

Please answer all questions with a \* beside them

# SECTION 1: INVESTIGATOR DETAILS

# \*S1-1 Principal Investigator

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-2 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

Not applicable

# \*S1-3 Principal Investigator Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-4 Is there more than one investigator?

Yes  No

# \*S1-5 How many other investigators do you have (up to 5)?

# Choose an item.

Only complete the following sections applicable to the number of investigators you have.

# \*S1-6 Investigator 1

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-7 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

Not applicable

# \*S1-8 Investigator 1 Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-9 Investigator 2

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-10 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

# Not applicable

# \*S1-11 Investigator 2 Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-12 Investigator 3

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-13 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

Not applicable

# \*S1-14 Investigator 3 Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-15 Investigator 4

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-16 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

Not applicable

# \*S1-17 Investigator 4 Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-18 Investigator 5

Title Choose an item.

Name Click or tap here to enter text.

Surname Click or tap here to enter text.

Qualifications Click or tap here to enter text.

Affiliated Institution Click or tap here to enter text.

Current position Click or tap here to enter text.

# \*S1-19 Professional Body Registration and registration number

HPCSA Registration number Click or tap here to enter text.

SANC Registration number Click or tap here to enter text.

SAPC Registration number Click or tap here to enter text.

Other Name of body Click or tap here to enter text.

Not applicable

# \*S1-20 Investigator 5 Contact Details

Contact numbers (format +27 11 123 4567)

\*Primary Office phone Click or tap here to enter text.

Alternative Office phone Click or tap here to enter text.

Mobile number Click or tap here to enter text.

\*Primary email Click or tap here to enter text.

Alternative email Click or tap here to enter text.

# \*S1-21 What is the purpose of the research?

\*Degree purpose  Yes  No

If yes, specify which degree Click or tap here to enter text.

# \*S1-22 Has this research/study been reviewed by any Scientific Committee? (Universities or Research Organizations)?

Yes  No

# \*S1-23 If yes, please specify:

\*Name of Institution Click or tap here to enter text.

Title Choose an item.

Contact person Firstname Click or tap here to enter text.

Contact person Surname Click or tap here to enter text.

\*Phone number Click or tap here to enter text.

\*Email address Click or tap here to enter text.

# You will be required to provide your Scientific Review Approval Letter with your application.

# 

# SECTION 2: STUDY DETAILS

# \*S2-1 Title of the study (3 lines maximum)

# *Please do not use abbreviations*

Click or tap here to enter text.

# \*S2-2 Aims and objectives of the study (6 lines maximum)

Click or tap here to enter text.

# \*S2-3 Relevant background and significance of the study (one page maximum)

Click or tap here to enter text.

# \*S2-4 Study design (3 lines maximum)

Click or tap here to enter text.

# \*S2-5 Procedures (half a page maximum)

Click or tap here to enter text.

# \*S2-6 Statistical analyses (half a page maximum)

Click or tap here to enter text.

# \*S2-7 Outcomes measures (half a page maximum)

Click or tap here to enter text.

# \*S2-8 Estimated study start date

\*When will the study start? Click or tap to enter a date.

# \*S2-9 Estimated study end date

\*When will the study end? Click or tap to enter a date.

# \*S2-10 Study Duration: Number of Years

Please round up to the closest year when selecting your answer. For example, if your study is 18 months long, please select 2 years.

# Choose an item.

# SECTION 3: STUDY PARTICIPANTS

# \*S3-1 Participant demographics - Age Group







# \*S3-2 Participant demographics - Gender

Choose an item.

# \*S3-3 Participant demographics – Race

African

Asian

Coloured

White

All race groups

Other Click or tap here to enter text.

# \*S3-4 Number of study participants

Click or tap here to enter text.

# \*S3-5 Number of control participants

Click or tap here to enter text.

# \*S3-6 What are the inclusion criteria?

Click or tap here to enter text.

# \*S3-7 What are the exclusion criteria?

Click or tap here to enter text.

# \*S3-8 How are participants going to be recruited?

Click or tap here to enter text.

# \*S3-9 How will privacy and confidentiality be protected during recruitment?

Click or tap here to enter text.

# \*S3-10 Are participants subordinate to the investigator?

Yes  No

# \*S3-11 Is there payment for participants?

Yes  No

# \*S3-12 If No, why not?

Click or tap here to enter text.

# \*S3-13 If Yes, what is the justification and amount?

Click or tap here to enter text.

# \*S3-14 What is the time commitment for participants in the study?

Click or tap here to enter text.

# \*S3-15 Does the study involve vulnerable groups?

Yes  No

# S3-16 If Yes, which groups?

Children

Pregnant Women

Disabled Persons

Prisoners

Homeless People

Minority Groups

# S3-17 What measures are taken to minimize risks/discomfort for such groups?

Click or tap here to enter text.

**SECTION 4: PROCEDURES**

# \*S4-1 What study procedures are to be done on participants?

Record review

Interview form

Questionnaire

Focus group discussion

Blood collection

Drug or other substance administration

Any other

# \*S4-2 If any other, please explain.

Click or tap here to enter text.

# \*S4-3 Give details of the procedure to be carried out.

Click or tap here to enter text.

# \*S4-4 Number of person(s) carrying out the procedures (up to 10)

Choose an item.

**DETAILS PERSON CARRYING OUT THE PROCEDURES**

(must be completed for each person doing the procedure(s))

# S4-5 Person 1

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-6 Person 2

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-7 Person 3

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-8 Person 4

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-9 Person 5

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-10 Person 6

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-11 Person 7

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-12 Person 8

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-13 Person 9

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# S4-14 Person 10

\*Title Choose an item.

\*Name Click or tap here to enter text.

\*Surname Click or tap here to enter text.

GCP Training (if applicable) Click or tap here to enter text.

Date of training Click or tap to enter a date.

Name of Service Provider Click or tap here to enter text.

Other training provided/experience Click or tap here to enter text.

# \*S4-15 At how many sites will this study be performed (up to 20)?

Choose an item.

**Site Details**

(must be completed per site)

# \*S4-16 Site 1

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-17 Site 1 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-17a Site 1 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-18 Site 2

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-19 Site 2 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-19a Site 2 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-20 Site 3

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-21 Site 3 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-21a Site 3 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-22 Site 4

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-23 Site 4 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-23a Site 4 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-24 Site 5

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-25 Site 5 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-25a Site 5 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-26 Site 6

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-27 Site 6 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-27a Site 6 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-28 Site 7

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-29 Site 7 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-29a Site 7 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-30 Site 8

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-31 Site 8 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-31a Site 8 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-32 Site 9

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-33 Site 9 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-33a Site 9 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-34 Site 10

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-35 Site 10 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-35a Site 10 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-36 Site 11

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-37 Site 11 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-37a Site 11 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-38 Site 12

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-39 Site 12 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-39a Site 12 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-40 Site 13

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-41 Site 13 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-41a Site 13 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-42 Site 14

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-43 Site 14 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-43a Site 14 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-44 Site 15

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-45 Site 15 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-45a Site 15 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-46 Site 16

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-47 Site 16 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-47a Site 16 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-48 Site 17

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-49 Site 17 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-49a Site 17 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-50 Site 18

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-51 Site 18 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-51a Site 18 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-52 Site 19

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-53 Site 19 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-53a Site 19 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

# \*S4-54 Site 20

\*Name of the site/Institution Click or tap here to enter text.

\*Person performing procedure on site Click or tap here to enter text.

\*Qualification of the person Click or tap here to enter text.

\*Has permission been given to conduct the study at this site?

Yes  No  Not required

# \*S4-55 Site 20 permission

\*Will you be including the site permission with your application?

Yes  No

# \*S4-55a Site 20 permission letter validity date

Please indicate the end validity date of the site permission letter.

Click or tap to enter a date.

If permission letter is not attached, this application will not be considered.

**SECTION 5: THERAPEUTIC INTERVENTION**

# \*S5-1 Does this study involve therapeutic intervention?

Yes  No

# S5-2

# If yes, has provision been made to deal with adverse events or complications

Yes  No

1. **What is the product given?** Click or tap here to enter text.
2. **What is the dose given?** Click or tap here to enter text.
3. **What is the frequency of dosing?** Click or tap here to enter text.
4. **What is the duration of treatment?** Click or tap here to enter text.

# \*S5-3 Will you be withholding standard therapy in the course of research?

Yes  No

# \*S5-4 If yes, please provide justification:

Click or tap here to enter text.

# \*S5-5 Are there any known risks associated with giving this product?

Yes  No

# \*S5-6 If yes, please highlight risks:

Click or tap here to enter text.

# \*S5-7 Are any other treatments that are contra-indicated during the study?

Yes  No

# \*S5-8 If yes, please specify:

Click or tap here to enter text.

# \*S5-9 Who will monitor the safety of the administered drug?

Click or tap here to enter text.

**SECTION 6: CONFIDENTIALITY AND PRIVACY OF PARTICIPANTS**

# \*S6-1 Are you collecting primary data with patient identifiers (Name, ID etc.)?

Yes  No

# \*S6-2 If yes which identifiers are you collecting?

Name Telephone Fax Date of birth ID Number

Passport number Insurance number Account number  License number

Email address URL  Biometric identifier  Photo

Address  Any dates

# \*S6-3 How will confidentiality be maintained so that patients/ participants /controls are not identifiable to persons not involved in the research?

Click or tap here to enter text.

# \*S6-4 How will the investigator maintain privacy of participants in the research setting?

Click or tap here to enter text.

# \*S6-5 Will data and participant identifiers be stored separately linked by a code?

Yes  No

# \*S6-6 Who will have access to code, data and data identification?

Click or tap here to enter text.

# \*S6-7 Is a sample data collection sheet or questionnaire attached?

Yes  No  Not required

You will be required to upload a sample data collection sheet or questionnaire during the application submission process.

# \*S6-8 If No, please explain?

Click or tap here to enter text.

# SECTION 7: INFORMED CONSENT

# \*S7-1 Is written informed consent required?

Yes  No

You will be required to upload the written consent during the application process.

# \*S7-2 If No, explain why written consent if not required:

Click or tap here to enter text.

# \*S7-3 For participants <18 years of age, a Parental Informed consent is required. Will this be provided?

Yes  No

You will be required to upload the Parental Written Consent during the application process.

This application will not be considered without the Parental Written Consent

# \*S7-4 For participants < 18 years of age who are able to read and write an Informed Assent form is required. Will this be provided?

Yes  No

You will be required to upload the Informed Assent form during the application process.

This application will not be considered without the Informed Assent form.

# SECTION 8: RISK ASSESSMENT

# \*S8-1 Are there risks to participants?

Yes  No

# \*S8-2 Explain how this will be mitigated:

Click or tap here to enter text.

# \*S8-3 Are there risks to SANBS?

Yes  No

# \*S8-4 Explain how the risk(s) will be mitigated:

Click or tap here to enter text.

# \*S8-5 Are there risks to the institution where the study is conducted?

Yes  No

# \*S8-6 Explain how this will be mitigated:

Click or tap here to enter text.

# \*S8-7 What is the DAIDS Risk/Benefit Category?

****

****

****

****

****

For research carrying more than minimal risk:

# \*S8-8 Do you have insurance cover?

Yes  No

# \*S8-9 Please give details of insurance cover:

Click or tap here to enter text.

# \*S8-10 Do you have plans to mitigate the risk?

Yes  No

# \*S8-11 If yes, please give details:

Click or tap here to enter text.

# \*S8-12 If no, please give details:

Click or tap here to enter text.

# \*S8-13 Does this research have a negative impact on the environment?

Yes  No  Uncertain

# \*S8-14 If yes, please elaborate.

Click or tap here to enter text.

# SECTION 9: BENEFITS

# \*S9-1 What are the benefits of the study to participants?

Click or tap here to enter text.

# \*S9-2 What are the benefits of the study to SANBS?

Click or tap here to enter text.

# \*S9-3 What are the benefits to the institution performing the study?

Click or tap here to enter text.

# \*S9-4 What is the contribution of sponsor / research to capacity building in the community which is studied?

Click or tap here to enter text.

# SECTION 10: RESULTS

# \*S10-1 Are the study results going to be made available to participants?

Yes  No

# \*S10-2 If no, explain

Click or tap here to enter text.

# \*S10-3 Are the study results going to be made available to SANBS?

Yes  No

# \*S10-4 If no, explain

Click or tap here to enter text.

# \*S10-5 Are the study results going to be made available to your institution?

Yes  No

# \*S10-6 If no, explain

Click or tap here to enter text.

# \*S10-7 Will any personal data or biological material be stored after the study?

Yes  No

# \*S10-8 If yes, has specific permission been obtained for this?

Yes  No

# SECTION 11: FUNDING

# \*S11-1 Is this study funded by an Institution?

Yes  No

# \*S11-2 Please give details of the Institution funding this study

Click or tap here to enter text.

# \*S11-3 Is this study funded by a National Body?

Yes  No

# \*S11-4 Please give details of the National Body funding this study.

Click or tap here to enter text.

# \*S11-5 Is this study funded by an International Body?

Yes  No

# \*S11-6 Please give details of the International Body funding this study

Click or tap here to enter text.

# \*S11-7 Is there a potential or actual financial conflict of interest for investigators?

Yes  No

# \*S11-8 If yes, explain:

Click or tap here to enter text.

You’ve reached the end of this questionnaire.