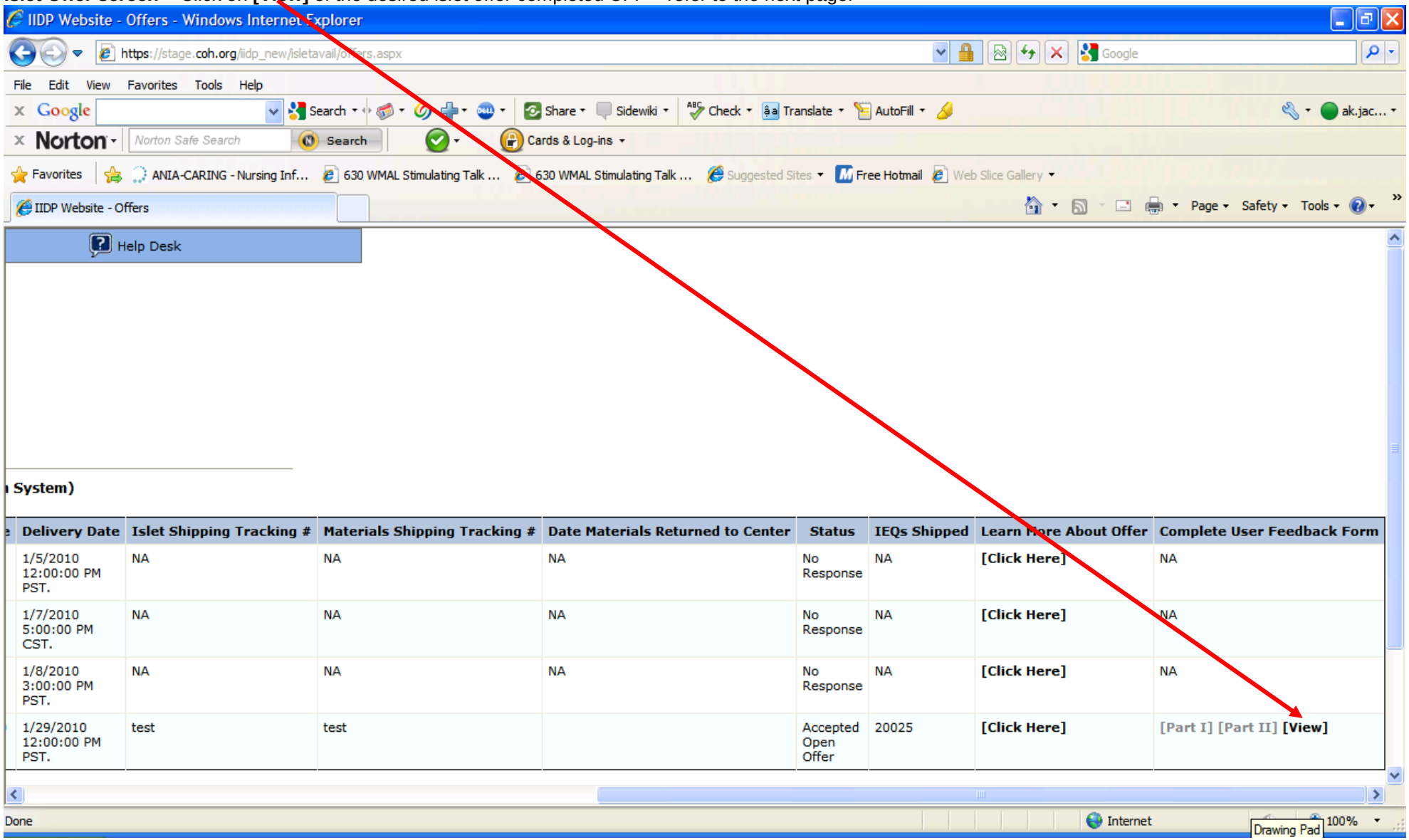
5.0 View Completed User Feedback Form (UFF)

Islet Offer screen – Viewing a completed UFF instructions are outlined. Scroll down to the desired islet offer UFF – refer to the next page.

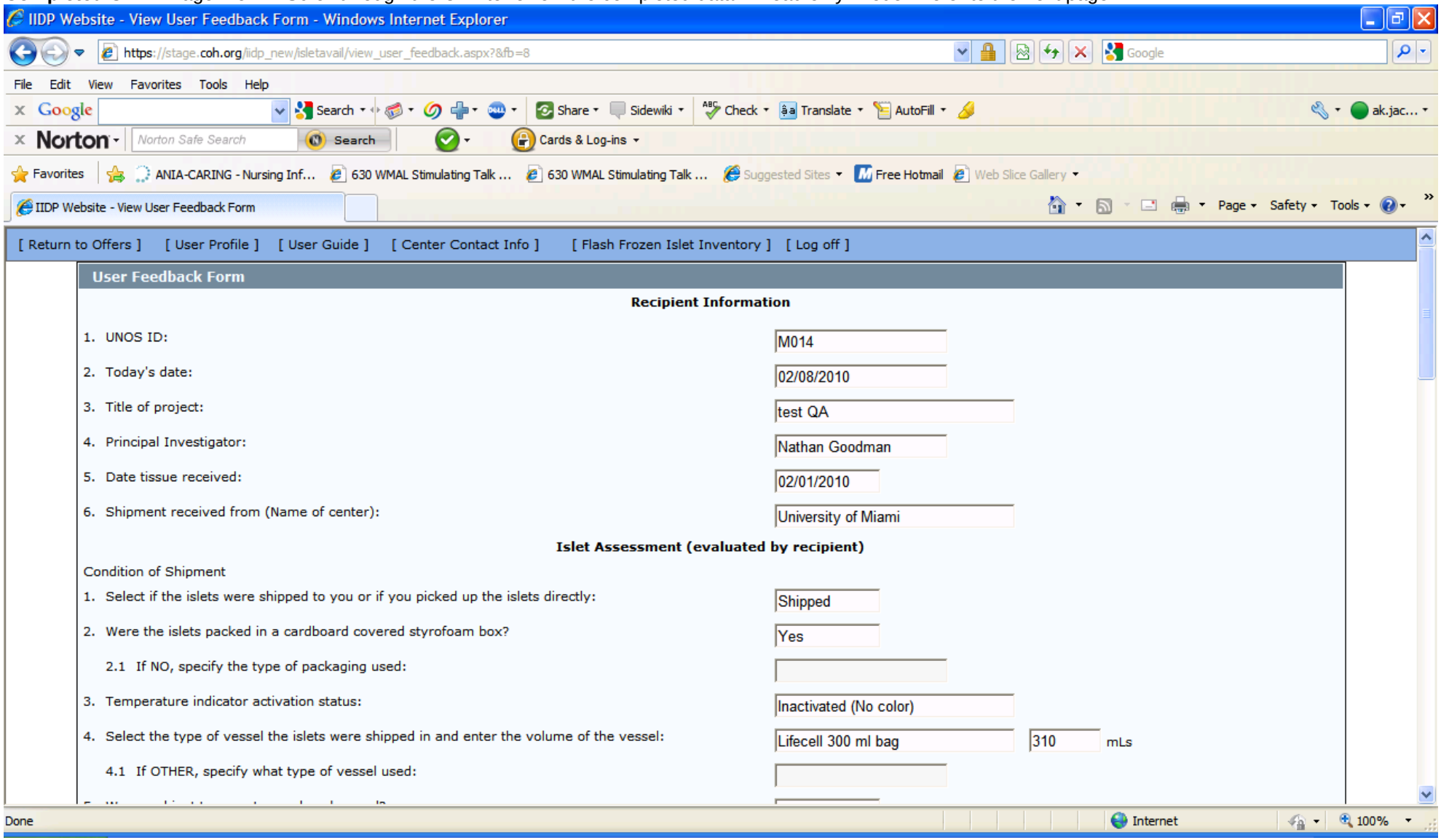


Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mater
	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
	Nathan Goodman	Open Offer	IIDP	20025	100%	100%	Most Pure	Fresh Cultured	University of Miami	1/28/2010 12:00:00 PM PST.	1/29/2010 12:00:00 PM PST.	test	test

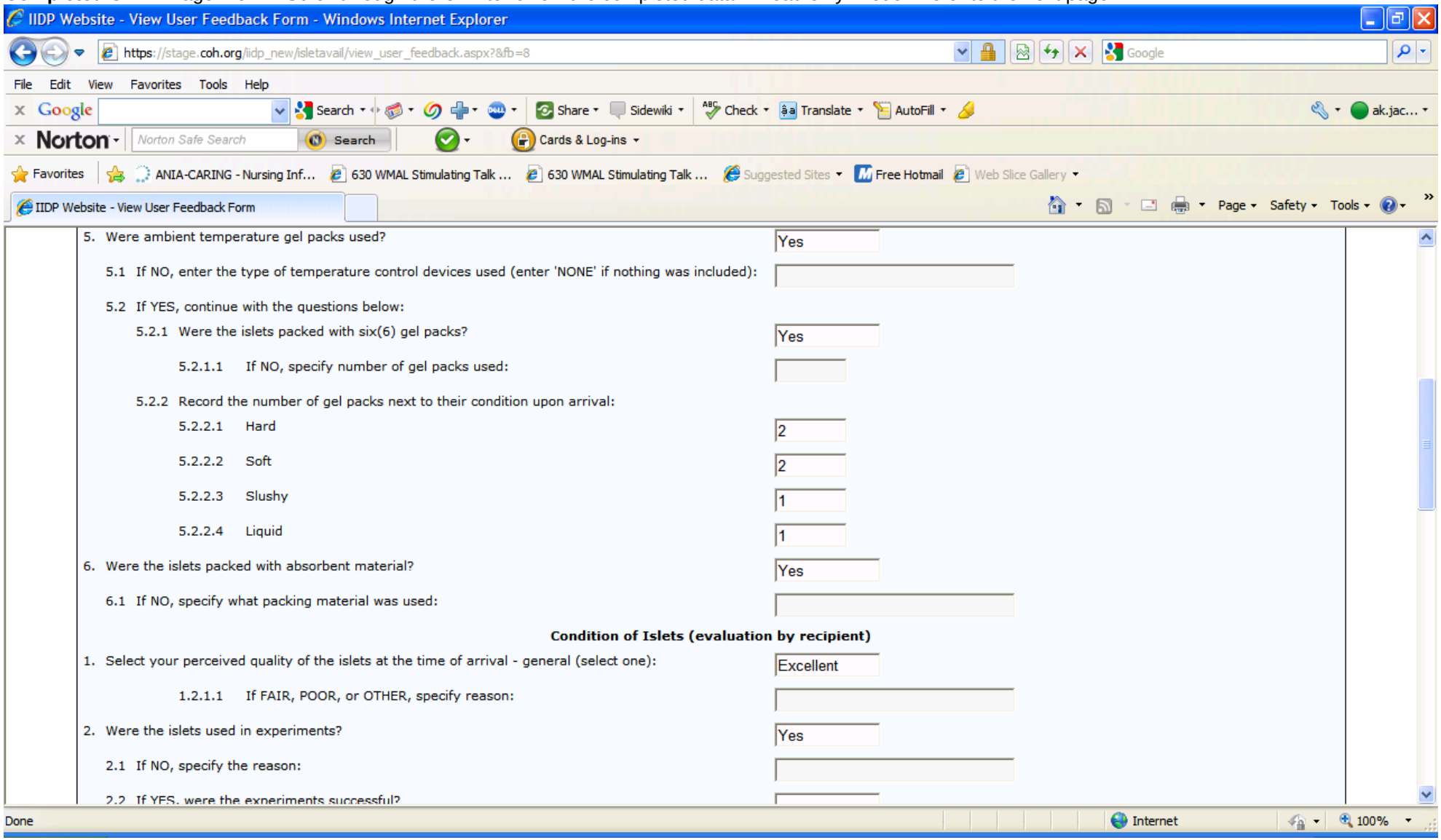
Islet Offer screen – Click on **[View]** of the desired islet offer completed UFF – refer to the next page.



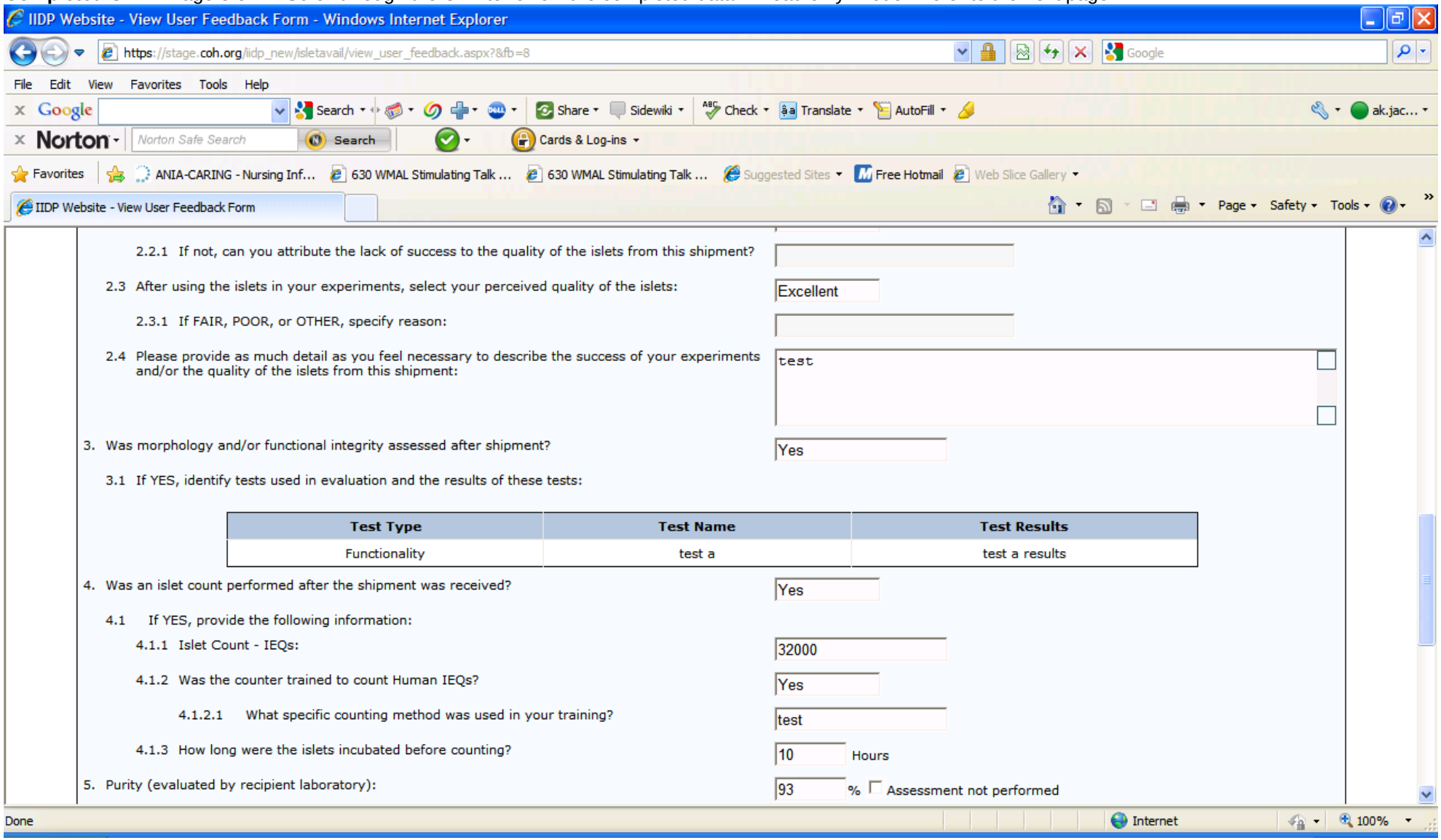
Completed UFF – Page 1 of 4 - Scroll through the UFF to review the completed data in 'read only' mode – refer to the next page.



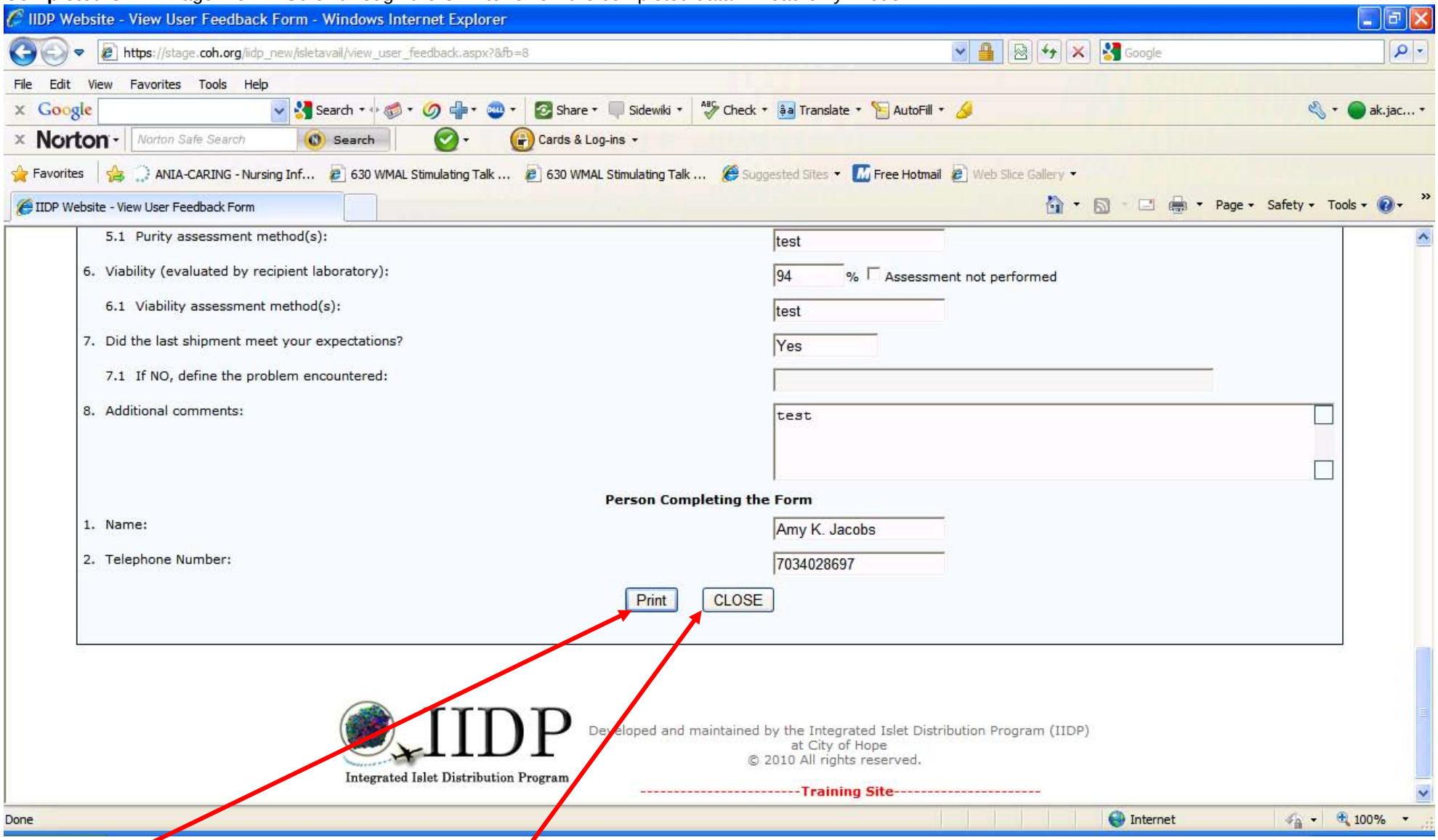
Completed UFF – Page 2 of 4 - Scroll through the UFF to review the completed data in 'read only' mode – refer to the next page.



Completed UFF – Page 3 of 4 - Scroll through the UFF to review the completed data in 'read only' mode – refer to the next page.

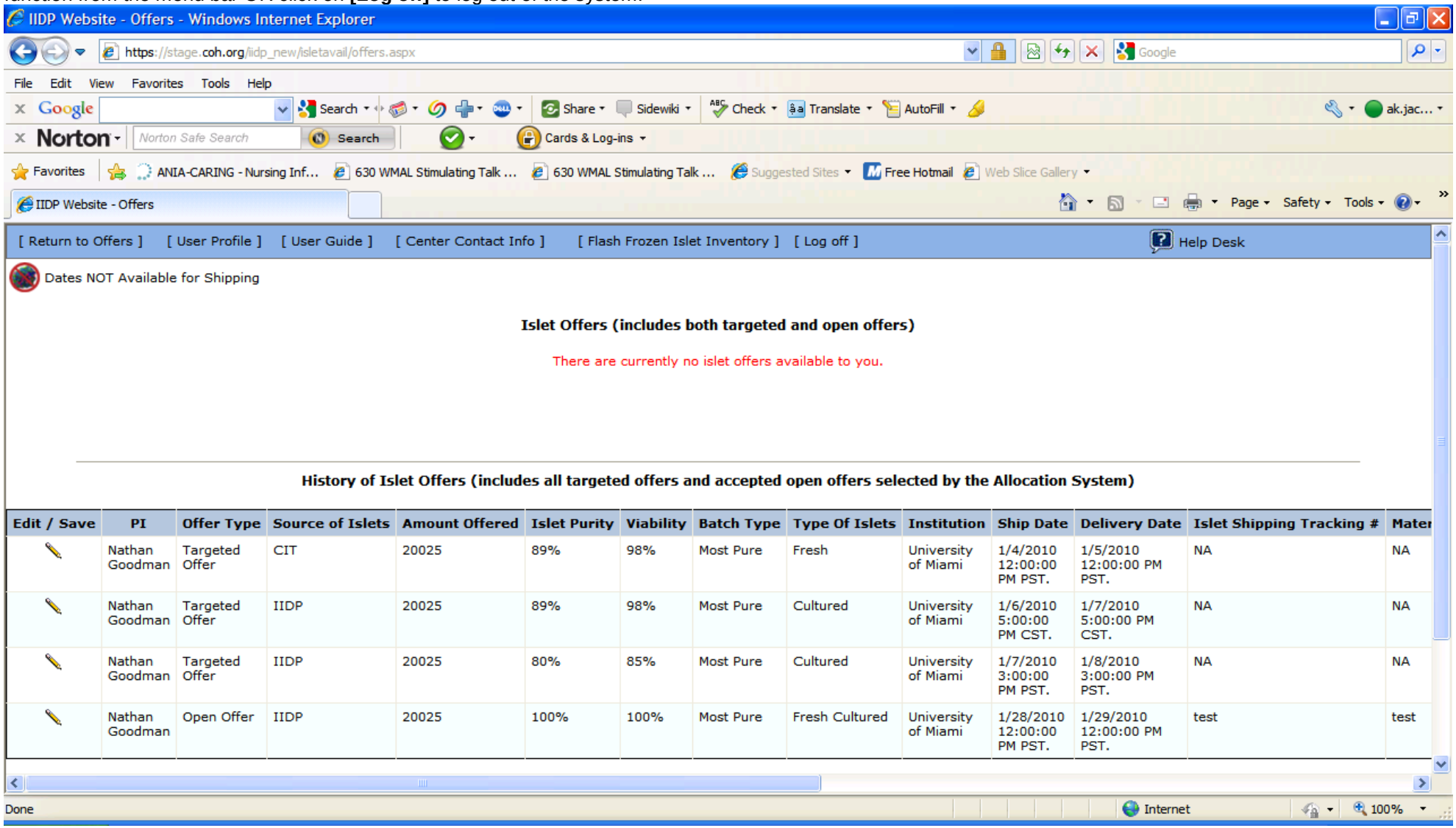


Completed UFF – Page 4 of 4 - Scroll through the UFF to review the completed data in 'read only' mode.



Click on **[Print]** to print the completed UFF OR click on **[Close]** to close the completed UFF and return to the Islet Offers screen – refer to the next page.

Islet Offers screen - Repeat the process as needed to complete Part I and/or Part II UFF(s) and/or view completed UFF(s) for other islet offers OR select another function from the menu bar OR click on **[Log off]** to log out of the system.



Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mater
	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
	Nathan Goodman	Open Offer	IIDP	20025	100%	100%	Most Pure	Fresh Cultured	University of Miami	1/28/2010 12:00:00 PM PST.	1/29/2010 12:00:00 PM PST.	test	test

IIDP
Integrated Islet Distribution Program

Attachment - 8
User Instructions for Islet Decanting and Return of Shipping Materials to the IIDP

1. Upon receipt of the IIDP package, remove the islet vessel, wipe with disinfectant and place under sterile hood.

2. Remove cap on port of bag, add luer tubing, and drain islet preparation into a sterile 250 ml conical.

3. Using a sterile syringe, add approximately 20 ml of media to the shipping bag. Rinse and decant.

4. Repeat as necessary to remove all the islets. Centrifuge the suspension at 1,000 rpm (280g) for one minute (at room temperature) or gravity settle for 10 minutes. Remove supernatant and discard in appropriate waste. Resuspend cells in appropriate media/solution for studies.

5. Remove Tissue Shipment Form and file in your records.

6. Complete the User Feedback Form on line at http://iidp.coh.org It is mandatory to complete Part I of this form to maintain your eligibility for future islet shipments. It is recommended to complete Part II as soon as your results are finalized.

7. Check the contents of the Standardized Shipping Box and note the activation status of the temperature indicator and the number and quality of the Ambient Gel Packs. Dispose of the absorbent packing pads if wet or soiled and the disposable temperature indicator after documentation of activation status on the User Feedback Form.

8. Remove the enclosed FedEx Return Shipping label and affix to outside of the Shipping Box.

   *Note: If the outer, cardboard box was damaged beyond use during shipping, please send the Ambient Gel Packs back in another appropriately sized container and alert the center and the IIDP (*mantler@coh.org).

It is essential that the both parts of the User Feedback Forms be completed on line and that the Shipping Boxes and the Ambient Gel Packs be returned to the supplying IDDP as soon as possible. Users will be ineligible for additional islet shipments if the above materials are not returned to the supplying IIDP.

Thank you for your help in keeping the costs of this project reduced by returning all supplies promptly!

Minimum Required Assessments for Islet Distribution

1.0 To insure consistent purity and viability, the following analyses are the minimum requirements to be performed by subcontractors on all islet preparations provided to the IIDP.

1.1 Islet Quantification: Dithizone-staining, cell size and enumeration evaluation using light microscopy with visual examination by 2 qualified personnel (or double counting by one individual of a duplicate sample.) This should be performed within 6 hours of shipping. Most studies show that the maximum loss of islets is over the first 12 hours after isolation so the IIDP require holding islets at 37° C in culture medium for at least 12 hours before shipping.

1.1.1 Counting should be performed and reported after the incubation.

1.2 Islet Purity: Dithizone-staining and determination of acinar-free islets using visual examination under microscope by 2 qualified personnel (or double counting by one individual of a duplicate sample.)

1.2.1 Purity determination should be performed and reported after culture and prior to shipping.

1.2.2 Human islet preparations will contain ≥80% for "most pure" and ≥50% for "impure" islet tissue as determined by dithizone staining and light microscopy in order to qualify for islet reimbursement

1.3 Viability: Fluorescent dye method using fluorescein diacetate and propidium iodide with visual examination by 2 qualified personnel (or double counting by one individual of a duplicate sample.) (Dyes can be substituted for other inclusion and exclusion dyes with the permission of the IDCC.)

1.3.1 Viability determination should be performed and reported after culture and prior to shipping.

1.3.2 Human islet preparations will consist of ≥ 80% viable islet particles as determined by fluorescence microscopy.

1.4 Sterility: Testing for microbial (both aerobic and anaerobic) and fungal contamination must be performed on the final preparation.

1.4.1 Preliminary results must be supplied to the IIDP within 10 days of shipping. Final results must be supplied within 30 days of shipping.

1.4.2 A sentinel flask of ≥ 100 IEQ should be aliquoted at the time of shipping and kept in house for 3 days at 24° C in the media used for shipping, in order to monitor islet quality in the event of complaints by the receiving investigators concerning contamination or islet quality.

1.5 Potency: A Glucose Stimulated Insulin Release (GSIR) Assay, a functionality assay that compares the amount of insulin secreted at a resting stage (low glucose concentration) of an islet preparation to the amount of insulin secreted during a stimulated stage (high glucose concentration), must be performed on the final islet preparation on the day of shipping.

1.5.1 The resulting ratio is called the Stimulation Index and must be reported to the IIDP within 10 days of broadcast.

1.6 Optional Assessments: Although optional, documentation of any additional quality assessments that a subcontractor normally performs on their preparations and is willing to share with the islet recipients and the IIDP is encouraged. These assessments should be entered into the IIDP database under Optional Assessments in the Quality Assessments section of the database and will be shared with the recipients who accepted islets from that broadcast.

Ciprofloxacin Stock Preparation

Note: Ciprofloxacin is no longer available through the COH pharmacy and therefore the IIDP will purchase powdered Ciprofloxacin Hydrochloride from Cellgro and request that the individual centers prepare a 10mg/ml stock using, filter sterilize and freeze for future use in preparing shipping media for the islets.

1.0 Cellgro Website Description for Ciprofloxacin:

Description:	**Ciprofloxacin Hydrochloride** **Cat #: 61-277**
Formula:	$C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_20$
Formula Weight:	385.82
CAS#:	86393-32-0
MSDS:	**Available upon request**
Shipping:	Ambient
Storage:	Store ambient at **15 - 30°C**. Protect from light and excessive heat.
Stability:	Avoid moisture uptake, as this can decrease the product's potency.
Applications:	Ciprofloxacin HCl is a highly active fluoroquinolone antibiotic effective against a broad spectrum of bacteria and mycoplasma. There are few resistant strains. The antibiotic is effective at low concentrations (10ug/ml) in water, buffered media and can effectively eradicate Mycoplasma in as little as 12 days. Cells are seeded into media with Ciprofloxacin HCl freshly added at 10ug/ml. Replacement of medium or subculturing of cells may be done in 3 to 4 days. After 14 days, it is no longer necessary to include Ciprofloxacin HCl in the media.

2.0 Preparation of New Ciprofloxacin Powder for Addition to Media:

2.1 Remove 1 gm (1000mg) of ciprofloxacin hydrochloride from the bottle and QS to 100 ml with distilled water. This will give a stock concentration of 10mg/ml.

2.2 Mix with a stir bar and stirring plate until totally dissolved.

2.3 Filter sterilize the solution using a 0.2µm filter.

2.4 Aliquot into sterile tubes, 5 ml samples, label, and freeze for later use.

2.5 Diluted solution is good for 1 year frozen and 1 month thawed.

3.0 Addition to Media:

3.1 Thaw aliquotted sample and label with thaw date.

3.2 Follow SOP SHP 001 Section 6.2 Media Preparation instructions.

3.2.1 Add 0.5ml of ciprofloxacin stock to each 500 ml bottle of CMRL 1066 Supplemented for islet shipping.