Northwell Health

View xForm - Human Subjects Research Determination Request

Use this form to request a determination if you are not sure whether your project requires IRB review and approval - signing off

PI data entry stage
- Submitted 09/21/2021 9:04 AM ET by Suratwala, Sanjeev

Protocol Information

ONLY SUBMIT THIS FORM IF YOU ARE NOT SURE AS TO WHETHER YOUR PROJECT SHOULD BE CONSIDERED HUMAN SUBJECTS RESEARCH. IF YOU KNOW THAT IRB APPROVAL/REVIEW WILL BE REQUIRED, PLEASE PROCEED TO SUBMIT THE INITIAL SUBMISSION APPLICATION.

All human subject research activities must be reviewed by the IRB prior to initiation.

Examples of projects that may not require IRB review and approval are included case reports of three or less patients, research on anonymous (i.e. no link to subject identity) specimens or data, medical practice innovation in which the physician's goal is to improve the well-being of a patient, quality improvement activities, surveillance programs, public health activities and resource utilization reviews.

Before submitting this form, please review the guidance on QI vs research, which can be found by clicking here.

Enter the email address of the submitter. Submitter must be a contact in the IRBManager system. If he or she is not, please email irb@northwell.edu to request the account to be created.

Suratwala, Sanjeev
Email: Ssuratwala@northwell.edu **Phone:**

Enter the email address of the person who would be the PI of the project. PI must be a contact in the IRBManager system. If he or she is not, please email irb@northwell.edu to request the account to be created.

Suratwala, Sanjeev
Email: Ssuratwala@northwell.edu **Phone:**

ProtocolTitle

Pathogenesis and Staging of Craniovertebral Tuberculosis

Please choose the correct department

Northwell Orthopedic Surgery

Indicate the main Northwell location where your project will take place.

Syosset Hospital
No locations selected from list

Is the Principal Investigator a student?

No

Enter email address of anyone else you would like to be notified of communication about this submission

No answer provided.

Has this project been submitted previously as a human subjects research determination request? If so, please clarify why it is being submitted again now.

Please note: submissions regarding the same project are generally not accepted, unless the original submission was significantly inaccurate, or the project has been altered in a way that might affect the determination.

No

Funding Source(s)

Is this a funded project

No

Case Reports

(Note: this question is often answered incorrectly – please consider your answer before marking Yes or No).

Will your research study ONLY involve the review of medical records for up to 3 Northwell patients? If so, this would meet the Northwell definition of a case report (a medical chart review of 3 or fewer patients), and IRB review would not be needed.

See this guidance document for the full definition of a case report.

No

Research

IS THIS PROJECT RESEARCH: As defined by Department of Health and Human Services' (DHHS) regulations: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

- **If ALL the answers on this page are marked "yes," then your activity meets the definition of research AND IRB Review and approval will be required.**
- **If ANY of the answers are checked "no," the activity does not meet the definition of research.**

Is the activity an investigation? (*Investigation*: a searching inquiry for determining facts; detailed or careful examination)

Yes

Is the investigation systematic? (*Systematic*: having or involving a system, method, or plan)

Yes

Is the systematic investigation designed to develop or contribute to knowledge? (*Designed*: done with purpose and intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: truths, facts, information.)

Yes

Is the knowledge generalizable? (Generalizable = universally applicable OUTSIDE of Northwell)

Yes

How will this study advance the scientific literature? (please be as detailed/specific as possible):

Craniovertebral Tuberculosis is an extremely rare condition in the US. However, TB is relatively more common in the rest of the developing world and so is the incidence of craniovertebral TB. This study evaluates this condition to provide a better understanding of the pathogenesis of the condition, radiographic classification, and a plan of care based on a systematic assessment of radiographic and clinical information.

Human Subject

DOES YOUR RESEARCH INVOLVE HUMAN SUBJECTS: As defined by DHHS regulations: "a living individual, about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information." Note: According to NY state law, the definition of human subject also includes deceased individuals.

The activity involves human subjects if EITHER of the following checked YES:

The investigator will gather data about living individuals through intervention OR interaction

No

Physical procedures or manipulations of those individuals or their environment. (*Intervention*)
No

Communication or interpersonal contact with the individuals. (*Interaction*)
NO

The investigator will access data about living individuals that is private AND identifiable.

No

The data includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). (*Private*)
No

The participant's identity is or may be readily ascertained by the investigator, or will be associated with the information. (*Identifiable*)
No

The research involves the use of coded* data/specimens (*Identifiable*)
No

Coded* means individual's identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof **and there is a key to link the code to the identifiable information of that individual. Coded data are considered identifiable under the Common Rule.*

If research involves the use of coded data/specimens, indicate which, if any, is true:

The private information or specimens were not collected specifically for the proposed research activity through an interaction or intervention with living individuals

No

AND

The investigator will destroy the code before the research begins

Yes

OR

The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstance. Provide a copy of this agreement (informal email exchange is sufficient);

Yes

OR

The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased (provide this documentation)

Yes

OR

There are other legal requirements prohibiting the release of the key to the investigator

Yes

Human Subject - FDA

As defined by FDA regulations: Human subject means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Does the activity involve human subjects as defined by FDA regulations? The activity involves human subjects if EITHER of the following checked YES:

An individual will be a recipient of any test article (i.e. drug, medical device) or as a control.

No

An individual on whose specimen a medical device will be used, even if the specimen is unidentified.

No

Study Activities

Provide a brief description of proposed activities, including target population. This should contain a clear but concise description of the methods/procedures/activities being used, with an emphasis on what will happen to the any patients (if applicable). If you believe that the proposed activities are not research involving human subjects, please explain why. If clarification of a previous determination is requested, describe change(s) below.

The research study was performed in India where a restrospective chart review performed over several years. The data was submitted for my review for analysis and interpretation without patient identifying information. As the PI, I have no access to the original patient information, only the de-identified images and outcomes information.

Use this area to attach any relevant documents in support of this study.

No answer provided.

Engagement

Is this project being performed as part of your job, or institutional responsibilities, at Northwell Health (i.e. completing research is part of your Northwell job expectations, and you are doing this project to fulfill that expectation)?

Yes

Will Northwell employee(s) be obtaining informed consent form research participants for this project?

No

Will this project be performed by Northwell employees during their designated working hours?

No

If this project results in a publication, will authors list their Northwell affiliation(s)?

Yes

Comments (if needed to clarify any answers above)

No answer provided.

Signature

Certification Language

By signing this form you are attesting that the information you provided is true and accurate. Misrepresenting your project as not being research, when it is, will be determined to be serious non-compliance which is reportable to the Federal Government, Institutional Official and Department heads.

Submitter Signature

Signed Tuesday, September 21, 2021 9:03:55 AM ET by Suratwala, Sanjeev

By entering my password, I am electronically signing this form and agreeing to the above statement.

Notify IRB
- Submitted 09/21/2021 1:19 PM ET by Newlin, Jon

IRB Determination

Date received

09/21/2021

Is this modification ready for review?

Yes

If any noticeable changes are needed, or the appropriate documents were not attached, select "no."

Choose IRB Staff Reviewer

Newlin, Jon

NHSR Number

HSRD21-0304

IRB

Northwell Health IRB

Load into IRB Manager
- Submitted 09/21/2021 1:20 PM ET by System, The

IRB Staff Review
- Submitted 09/24/2021 10:14 AM ET by Newlin, Jon

IRB determinations

IRB Determination

Proposed study activities do not meet the definition of human subject research, and therefore are deemed to be not human subjects research. Therefore no Northwell IRB review is required for this project as described. This determination applies only to the activities described in this request. Any changes that may alter this determination must be submitted to the IRB for review.

Please attach any documents here to go back to the submitter of this form.

No answer provided.

Reason for determination – this language will be included in the email to the submitter

Based on prior communication with submitter, Northwell personnel did not originate the research idea or instigate this research. The human subjects research activity was performed in India. Northwell personnel were sent de-identified data/materials without an ability to re-identify. Therefore the research activity performed at Northwell did not involve human subjects, and no IRB review is required for the Northwell personnel participation. The research activity performed in India would fall under the regulatory review requirements of that country.