Participant SIN: _____

BASELINE AND PLACEMENT

Version 4.1

June 2014

Participant's Initials:
Participant's SIN:
Date of Visit:

Date of Birth (dd/mm/yyyy):

GENERAL HOUSEHOLD AND EMPOLYMENT INFORMATION

Dwelling you are living in: ___ ___

1= Brick/concrete House
2= Apartment
3= Traditional hut/dwelling
4= Garage
5= 1 room
6= Shack
7 =Homeless
9= Other

If other specify: _____

Access to piped water: ___ ___

1= Piped water inside the dwelling

2= Piped water inside the yard

3= Piped water on a community stand <100m of household

4= Piped water within 100m of household but not inaccessible

5= Piped water inaccessible

Source of water: ___ ___

1= Government piped water

2= Borehole

3= Spring

4= Dam/pool/stagnant water

5= River or stream

9= Other

If other specify: _____

Residential Address:				
Description of Area of residence: ___ ___ **1=Farm** **2=Location/township** **3=Suburb** **4= Town/City** **5=Village**				
Contact number:				
Employed currently?	**Yes**		**No**	
If Yes, are you a miner?	**Yes**		**No**	
If miner or doing hard physical work in the mining industry: ___ ___ **1 = Underground 2 = Above ground**				

GENERAL MEDICAL HISTORY

HIV Serostatus

	Positive	Negative
Participant's HIV Serostatus	☐	☐
If "Negative," document the date of test: *Counselor's name:*		
If "Positive, CD4 count __ __ __ __cells/mm3 *Date taken (dd/mm/yyyy):* *(must be within two months of circumcision and above 350 cells.)*		

Based on general examination and medical history provided by the participant, is he suitable for Prepex Medical Male Circumcision? YES ☐ NO ☐
If NO, give reasons:

**If the individual has diabetes, he is ineligible for the study.*

PHYSICAL EXAMINATION, VITAL SIGNS & MEDICATION

Body System	Normal	Abnormal	Comments
Genital	☐	☐	

Current Medication

	Yes	No
Is the participant currently taking medication?	☐	☐

Participant SIN: _____

If yes, record medication below						
Medication Name (generic)	**Medication Dosage**			**Medication Course**		**Ongoing**
	Units	**Frequency**	**Route**	**Start**	**Stop**	
1.	☐☐	☐☐	☐☐	Date:	Date:	☐
2.	☐☐	☐☐	☐☐	Date:	Date:	☐
3.	☐☐	☐☐	☐☐	Date:	Date:	☐

Units: 01. Gram (g); **02.** Milliliter (ml); **03.** Milliequivalent (MEQ); **04.** Milligram (mg); **05.** Drops; **06.** International Units (IU); **07.** Unknown
Frequency: 01. Once a day; **02.** Every night; **03.** Twice a day; **04.** Three times a day; **05.** Four times a day; **06.** Five times a day; **07.** Once a week; **08.** Every 6 hours; **09.** Every 8 hours; **10.** Every 12 hours; **11.** As needed; **12.** Unknown
Route: 01. Intravenous; **02**. Oral; **03.** Rectal; **04.** Intramuscular; **05.** Intradermal; **06.** Inhalation; **08.** Subcutaneous; **09.** Sublingual; **10.** Topical; **11.** Unknown

	Yes	**No**
Following medical examination is the participant suitable for PrePex Medical Male Circumcision	☐	☐
If not, why?		

Device Placement

Did this person refuse application after signing informed consent? YES ☐ NO ☐

Date of Device Application (dd/md/yyyy): _____

If the date is different from the screening visit, record the participant's vital signs and genital condition.

Vital Signs

Blood Pressure	/ mm Hg		Pulse	b/m
Genital condition	Normal	☐	Abnormal	☐

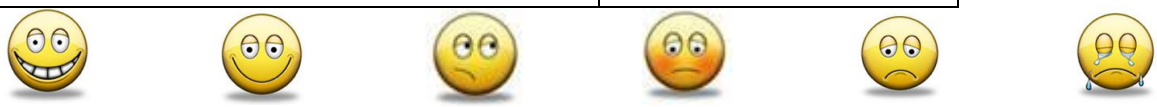
Start Time (Cleaning Patient Genital)	
Placement Completed (Patient Getting off the bed)	

Operator	
Assistant	

Participant SIN: _____

Visual Analog Scale

Evaluation of pain level per VAS during placement	☐☐



0	2	4	6	8	10
Very happy, no hurt	**Hurts just a little bit**	**Hurts a little more**	**Hurts even more**	**Hurts a whole lot**	**Hurts as much as you can imagine**

Prepex Device

Measured PrePex Size	A ☐	B ☐	C ☐	D ☐	E ☐	Other ☐	No Size ☐
If the device application is not the same day as the screening, has there been a change in the genitals (compare to screening visit report)?				Yes ☐	No ☐		
Was the device applied according to its Instructions For Use? If "No," explain in detail:				Yes ☐	No ☐		
Provider evaluation of application/placement from 1 to 10 (1 being worst):				☐☐			

Prepex Device Details

SIZE		**OR ATTACH PREPEX LABEL**
LOT. NO		
MAN. Date		
EXP. Date		

ADVERSE EVENTS DURING PLACEMENT

Were there any device related events or AE that occurred in this visit? Yes ☐ No ☐

If "Yes", please record below.

Onset/Start

Date of AE: __ __/__ __/201__

Time of AE: __ __: __ __

Participant SIN: _____

Date/time observed (if different) _____

Status of AE: New ☐ Ongoing ☐

Diagnosis: Primary ☐ Secondary ☐

Tick the relevant AE and classification

Pain	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Bleeding	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Analgesia/Anesthesia-Related	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Damage to penis	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Other: *Please specify* _____		Mild Moderate Severe (complete SAE form)	☐ ☐ ☐

Describe the AE

_____
_____
_____

Action:

☐ None ☐ Surgical ☐ Non-Surgical ☐ Pharmaceutical

☐ Study termination ☐ Other: _____

DEVICE EVENTS

Was there any difficult during placement? Yes ☐ No ☐

If 'Yes' Describe difficulty during placement

Participant SIN: _____

_____
_____
_____

Were there any other events that occurred during the placement that you would like to record? (e.g. crying, shouting, needing excessive reassurance prior to or during procedure, wanting to stop procedure e.t.c.)

Yes ☐ No ☐

If 'Yes' describe

_____
_____

_____
_____

I have checked all data introduced to this form until this point and verified that they are complete, correct and reconcilable with the original documentation.

Name:	Position:
Signature:	Date:

Visit #2: DEVICE AND FORESKIN REMOVAL Version 1.5 July 2014
Day 7

Participant's Initials:
Participant's SIN:
Date of visit:

Work Leave

Did the participant take day(s) off from work following the circumcision?

Yes ☐ No ☐ NA ☐

If "Yes", number of days:

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Pain – Before removal

Visual Analog Scale – Before Removal

0	2	4	6	8	10
Very happy, no hurt	**Hurts just a little bit**	**Hurts a little more**	**Hurts even more**	**Hurts a whole lot**	**Hurts as much as you can imagine**

Write the number associated with the face that best describes pain level in the blocks provided

1. Evaluation of pain level per VAS before removal procedure: ☐ ☐

1.1. Has the participant experienced anything else that they did not like related to the circumcision apart from pain or discomfort?

Yes ☐ No ☐

1.2. *If "Yes",* what was it they experienced?

_____

_____

_____

_____

_____

Participant SIN: _____

Current Medication

	Yes	No
Has there been any change to participant's medication since device placement?	☐	☐

If yes, record medication below

Medication Name (generic)	Medication Dosage			Medication Course		Ongoing
	Units	Frequency	Route	Start	Stop	
1.	☐☐	☐☐	☐☐	Date:	Date:	☐
2.	☐☐	☐☐	☐☐	Date:	Date:	☐
3.	☐☐	☐☐	☐☐	Date:	Date:	☐

Units: 01. Gram (g); **02.** Milliliter (ml); **03.** Milliequivalent (MEQ); **04.** Milligram (mg); **05.** Drops; **06.** International Units (IU); **07.** Unknown
Frequency: 01. Once a day; **02.** Every night; **03.** Twice a day; **04.** Three times a day; **05.** Four times a day; **06.** Five times a day; **07.** Once a week; **08.** Every 6 hours; **09.** Every 8 hours; **10.** Every 12 hours; **11.** As needed; **12.** Unknown
Route: 01. Intravenous; **02**. Oral; **03.** Rectal; **04.** Intramuscular; **05.** Intradermal; **06.** Inhalation; **08.** Subcutaneous; **09.** Sublingual; **10.** Topical; **11.** Unknown

Removal Procedure

Start Time (Cleaning Patient Genital)	
Removal Completed (Patient Getting off the bed)	

Operator Name	
Assistant Name	

Pain –During removal of PrePex

Visual Analog Scale – Pain During Removal of PrePex

0	2	4	6	8	10
Very happy, no hurt	**Hurts just a little bit**	**Hurts a little more**	**Hurts even more**	**Hurts a whole lot**	**Hurts as much as you can imagine**

Write the number associated with the face that best describes pain level in the blocks provided

2. Evaluation of pain level per VAS during removal procedure: ☐☐

Removal Particulars		
5.1 Was preventive pain medication administered to the patient in the hour prior to the removal of PrePex, specifically to prevent pain of removal? *If "Yes",* What medication? Paracetamol alone ☐ Codeine alone ☐ Paracetamil with codeine combination tablets ☐ Ibuprofen alone ☐ Emla cream ☐ Other ☐ If other, specify:_____	Yes ☐	No ☐
5.2 Was Lidocaine spray used *If "Yes"* Evaluation of pain level per VAS after removing the elastic ring ☐☐ Evaluation of pain level per VAS after removing the inner ring ☐☐ Evaluation of pain per VAS 15 minutes after removal ☐☐	Yes ☐	No ☐
5.3 Was any medication or anesthesia required during removal? *If "Yes",* What*?*_____	Yes ☐	No ☐
5.4 Was a spatula used to remove the inner ring?	Yes ☐	No ☐
5.5 Was a finger used to remove the inner ring?	Yes ☐	No ☐
5.6 Were there any device related events or AE that occurred during the removal? *If "Yes", please record on the device related events form and adverse events form, if needed.*	Yes ☐	No ☐

5.7	How would you rate the removal procedure from 1 to 10 (with 1 being worst): ☐ ☐		

ADVERSE EVENT

6. Has the participant experienced an AE since ther last visit or at this visit?

Yes ☐ No ☐

If 'Yes' complete below

6.1. Onset/Start

Date of AE: __ __/__ __/201__

Time of AE: __ __:__ __

Date/time observed (if different) _____

6.2. Status of AE: New ☐ Ongoing ☐

6.3. Diagnosis: Primary ☐ Secondary ☐

6.4. Tick the relevant AE and classification

Pain ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐
Bleeding ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐
Amount of blood: PLEASE RECORD ANY BLEEDING	Minimal ☐ At least 5ml ☐ 10-40ml ☐ >50ml ☐
Intervention: This means did the person removing PrePEx or anyone else provided an intervention or treatment that they would not normally have done for a PrePex patient	No intervention/treatment required ☐ Required local pressure to stop the bleeding ☐ Other

	_____ _____

Infection	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Hematoma	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Problems Voiding	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Damage to Penis	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Wound Dehiscence	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Other:	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐

7. Describe the AE

_____
_____
_____

8. Action:

☐ None ☐ Surgical ☐ Non-Surgical ☐ Pharmaceutical

☐ Study termination ☐ Other: _____

Participant SIN: _____

DEVICE EVENTS

9. Was there any device:

Displacements ☐ Early removal ☐

Detachment ☐ Self removal ☐

9.1. If 'Yes' Describe condition resulting in either of the above mentioned

_____
_____
_____
_____

10. Was there difficulty during device removal?

Yes ☐ No ☐

10.1. If 'Yes', describe the difficulty experienced during removal

_____
_____
_____

Name:	Position:
Signature:	Date:

PARTICIPANT REVIEW FORM

To be used at any contact after Prepex Application Except Day of Removal

Version 1.5

July 2014

Participant's Initials:
Participant's SIN:
Date:

Scheduled Visit		**Unscheduled Visit**	
Visit Occurred while device ON		**Visit Occurred while Device OFF**	
Day of Visit Day: Visit 21 ☐ **Visit 49** ☐ **Other:**			
Telephonic ☐ **or Clinical Visit** ☐ **or Home Visit** ☐			
Conform spoken to patient ☐ **or Spoken to a relative/friend** ☐			

1.1. Has the participant experienced anything else that they did not like related to the circumcision apart from pain or discomfort?

Yes ☐ No ☐

1.2. *If "Yes",* what was it they experienced?

_____

_____

_____

Current Medication

	Yes	**No**
Has there been any change to the participant's medication since last visit?	☐	☐

If yes, record medication below

Medication Name (generic)	**Medication Dosage**			**Medication Course**		**Ongoing**
	Units	**Frequency**	**Route**	**Start**	**Stop**	
1.	☐☐	☐☐	☐☐	Date:	Date:	☐
2.	☐☐	☐☐	☐☐	Date:	Date:	☐
3.	☐☐	☐☐	☐☐	Date:	Date:	☐

Participant SIN: _____

Units: 01. Gram (g); **02.** Milliliter (ml); **03.** Milliequivalent (MEQ); **04.** Milligram (mg); **05.** Drops; **06.** International Units (IU); **07.** Unknown

Frequency: 01. Once a day; **02.** Every night; **03.** Twice a day; **04.** Three times a day; **05.** Four times a day; **06.** Five times a day; **07.** Once a week; **08.** Every 6 hours; **09.** Every 8 hours; **10.** Every 12 hours; **11.** As needed; **12.** Unknown

Route: 01. Intravenous; **02**. Oral; **03.** Rectal; **04.** Intramuscular; **05.** Intradermal; **06.** Inhalation; **08.** Subcutaneous; **09.** Sublingual; **10.** Topical; **11.** Unknown

Wound Description

_____

_____

_____

Device related event or Adverse Event

1. Has the participant experienced any AE since the PrePex device was applied?

Yes ☐ No ☐

If 'Yes' complete below

1.1. Onset/Start

Date of AE: __ __/__ __/201__

Time of AE: __ __: __ __

Date/time observed (if different) _____

1.2. Status of AE: New ☐ Ongoing ☐

1.3. Diagnosis: Primary ☐ Secondary ☐

1.4. Tick the relevant AE and classification

Pain	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Bleeding	☐	Mild	☐

Participant SIN: _____

	Moderate ☐ Severe (complete SAE form) ☐
Amount of blood:	Minimal ☐ At least 5ml ☐ 10-40ml ☐ >50ml ☐
Intervention:	No intervention/treatment required ☐ Required local pressure to stop the bleeding ☐ Other: _____ _____
Infection ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐

Hematoma ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐
Problems Voiding ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐
Damage to Penis ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐
Wound Dehiscence ☐	Mild ☐ Moderate ☐ Severe (complete SAE form) ☐

Excessive skin removed	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Insufficient skin removed	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Torsion	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐
Other: *Please specify* _____	☐	Mild Moderate Severe (complete SAE form)	☐ ☐ ☐

2. If the participant experienced any of the below then tick and describe.

Delayed Wound Healing Yes ☐ No ☐ If 'Yes', Describe: _____ _____ _____	
Scarring/disfigurement Yes ☐ No ☐ If 'Yes', Describe: _____ _____ _____	
Erectile Dysfunction Yes ☐ No ☐ If 'Yes' Describe: - _____ _____ _____ Frequency: ☐☐ Timing with regard to circumcision: _____	
Psychosocial behavior Yes ☐ No ☐ If 'Yes' Describe: _____ _____ _____	
Timing or onset:	

Participant SIN: _____

3. Describe the AE

_____
_____
_____

4. Action:

☐ None ☐ Surgical ☐ Non-Surgical ☐ Pharmaceutical

☐ Study termination ☐ Other: _____

Appearance after circumcision

5. Are you satisfied with the appearance of your penis post circumcision?
   Yes ☐ No ☐

If "No" then explain why not and what you expected to see

_____
_____
_____

6. Is the wound healed completely?
   Yes ☐ No ☐
7. Is the participant terminated from the study according to the protocol?

   7.1 Yes ☐ No ☐
   7.1.1 If 'No' – Date of Next Visit:_____

   7.2 Reason for termination if participant terminated NOT according to protocol

   Loss to follow up ☐ Moved out of area ☐
   Unable to contact ☐ Death ☐
   Other: _____

Name:	Position:
Signature:	Date:

Participant's Initials:	
Participant's SIN:	Page Number ___

Concomitant Medication Form

USE ONE FORM FOR THE ENTIRE STUDY
UPDATE THIS FORM AT EACH VISIT
IF NECESSARY GO TO A SECOND OR THIRD PAGE

Has the participant taken concomitant medication (including pain killers) since the last visit?
Y N
If "No", do not enter information on this form.
If "Yes", please complete below.

Medication Name (generic)	Medication Dosage			Medication Course		Ongoing
	Units	Frequency	Route	Start	Stop	
1.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
2.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
3.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
4.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
5.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
6.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐
7.	☐☐	☐☐	☐☐	Date: Time:	Date: Time:	☐

Units: 01. Gram (g); **02.** Milliliter (ml); **03.** Milliequivalent (MEQ); **04.** Milligram (mg); **05.** Drops; **06.** International Units (IU); **07.** Unknown

Frequency: 01. Once a day; **02.** Every night; **03.** Twice a day; **04.** Three times a day; **05.** Four times a day; **06.** Five times a day; **07.** Once a week; **08.** Every 6 hours; **09.** Every 8 hours; **10.** Every 12 hours; **11.** As needed; **12.** Unknown

Route: 01. Intravenous; **02**. Oral; **03.** Rectal; **04.** Intramuscular; **05.** Intradermal; **06.** Inhalation; **08.** Subcutaneous; **09.** Sublingual; **10.** Topical; **11.** Unknown

Name:	Position:
Signature:	Date:

Severe Adverse Events (SAE) Form

Participant's Initials:
Participant's SIN:

Is there a photographer present to take a photo of the SAE
Yes ☐ **No** ☐
Do not continue until a photographer is present

Onset/Start
Date of SAE: __ __/__ __/201__

Time of SAE: __ __:__ __

Date/time observed (if different) _____

Number of SAE for this participant? ☐ ☐

Status

New ☐
Ongoing ☐

Description
Please describe SAE in block letters
_____
_____
_____
_____

Criteria
Chose criteria for SAE

☐ Death

☐ Permanent disability

☐ Life threatening

☐ Hospitalization or prolongation of inpatient hospitalization

☐ Required intervention to prevent one of the above

☐ Other:

_____

_____

Outcome

☐ Resolved

☐ Resolved with sequel

☐ Persistent

☐ Unchanged

☐ Unknown

End/Termination

Date of SAE: __ __/__ __/201__

Time of SAE: __ __:__ __

Please add any additional comments related to this AE. Please write in block letters and sign and date your comments.

_____

_____

_____

_____

_____

Does Human Research Ethics Committee need to be immediately notified of AE? Y N

If Y please draft notification and send notification now.

I have checked all data introduced to this form until this point and verified that they are complete, correct and reconcilable with the original documentation.

Name:	Position:
Signature:	Date: