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1. Accessing the SANBS HREC system

The system can be accessed via the link on the SANBS Website research page
https://sanbs.org.za/research/ or by copying and pasting the following URL link in your browser
https://k2.sanbs.org.za/Runtime/_trust/Login.aspx?ReturnUrl=%2fRuntime%2fRuntime%2fForm%2fSANBS.HREC.Dashboard. It is advisable to create a shortcut on your browser using this URL.

> **The SANBS HREC System has been optimised for use on a notebook or desktop computer and not for a mobile device (smart phone or tablet).**
>
> **Throughout this manual, test data in the screenshots have been redacted.**

2. Principal Investigator self-registration

Access the system as indicated in 1 above.

Step	System/field	Your input
❶	SANBS Staff Windows Authentication	If you are a <u>SANBS employee</u>, click on SANBS Staff Windows Authentication. Use your SANBS network ID and password to log in. If you are a SANBS employee but are using a non-SANBS email address, follow step ❷ below.
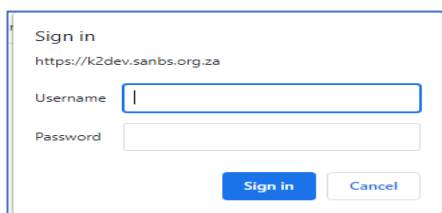
Step	System/field	Your input
❷	External Forms Authentication	If you are an external person, or a SANBS employee using a non-SANBS external email address, click on External Forms Authentication.

Step	System/field	Your input
❶	Register new user	Click on **Register new user** to register

Step	System/field	Your input
❶	Primary Email	Enter your **Primary email address** All research applications must be submitted under the primary email address of the Principal Investigator. Applications will not be reviewed if this requirement is not adhered to.
❷	Name	Enter your **First Name**
❸	Surname	Enter your **Surname**
❹	Submit	Click on **Submit** to continue

The following message will be displayed:

Step	System/field	Your input
❶	OK	Click **OK** to continue
	System response	The system will send you an email for you to complete the registration process. Access your email and click on the link in the email to enter a password.

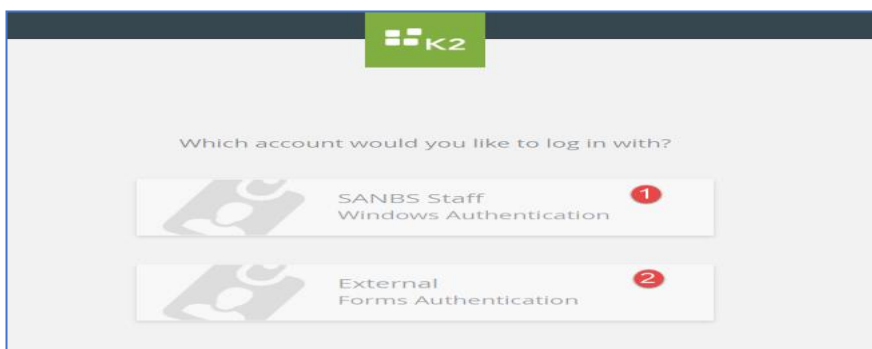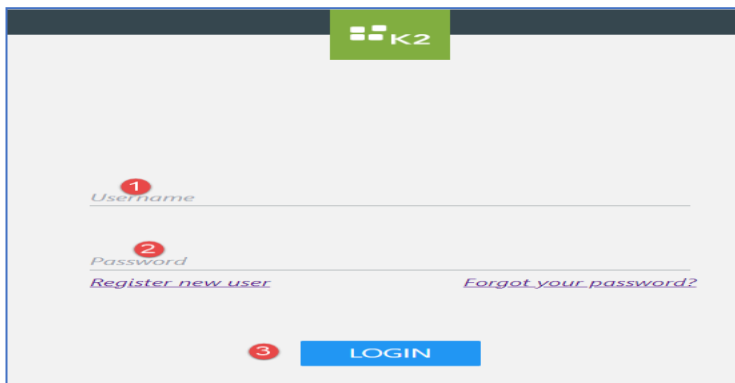| Step	System/field	Your input
❶	New Password	Enter a strong password using a combination of upper case, lower case, numbers and special characters. Minimum password length is 8 characters.
❷	Confirm Password	Confirm the password by retyping it.
❸	Submit	Click on **Submit** to continue

The following message will be displayed:
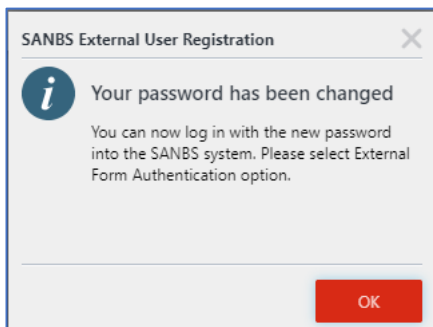
Access the system via the link listed 1 above.

3.   Logging in

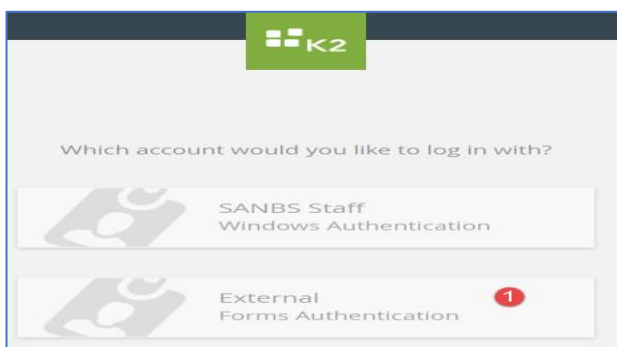| Step	System/field	Your input
❶	SANBS Staff Windows Authentication	If you are a <u>SANBS employee</u>, click on **SANBS Staff Windows Authentication**. Use your SANBS network ID and password to log in. If you are a SANBS employee but are using a non-SANBS email account, follow step ❷ below.
❷	External Forms Authentication	If you are an external person or a SANBS employee using a non-SANBS email address, click on **External Forms Authentication.**

Step	System/field	Your input
❶	Username	Enter your **Username** that you used to register on the system.
❷	Password	Enter your Password.
❸	Login	Click on **Login** to continue or press ENTER on the keyboard.

4. Resetting your password

Step	System/field	Your input
❶	If you have used your SANBS Network credential to register	You cannot reset the password to the HREC system via the SANBS HREC System. Instead, you may reset your network password as you currently do on the network. You may then use the new password to login into the SANBS HREC System.
❷	If you have used a non-SANBS email address to register	Follow the steps below to reset your SANBS HREC System password.

Access the system via the link listed 1 above.

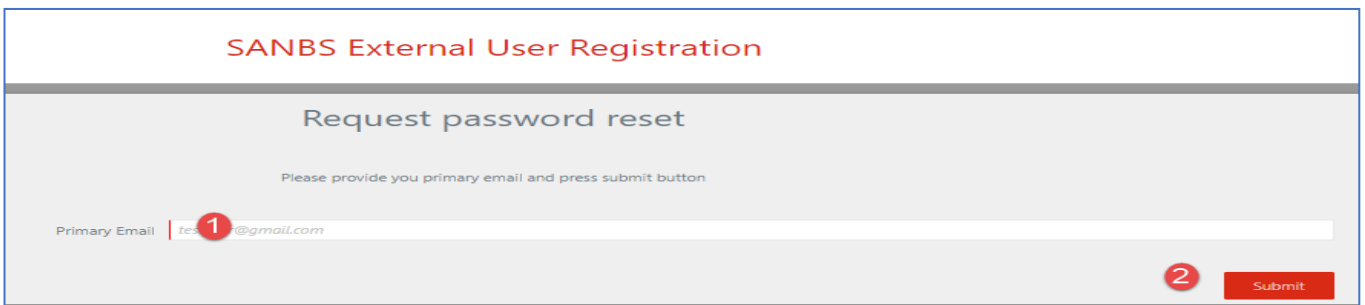| Step	System/field	Your input
❶	External Forms Authentication	If you have registered using a non-SANBS email address, click on ***External Forms Authentication***.
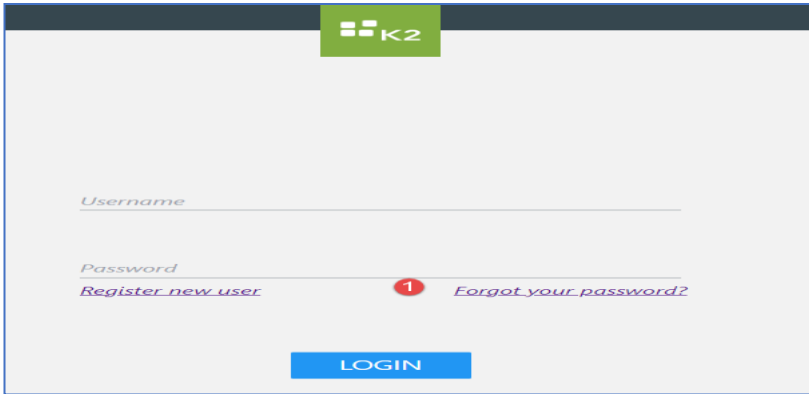
Step	System/field	Your input
❶	Forgot your password	Click on ***Forgot your password***

Step	System/field	Your input
❶	Primary Email	Enter your ***Primary Email address*** that you used to register on the system.
❷	Submit	Click on ***Submit*** to continue.

The following message will be displayed:
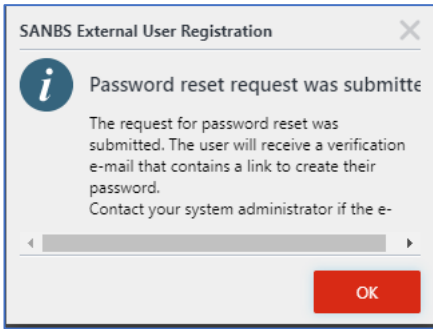
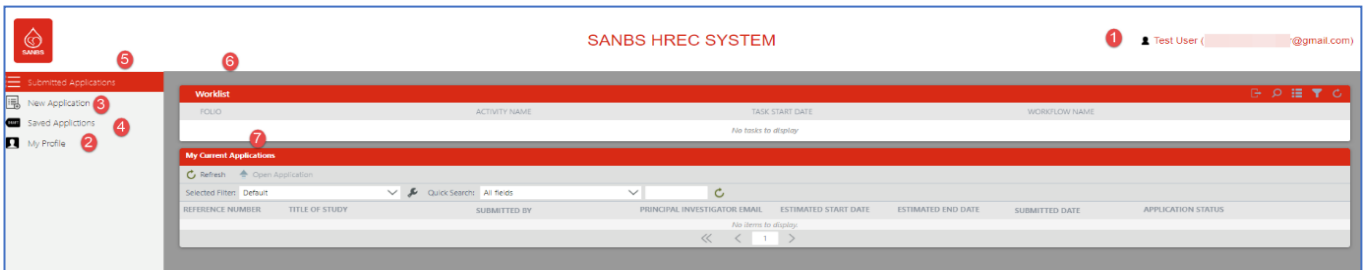| Step	System/field	Your input
❶	OK	Click **OK** to continue
	System	An email will be sent to your email address to reset your password. Click on the link in the email to reset your password, bearing in mind to use a strong password.

5.   Logging off

To log off the system, simply close your browser. All unsaved work will be lost.

6.   Principal Investigator landing page

Step	System/field	Your input
❶	Username	This is the name of the user logged into the system at that point in time.
❷	My profile	By selecting this menu item, a new screen will be displayed for you to complete your personal profile. Your personal profile must be completed before you commence creating a new submission. The data you enter in the personal profile will be pulled through into the submission and will be saved with the submission. Changes made to your personal profile will only be pulled through to your next submission i.e., submissions that were started, saved or submitted will not be changed retrospectively. See section **7** below to complete your profile.
❸	New applications	This menu item allows you to create a new application for review by the SANBS Scientific Review Committee and or the Human Research Ethics Committee. Refer to section **8 Creating and submitting an application**
❹	Saved applications	Applications that are still work in progress will be saved here. Saved applications will not be assigned a reference number. Refer to section **12 Saved Applications**
❺	Submitted applications	Applications that have been submitted for review will be displayed here. You will not be able to change a submitted application unless

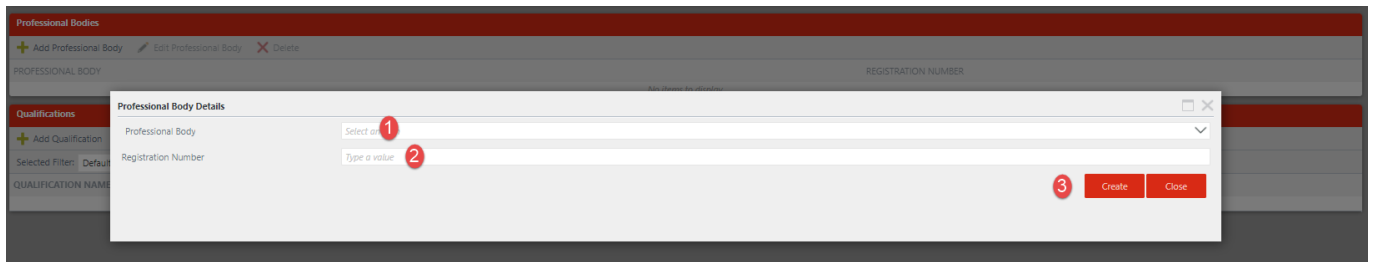|		you are requested to do so by the SRC or HREC Administrator. Only the sections that you may be requested to change will be available for you to change and resubmit.
⑥	Worklist	During the review process, tasks may be created for you to complete. You will find these tasks here.
⑦	My current applications	Your current applications will be displayed here. You will be able to see the status of each application in the Application Status field.

7. Updating My Profile

On the landing page menu, click on ❷ *My Profile*

Step	System/field	Your input
❶	User type	The system will select SANBS Staff by default if you registered as a SANBS employee using a SANBS email address. The system will select External if you registered using a non-SANBS email address.
❷	Title	Select your *Title*
❸	Name	Enter your *First name*
❹	Surname	Enter your *Surname*
❺	Display name	The system will display your first name and surname.
❻	Affiliated institutions	Enter *Affiliated Institutions*. Separate multiple entries with a semi colon(;).
❼	Current position	Enter you *Current Position* at the institution or organisation that you work at.
❽	Are you a member of any Professional bodies?	If you select *Yes*, proceed to number 15 below. If you select *No*, proceed to question 9.
❾	Primary number	Enter your *Primary number*. Use the following format +country code and area code space next 3 digits space next 4 digits (e.g., +2711 555 9999)
❿	Primary email	The system will default to the email address you used to register with on the SANBS HREC system.

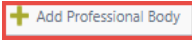|		
⑪	Mobile number	Enter your **Mobile number.** Use the following format +country code and area code space next 3 digits space next 4 digits (e.g., +2782 555 9999)
⑫	Alternative number	Enter an **Alternative number** that you can be contacted at. Use the following format +country code and area code space next 3 digits space next 4 digits (e.g., +2782 555 9999)
⑬	Alternative email	Enter an **Alternative Email** address.
⑭	Country	Enter the first few characters and then click on these characters to see a shortened list that you can select from.
⑮	Professional bodies	If you selected **Yes** to ❽ above, follow the steps in section **1** to add, **7.2** to edit or **7.3** to delete **Professional Bodies**.
⑯	Qualifications	To enter your qualifications, follows the steps in section **7.4** to add, **7.5** to edit or **7.6** to delete **Qualifications**.

7.1. Adding a Professional Body

To enter your first professional body, click on [+ Add Professional Body], then follow the steps below.

Step	System/field	Your input
❶	Professional body	Select a **Professional Body** from the dropdown list.
❷	Registration number	Enter the **Registration number** for the body you selected.
❸	Create or close	Select **Create** to save the entry or Close to abort.

Adding another Professional Body

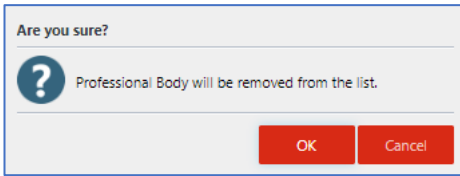To add another Professional body, click on [+ Add Professional Body]. Thereafter, follow the steps in the abovementioned table.

7.2. Editing a Professional Body

To edit a Professional Body that you have created, click on the saved professional body once, and then click on [Edit Professional Body] or double click on the entry to amend it. Click on [Update] to save or [Close] to exit without saving the changes.

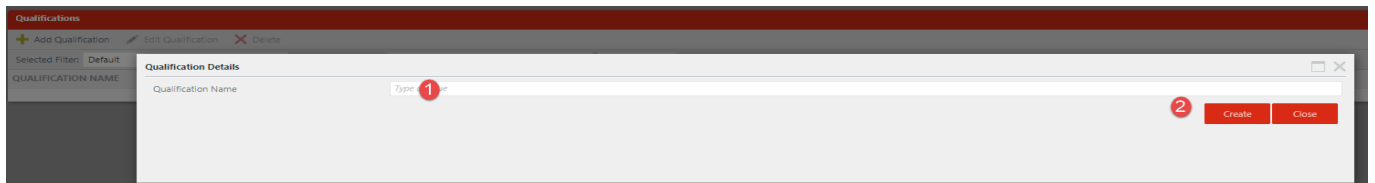## 7.3. Deleting a Professional Body

To delete a Professional Body, click on the entry once, then click on [X Delete] to delete it.

Click **OK** to confirm deletion or **Cancel** to abort.

7.4. Adding a Qualification

To enter your first qualification, click on , then follow the steps below.

Step	System/field	Your input
❶	Qualification name	Enter your **Qualification**.
❷	Create or Close	Click on **Create** to save the qualification or **Close** to abort.

Adding another Qualification

To add another qualification, click on . Thereafter, follow the step in the abovementioned table.

7.5. Editing a Qualification

To edit a qualification that you have created, click on the saved qualification once, and then click on or double click on the entry to amend it. Click on to save or to exit without saving the changes.

7.6. Deleting a Qualification

To delete a qualification, click on the entry once, then click on to delete it.
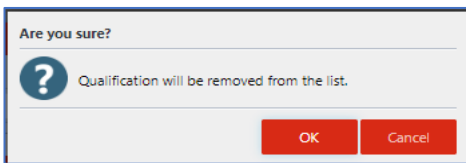
Click **OK** to confirm deletion or **Cancel** to abort.

8. Creating and submitting a new application

- Throughout this user manual, personal information and test data have been redacted.
- All questions prefixed with an asterisk (*) are mandatory.
- All documents to be uploaded by the Principal Investigator must be in the PDF format only.
- This user manual provides guidance on all questions in all 11 sections of the application that the Principal Investigator may be required to complete.
- Depending of the choices made to certain questions, some questions or whole sections may be suppressed i.e., no input is required from you for the suppressed questions or sections.
- Throughout the system, where you have made a selection to a question, entered data in subsequent questions or sections, but then change the selection to that question, the system will alert you that the subsequent data you entered will be deleted. Therefore, carefully consider your answer choices.
- Where abbreviations or acronyms are used, type out the full word or name followed by the abbreviation or acronym in brackets. Thereafter you may use the abbreviation or acronym only.

On the landing page menu, click on ③ **New Application > New Application**

8.1. SECTION 1: INVESTIGATOR DETAILS

Question number	System/field/question	Your input
*S1-1 *S1-2 *S1-3	Principal Investigator Professional body PI Contact details	The data displayed in this question is pulled through from **My Profile** section (refer section 7 above). The data cannot be changed in the application but only in your profile. If you want to make a change to your profile that should reflect in the new application, abort this application now and update your profile, then restart the new application creation process.
*S1-4	HOD Details	Complete the details for the Head of Department (HOD).
*S1-5	Is there more than 1 Investigator?	If you select **No**, proceed to *S1-6.

		If you select **Yes**, proceed to the 8.1.1 **Investigators** that will appear at the bottom of the screen.
*S1-6	Purpose of the research	If you select **No**, proceed to *S1-7. If you select **Yes**, enter the degree related to your research.
*S1-7	Has this research/study been reviewed by a Scientific Committee?(Universities or Research Organizations)	If you select **No**, proceed to *S1-8. If you select **Yes**, proceed to *S1-7a.
*S1-7a	Upload Scientific Review Approval Letter from your Institution (PDF format only)	Upload the Scientific Review Approval letter that you received from your Institution.
*S1-8	Did you submit and received pre-approval from SANBS to undertake this research?	If you select **No**, you will not be able to proceed with this application. You may choose to [Save] the application and return to it at a later time or [Close] to abort the application. If you select Yes, proceed to *S1-8a.
*S1-8a	Upload the SANBS pre-approval letter (PDF format only).	Upload the pre-approval letter that you received from SANBS.

8.1.1. Adding a Secondary Investigator
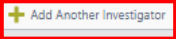
To add a secondary investigator, click on [+ Add Another Investigator], then follow the steps below.

Step	System/field	Your input
❶	Type of user	Select SANBS staff or External as appropriate.
❷	Internal user name	If the secondary investigator is a SANBS employee, enter the users first name in this field and then select the correct name from the list other SANBS employees with a similar first name. Then proceed to select the employees' title. All other fields will be populated from data stored on the SANBS Network.

❸	Name	If you selected External in 1 above, enter the secondary investigators; *first name*
❹	Surname	Enter the secondary investigators' *Surname*
❺	Title	Enter the secondary investigators' *Title*
❻	Primary email	Enter the secondary investigators' *Primary email* address
❼	Save or Close	Select *Save* to save the data or *Close* without saving the data.

8.1.2. Adding another Secondary Investigator

To add another secondary investigator, click on [Add Another Investigator]. Thereafter, follow the step in **8.1.1 Adding a Secondary Investigator**.

8.1.3. Editing a Secondary Investigator

To edit a secondary investigator that you have created, click on the saved secondary investigator once, and then click on [Edit Investigator] or double click on the entry to amend it. Click on [Save] to save or [Close] to exit without saving the changes.

8.1.4. Deleting a Secondary Investigator

To delete a secondary investigator, click on the entry once, then click on [X Delete] to delete it.

When done with Section 1, click on [Save] to save or [Close] to exit without saving the changes.
You may then click on the next section at the top of the screen.

8.2.   SECTION 2: STUDY DETAILS

Question number	System/field/question	Your input
*S2-1	Title of the study	Enter a short but meaningful title for your study.
*S2-2	Aims and objectives of the study	Enter the requested information.
*S3-3	Relevant background and significance of the study	Enter the requested information.
*S2-4	Study design	Enter the requested information.
*S2-5	Procedures	Enter the requested information.
*S2-6	Statistical analyses	Enter the requested information.
*S2-7	Outcomes measures	Enter the requested information.
*S2-8	Estimated study start date	Select an estimated study start date. Please take into account the dates of the next SRC and HREC meeting before you select the estimated start date.
S2-9	Estimated study end date	Select an estimated study end date. Please take into account the dates of the next SRC and HREC meeting before you select the estimated end date.
*S2-10	Study duration: number of years	Select the appropriate option from the available options.

When done with Section 2, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.3. SECTION 3: STUDY PARTICIPANTS

Question number	System/field/question	Your input
*S3-1	Study type	This section comprises 4 questions S3-1a to S3-1d. Depending on your selection to each question, subsequent questions or sections may be suppressed. If you should change your selection to any of these 4 questions, the subsequent data you have entered after your original selection will be deleted. The system will warn you of this and offer you an opportunity to reconsider the change.
S3-1a	Will your research involve study participants directly or indirectly?	If you select **No**, save and proceed to section 4. If you select **Yes**, proceed to S3-1b.
S3-1b	Will your research involve the review of participant data only?	If you select **No**, proceed to S3-1d. If you select **Yes**, proceed to S3-1c.
S3-1c	Will you only analyse data from participant who gave consent on the SANBS Donor questionnaire that their data can be used for research purpose?	If you select **No**, a warning message will be displayed informing you that the application cannot be considered without participant consent. You may click on [OK] to abort this application or [Cancel] to reconsider your response. If you clicked on [OK], the system will not save your data and you will be returned to your dashboard page. If you select **Yes**, proceed to *S3-2.
S3-1d	Will the participants undergo a procedure or intervention?	After your **Yes** or **No** selection, proceed to *S3-2.
*S3-2	Participant demographics - Age Group	Make a selection from the available options.
*S3-3	Participant demographics - Gender	Make a selection from the available options.
*S3-4	Participant demographics - Race	Make a selection from the available options.
*S3-5	Number of study participants	Enter a number from zero upwards.
*S3-6	Number of control participants	Enter a number from zero upwards.
*S3-7	What are the inclusion criteria?	Enter the requested information.
S3-8	What are the exclusion criteria?	Enter the requested information.
*S3-9	How are participants going to be recruited?	Enter the requested information.
*S3-10	How will privacy and confidentiality be protected during recruitment?	Enter the requested information.
*S3-11	Are participants subordinate to investigator?	Make a selection from the available options.

Question number	System/field/question	Your input
*S3-12	Is there payment for participants?	If you select **No**, proceed to *S3-13. If you select **Yes**, proceed to *S3-14.
*S3-13	If *no,* why not?	Enter the requested information.
*S3-14	If *yes*, what is the justification and amount?	Enter the requested information.
*S3-15	What is the time commitment for participants in the study?	Enter the requested information.
*S3-16	Does this study involve vulnerable groups?	If you select **No**, [Save] and proceed to the next section. If you select **Yes**, proceed to *S3-17.
*S3-17	If *yes*, which group?	Make a selection from the available options. If you select Other, proceed to *S3-18.
*S3-18	If *other*, please specify.	Enter the requested information.
*S3-19	What measures will be taken to minimize risks/discomfort for such groups?	Enter the requested information.

When done with Section 3, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.4. SECTION 4: PROCEDURES

Question number	System/field/question	Your input
*S4-1	What study procedures are to be performed on participants?	Select one or more entries from the available options. If you select *Any Other,* proceed to *S4-2.
*S4-2	Any other (Please explain)	Enter the requested information.
*S4-3	Give details of the procedure to be carried out:	Enter the requested information.
*S4-4	Are there one or more person(s) carrying out the procedures?	If you select **No**, proceed to *S4-5. If you selected **Yes**, follow the steps under **8.4.1** to DD, **8.4.2** to edit or **8.4.3** to delete **person(s) carrying out the procedures.**
*S4-5	Are there one or more sites where the study will be performed?	If you select **No**, [Save] and proceed to the next section. If you selected **Yes**, follow the steps under **8.4.4** to add, **8.4.5** to edit or **8.4.6** to delete **Site Details.**

8.4.1. Details of person(s) carrying out the procedures.

To add the details of the person(s) carrying out the procedures, click on [Add Person Performing Procedure] , then follow the steps below.

Step	System/field	Your input
❶	Title	Make a selection from the available options.
❷	Name	Enter the requested information.
❸	Surname	Enter the requested information.
❹	GCP Training	Enter the requested information if this is applicable.
❺	Name of Service Provider	Enter the requested information if this is applicable.
❻	Other training provided/experience	Enter the requested information if this is applicable.
❼	Save or Close	Select **Save** to save the data or **Close** without saving the data.

Adding the details of another person carrying out the procedures

To add another person carrying out the procedures, click on [Add Person Performing Procedure] . Thereafter, follow the steps in section **8.4.1** mentioned above.

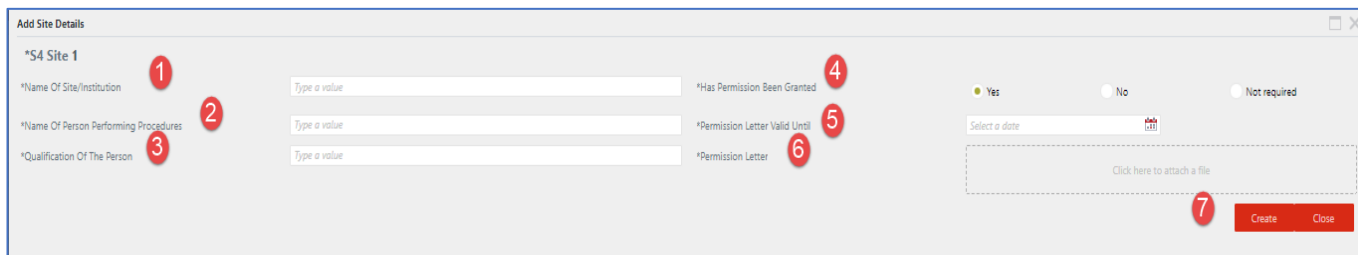8.4.2. Editing the details of a person carrying out the procedures

To edit an entry, click on the saved entry once, and then click on [Edit Person Performing Procedure] or double click on the entry to amend it. Click on [Update] to save or [Close] to exit without saving the changes.

8.4.3. Deleting the details of a person carrying out the procedures

To delete an entry, click on the entry once, then click on [X Delete] to delete it. Click [OK] to delete or [Cancel] to abort the deletion.

8.4.4. Site details

To add a site where the study will be performed, click on [+ Add Another Site], then follow the steps below.

Step	System/field	Your input
❶	Name of site/institution	Enter the requested information.
❷	Name of person performing the procedures	Enter the requested information.
❸	Qualification of the person	Enter the requested information.
❹	Has permission been granted?	If you select **Yes**, proceed to ❺ below. If you select **No**, your application will not be reviewed by the SRC or HREC Committees. You may choose to click on [Save] to save and complete this information later or [Close] to exit without saving the changes. If you select **Not Required**, proceed to ❼ below
❺	Permission letter valid until	Select a date from the calendar.
❻	Permission letter	Upload the permission letter in PDF format.
❼	Save or Close	Select **Save** to save the data or **Close** without saving the data.

Adding another site

To add another site, click on [+ Add Another Site]. Thereafter, follow the steps in section **8.4.4** mentioned above.

8.4.5. Editing the site details

To edit an entry, click on the saved entry once, and then click on [Edit Selected Site] or double click on the entry to amend it. Click on [Update] to save or [Close] to exit without saving the changes.

8.4.6. Deleting the site details

To delete an entry, click on the entry once, then click on [X Delete] to delete it. Click [OK] to delete or [Cancel] to abort the deletion.

When done with Section 4, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.5. SECTION 5: THERAPEUTIC INTERVENTION

Question number	System/field/question	Your input
*S5-1	Does this study involve therapeutic intervention?	If you select **No**, proceed to *S5-3 If you select **Yes**, proceed to *S5-2a
*S5-2a	If yes, has provision been made to deal with adverse events or complications?	If you select **No**, proceed to *S5-2b If you select **Yes,** provide further information in the textbox that will be displayed.
*S5-2b	What is the product given?	Enter the requested information.
*S5-2c	What is the dose given?	Enter the requested information.
*S5-2d	What is the frequency of dosing?	Enter the requested information.
*S5-2e	What is the duration of treatment?	Enter the requested information.
*S5-3	Will you be withholding standard therapy in the course of research?	If you select **No**, proceed to *S5-5 If you select **Yes**, proceed to *S5-4
*S5-4	If yes, please provide justification:	Enter the requested information.
*S5-5	Are there any known risks associated with giving this product?	If you select **No**, proceed to *S5-7 If you select **Yes**, proceed to *S5-6
*S5-6	If yes, please highlight risks:	Enter the requested information.
*S5-7	Are any other treatments that are contra-indicated during the study?	If you select **No**, proceed to *S5-9 If you select **Yes**, proceed to *S5-8
*S5-8	If yes, please specify:	Enter the requested information.
*S5-9	Who will monitor the safety of the administered drug?	Enter the requested information.

When done with Section 5, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.6. SECTION 6: CONFIDENTIALITY AND PRIVACY OF PARTICIPANTS

Question number	System/field/question	Your input
*S6-1	Are you collecting primary data with patient identifiers (Name, ID, etc.)?	If you select **No**, proceed to *S6-3 If you select **Yes**, proceed to *S6-2
*S6-2	If yes, which identifiers are you collecting?	Select one or more entries from the available options.
*S6-3	How will confidentiality be maintained so that patients/ participants /controls are not identifiable to persons not involved in the research? Type a value	Enter the requested information.
*S6-4	How will the investigator maintain privacy of participants in the research setting? Type a value	Enter the requested information.
*S6-5	Will data and participant identifiers be stored separately linked by a code?	If you select **No**, proceed to *S6-7 If you select **Yes**, proceed to *S6-6
*S6-6	Who will have access to code, data and data identification?	Enter the requested information.
*S6-7	Is a sample data collection sheet or questionnaire attached?	If you select **No**, proceed to *S6-8 If you select **Yes**, proceed to *S6-7a If you select **Not Required**, [Save] or [Close] this section.

When done with Section 6, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.7. SECTION 7: INFORMED CONSENT

Question number	System/field/question	Your input
*S7-1	Is written informed consent required?	If you select **No**, proceed to *S7-2 If you select **Yes**, proceed to *S7-1a
*S7-1a	Upload sample written consent form	Upload the required document in PDF format.
*S7-2	If *no*, explain why written consent if not required:	Enter the requested information.
*S7-3	For participants <18 years of age, a Parental Informed consent is required. Will this be provided?	If you select **No**, a warning message will be displayed informing you that the application cannot be considered without the sample Parental Written consent. You may choose to click on [Save] to save and complete this information later or [Close] to exit without saving the changes If you select **Yes**, proceed to *7-3a.
*S7-3a	Upload sample Parental Informed consent form	Upload the required document in PDF format.
*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?	If you select **No**, a warning message will be displayed informing you that the application cannot be considered without the sample Informed Assent. You may choose to click on [Save] to save and complete this information later or [Close] to exit without saving the changes If you select **Yes**, proceed to *7-4a.
*S7-4a	Upload sample Informed Assent form	Upload the required document in PDF format.

| |
|---|
| When done with Section 7, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen. |

8.8. SECTION 8: RISK ASSESSMENT

Question number	System/field/question	Your input
*S8-1	Are there risks to participants?	If you select **No**, proceed to *S8-3 If you select **Yes**, proceed to *S8-2
*S8-2	Explain how this will be mitigated:	Enter the requested information.
*S8-3	Are there risks to SANBS?	If you select **No**, proceed to *S8-5 If you select **Yes**, proceed to *S8-4
*S8-4	Explain how the risk(s) will be mitigated:	Enter the requested information.
*S8-5	Are there risks to the institution where the study is conducted?	If you select **No**, proceed to *S8-7 If you select **Yes**, proceed to *S8-6
*S8-6	Explain how this will be mitigated:	Enter the requested information.
*S8-7	What is the DAIDS Risk/Benefit Category?	Select one of the available options.

When done with Section 8, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.9. SECTION 9:   BENEFITS

Question number	System/field/question	Your input
*S9-1	What are the benefits of the study to participants?	Enter the requested information.
*S9-2	What are the benefits of the study to SANBS? Type a value	Enter the requested information.
*S9-3	What are the benefits to the institution performing the study?	Enter the requested information.
*S9-4	What is the contribution of sponsor / research to capacity building in the community which is to be studied?	Enter the requested information.

When done with Section 9, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.10. SECTION 10:   RESULTS

Question number	System/field/question	Your input
*S10-1	Are the study results going to be made available to participants?	If you select **Yes**, proceed to *S10-3 If you select **No**, proceed to *S10-2
*S10-2	If *no*, explain.	Enter the requested information.
*S10-3	Are the study results going to be made available to SANBS?	If you select **Yes**, proceed to *S10-5 If you select **No**, proceed to *S10-4
*S10-4	If *no*, explain.	Enter the requested information.
*S10-5	Are the study results going to be made available to your institution?	If you select **Yes**, proceed to *S10-7 If you select **No**, proceed to *S10-6
*S10-6	If *no*, explain.	Enter the requested information.
*S10-7	Will any personal data or biological material be stored after the study?	If you select **Yes**, proceed to *S10-8 If you select **No**, [Save] or [Close] this section.
*S10-8	If yes, has specific permission been obtained for this?	If you select **Yes**, proceed to *S10-8a If you select **No**, proceed to *S10-8b
*S10-8a	Upload sample permission letter	Upload the required document in PDF format.
*S10-8b	If *no*, please explain.	Enter the requested information.

When done with Section 10, click on [Save] to save or [Close] to exit without saving the changes.

You may then click on the next section at the top of the screen.

8.11. SECTION 11:   FUNDING

Question number	System/field/question	Your input
*S11-1	Is this study funded by an Institution?	If you select **Yes**, proceed to *S11-2 If you select **No**, proceed to *S11-3
*S11-2	Please give details of the Institution funding this study	Enter the requested information.
*S11-3	Is this study funded by a National Body?	If you select **Yes**, proceed to *S11-4 If you select **No**, proceed to *S11-5
*S11-4	Please give details of the National Body funding this study.	Enter the requested information.
*S11-5	Is this study funded by an International Body?	If you select **Yes**, proceed to *S11-6 If you select **No**, proceed to *S11-7
*S11-6	If *no*, explain.	Enter the requested information.
*S11-7	Is there a potential or actual financial conflict of interest for investigators?	If you select **Yes**, proceed to *S11-8 If you select **No**, [Save] to return to the application at a later time or [Close] to exit without saving or [Save & Submit] to save and submit to the SANBS HREC for review.
*S11-8	If *no*, explain.	Enter the requested information.

When done with Section 11, click on [Save] to save or [Close] to exit without saving the changes or [Save & Submit] to save and submit to the SANBS HREC for review.

When you [Save & Submit] your application:
- you will not be able to amend the application
- the system will assign a reference number for your application with the format HREC-yyyy/nnnn.
- an email will be sent to you advising you of the reference number.
- an email will be sent to any Secondary Investigator(s) to update their profile where applicable
- when all Secondary Investigators have updated their profiles, the Principal Investigator will be sent an email that the application has been routed to the SRC Administrator to commence the review process.
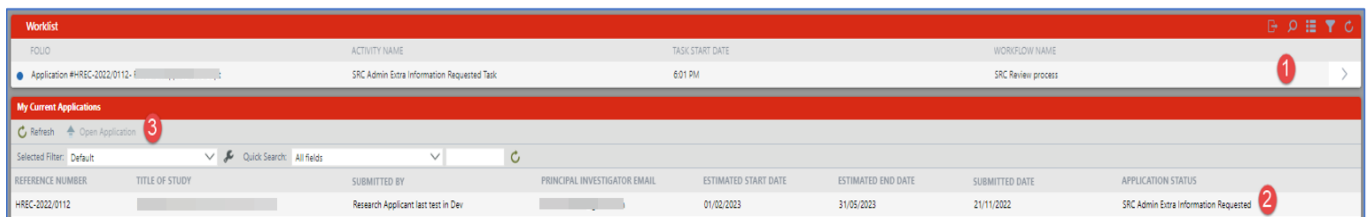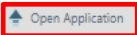
9. Submitting extra information

9.1. Introduction

At different stages of the application review process, you may be requested to provide extra information or elaborate on information already provided. At each stage, an email will be sent to the Principal Investigator specifying what extra information is required. The email will contain the link to login to the system and also details of when the next SRC and/or HREC meeting is scheduled. The extra information must be uploaded or corrected within 3 months of the request, failing which the application will be closed and you will be required to restart the entire submission process if you wish to continue with the application.

9.2. Submitting extra information

After you've clicked on the link in the email and logged into the system, follow the steps below to submit extra information.

Step	System/field	Your input
❶	Worklist task	Click on the arrow on the right to open the application and submit the extra information or correct the information already provided.
❷	My Current Application – Application status	Note the status of the application. In this example, the SRC Administrator requested extra information.
❸	My Current Application – Open Application	Another way to provide the extra information is to click once on the reference number and then click on ⬆ Open Application or double click on the reference number.

The application will be opened, defaulting to Section 1.

Scroll down to the bottom of screen to a section titled **Rework instructions.** Here you find the sections and questions that you are required to provide the extra information or correct the information already provided. In this example, the Principal Investigator is required to elaborate on question S4-3.
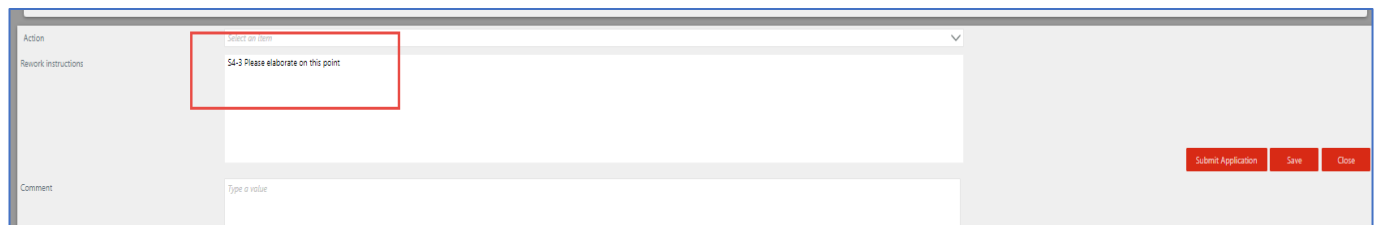
Go to the relevant question. You will note a tick next to the question.
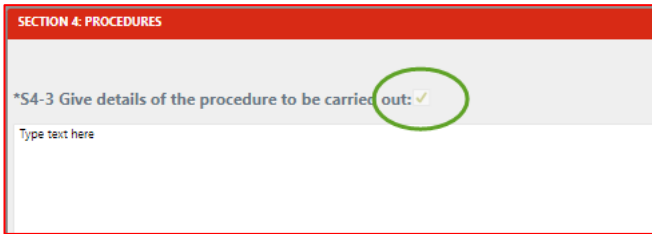
This is also an indicator that you are required to provide extra information for this question. Only the questions with the tick will be editable. All other questions will be locked for editing. This is to ensure that other questions that were already reviewed and found to be in order are not changed when extra information is requested.

At this point, you may edit the question as requested. If the request is for an uploaded document to be replaced with a corrected version, click on the uploaded document once, and then click on the delete icon on the extreme right of that field. You may then upload a new version (PDF version only).

Below is an example of the edited question.
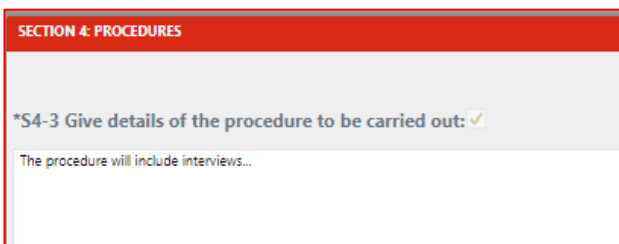
You may add an optional comment at the bottom of the screen under the Comment section.

Once you have updated the extra information for all flagged questions and added your comment, click on the Action dropdown list and select **Submit amended information**, then click on [Submit Application]. You may choose to [Save] the application and return to it at a later time or [Close] to abort the changes.

The system will return you to the Principal Investigator dashboard. If you refresh the screen (press F5 on the keyboard), you will note the status of the application change, in this example where the SRC Administrator has requested the extra information, to SRC Admin Review. In this example the SRC Administrator will need to review the extra information provided.

An email will be sent to the Principal Investigator confirming that the extra information has been submitted.

In this example, should the SRC Administrator accept the extra information, the application will be accepted and automatically moved to the next stage in the process. If the reviewer is not satisfied with the extra information, the process outlined in this section will be repeated until there is acceptance.

9.3. Requesters of extra information
The following reviewers may request extra information:
   9.3.1. SRC Administrator after reviewing the application for SRC administrative correctness
   9.3.2. SRC Committee after they meet to discuss the application for Scientific merit/soundness
   9.3.3. HREC Administrator after reviewing the application for HREC administrative correctness
   9.3.4. HREC Committee after they meet to discuss the application for Ethical merit/soundness

The procedure outlined in **9.2 Submitting extra information** applies to all requests for extra information.

> Although there may be a number of requesters of extra information, the email you receive will only be sent by the SRC Administrator or HREC Administrator.

10. Digitally signing the PI Declaration form

One of the mandatory requirements when submitting a research application is for a declaration form to be completed by the Principal Investigator and his or her Head of Department. This form must be signed after the SRC Administrator is satisfied that all administrative requirements are met and that the protocol can be routed to the SRC Committee Members for review.

10.1. Signing of the Declaration form

On approval of the protocol by the SRC Administrator, the system will generate the declaration form. The form will then be added to a digital signature software named Adobe Sign. Both the Principal Investigator and Head of Department must consecutively sign the form electronically and submit it in the Adobe Sign software. On receipt of the fully signed form, the SRC Administrator will upload the signed form to the system. This will trigger the application to be routed to the SRC Review Members to review the application.

Note that you do not need Adobe Sign to be loaded onto your computer. On receipt of the email, click on Review and Sign, click on start (flagged in yellow on the left of your screen), add your signature and any other requested information and click on submit at the bottom of the screen. Do not print the form and sign it manually, as the signature has to be an electronic one. For a short tutorial on signing a document using Adobe Sign, click on this YouTube link
https://www.youtube.com/watch?v=wLS1vuvBqN0

Adobe Sign will keep you apprised of the status of the signing process as well as send each signing party and the SRC Administrator a copy of the fully signed document.

11. Submitted applications

On the Principal Investigator Landing Page in section **6**, click on ❺ *Submitted Applications*.

Submitted applications are applications that you have submitted for review. These applications cannot be edited unless you are requested to do so by unless requested to do so by the SRC or HREC Administrators.

Below is an example of applications submitted. Take note of the different statuses of each application. These statuses indicate to you exactly where in the review process each application is.

REFERENCE NUMBER	TITLE OF STUDY	SUBMITTED BY	PRINCIPAL INVESTIGATOR EMAIL	ESTIMATED START DATE	ESTIMATED END DATE	SUBMITTED DATE	APPLICATION STATUS
HREC-2023/0001				01/03/2023	30/06/2023	15/02/2023	SRC Admin Review
HREC-2022/0112				01/02/2023	31/05/2023	21/11/2022	SRC Admin Review
HREC-2022/0096				01/12/2022	30/11/2023	05/11/2022	HREC Accepted
HREC-2022/0085				14/11/2022	30/12/2022	03/10/2022	HREC Accepted
HREC-2022/0078				03/10/2022	28/06/2024	18/09/2022	HREC Admin Prepare Acceptance Letter
HREC-2022/0069				01/11/2022	31/03/2023	13/09/2022	HREC Admin Prepare Acceptance Letter
HREC-2022/0071				03/10/2022	30/09/2023	10/09/2022	Secondary Investigators Complete Details

12. Saved Applications

On the Principal Investigator Landing Page in section **6**, click on ④ *Saved Applications*.

Saved applications are applications still in draft and can be edited at any time until it is submitted for review. Thereafter, no changes can be made unless requested to do so by the SRC or HREC Administrators. No reference number is assigned to draft applications.

Step	System/field	Your input
❶	Edit application	Click once the draft application that you want to edit, then click on Edit Application or double click on the entry. Follow the steps in section **8 Creating and submitting an application** to submit the application for review.
❷	Delete application	Click once on the draft application, then click on **Delete application.** Click [OK] to delete or [Cancel] to abort the deletion.
❸	Submit	Click on **Submit** to continue.

13. Approved or declined applications

Only the SRC and HREC Committee may approve or decline your application following a meeting of committee members.

On approval of the application by the HREC Committee, an email with a Clearance Certificate will be sent by the HREC Administrator. No certificate is sent after the SRC approves the application.

Should your application be declined for whatever reason by either the SRC or HREC Committee, you will be sent an email outlining the details of why the application was declined. You may choose to rework your application and resubmit (starting from scratch) or abort the process.

14. Progress reports

There is currently no functionality built into the system for you to electronically submit your progress report. However, the progress report may be sent to the HREC Administrator (HRECAdmin@sanbs.org.za)

Progress reports are to be submitted annually until the research is completed. For applications whose duration is less than a year, the progress report must be sent as soon as the research is concluded.

15. Getting help

For all application and system related queries, please send an email to SRCAdmin@sanbs.org.za.

16. Revision Summary

VERSION NUMBER	REVISION DETAILS
0	New document