

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.