STELLENBOSCH UNIVERSITY

Research Information Management System

INFONETICA



Training Manual

Compliance/Ethics – New Application





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1. Login

The URL for the Infonetica site is https://applyethics.sun.ac.za/

You will be required to login using your <u>username@sun.ac.za</u> and network password. Follow the instructions that are applicable to you.



If you do struggle to gain access; please try the following before you contact us for further assistance:

1. Try logging in to <u>https://portal.office.com</u>; if you aren't able to login then you need to be setup and IT will be able to do this for you before you can gain access to the new Online Ethics Research Appilcation site



2. Can you please go to <u>https://maties2.sun.ac.za/rtad4/useradm/</u>, sign in with your existing SU credentials, change your password, and try to log in to Infonetica again.

If you still experience login issues, contact Xabiso Xesi (<u>xabiso@sun.ac.za</u>) or Nicole Walker (<u>nwalker@sun.ac.za</u>) for further assistance.

| STOP | <u>STUDENTS PLEASE NOTE</u> : Please make sure you are registered before attempting to login. |
|---------------------|---|
| CRITICAL WARNING | Students who require applying for ethics clearance before they are registered must do this in consultation with their relevant department as the department will have to add them to the Information Technology SUNID temporary user database so that the student can be issued a username (active sun email address) and password by IT. <u>Please note that the SUNID process in not an</u> <u>ethics process, it is a completely separate process and is handled</u> <u>entirely by the relevant department</u> |

2. Create your project

Once logged in, you will see the Infonetica landing page. To create your ethics project online follow the instructions below:

| Re | search Eth | iics Appli | cations Home Conta | cts Help + | | | | | Miss A Applicant + | |
|-------------------|----------------------|-------------------|-----------------------------|-----------------------|---------------|---------------------|---------------------|------------------|--------------------|-----------|
| | Work Area 🖌 | , | Work Are | 23 | Your | Work Area will | | | | 0 |
| ff. | 1 | | | | | open up | | | | |
| Home | Notifications | | General | | | | | | | |
| | Actions 🗸 | | Notifications | Signatures | Transfers | Shared | | | | |
| Create Folder | Delete Folder | Create Project | 1 | 0 | 0 | 0 | | | | |
| Delete Project | Duplicate Project | Transfer | n ojects | | | | | | | |
| | | | 1. Click on 'Cre | eate + Pro | iect ID 💡 Own | er \$ | Date Created | Date Modified | Transfer Status | \$ |
| | | | Project' | 74 | Miss | A Applicant | 18/05/2017 16:33 | 18/05/2017 17:46 | | |
| | | | Showing 1 to 2 of 2 entries | 65 | | | | | 📹 Previo | us Next 🕨 |
| | | | | | | © Infonetica Ltd 20 | 17 Version 8.7.0.0 | | | |
| | | | | | | Terms and Condition | ns Privacy Policy | | | |
| | | | | | | | | | | |

| ĸА | Create Project | 2. Enter Project × Title |
|-----|---|---|
| | Project Title:* | |
| 1 | Enter project title here | |
| ons | Main Form Please Select | 3. Click on down-arrow and <u>SELECT</u> <u>APPROPRIATE</u> APPLICATION FORM |
| | Please Select REC Humanities New Application Form Animal Care and Use New application Form | |
| S | Biosafety-facility Registration Form Health Research New Application Form HREC Biobank Application Form | Close |
| cts | Animal Ethics Notification Form HREC Case Report Form HREC Exemption Application Form | |
| le | 🍦 Project ID 🛛 👻 Owner | 🔶 Date Created 🔶 |



**** NB: PLEASE ENSURE THAT YOU SELECT THE CORRECT APPLICATION FORM**

3. Complete the questions online

The system has now created a record for you with a system generated number. The next step is to complete the electronic application form.

| Re | esearch Eth | nics Applica | ations Home Contacts Help + | Beta Test M | lode | Miss A Applicant + |
|------------------------------|-----------------------|---------------------|---|---|--|------------------------|
| | Work Area 🔹 | • | Enter project title | here | | 0074 🕘 |
| Home | O Notifications | | Project Tree ♥ | | | |
| Project | Actions 🕶 | Create Sub- form | Enter project title here Health Research New Appl | ication Form | | |
| < | ~ | £ | Form Status | Review Reference | Date Modified | |
| Share | Completeness Check | Submit | Not Submitted | N/A | | |
| A Automatic Submission | Refresh | Print | Navigation | Documents Signatures Collaborators Submissi | ons Correspondence History | |
| Correspond | i | | Health Research I | New Application Form | | Show Inactive Sections |
| | | | Section Filter | Questions Filer Questions © Infonetica Ltd 2. Terms and Continen | 4. CLICK ON THE BLUE LINK TO OPEN UP YOUR FORM AND BEGIN ANSWERING THE QUESTIONS | |

You can now complete all the relevant questions in the e-form. Use the NEXT OR PREVIOUS BUTTONS on the left panel to navigate the online form.

| Research Ethics Applica | tions Home Contacts Help - | Beta Test Mode | | Miss A Applicant 🗸 |
|--------------------------------|---|---|----------------------------------|--------------------|
| Actions V | Health Research N | lew Application Form | 2. COMPLETE ALL THE QUESTIONS | 0074 OVERSION 1 |
| Previous Next Navigate | 3. CLICK ON THE NEXT BUTTON TO MOVE TO THE NEXT PAGE OF THE FORM | Ethics Committees (HRECs) mittees (HRECs) only search Ethics Committee Application Form. This is an appli | ON EACH PAGE | |
| Save Share Collaborators | P 1. SHARE YOUR APPLICAT | for: on of Clinical and Health Research. | | 0 |
| Completeness mit | FORM WITH YOUR SUPERVISOR | | | |
| CONTINUING TO THE NEXT PAGE | Study for Degree purposes | | | Ŷ |
| | Is this a study for Degree purposes (inclu | ding electives and skripsies)? | | |
| | Current level of study: Masters | v | | |

| | <i>Tip: If you are working on your e-form and you want to stop and continue at a later stage, you have to SAVE the e-form information and click on SAVE button icon</i> |
|------|---|
| Tips | on the left panel. When you are ready to work on the e-form again, login and click on Filter questions again. |

| | <i>Tip: If you wish to go back to the beginning of your form then click on the Navigate button to direct you to the sections page.</i> |
|------|--|
| Tips | |

PLEASE NOTE:

Always update the form when the system prompts you to do so as a new version of the form has been created. When this happens a message will appear on top for you to click on the Update link.

| Project Tree 🛩 | | not. | | of the project. Opdate | | | |
|---|---------------------------------|-------------------|---|---|---|--|------------------|
| Nicole Te O RE(| esting) C Humanities New App | ication Form | Alwa foi appli | ys click on upda m before contir cation as you w submit the late | ate to up nuing with vill only be est versio | date the h your e able to on. | |
| Form Status | | Review Refe | rence | | | | |
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4. Share your application with your supervisor



A notice will appear that your form has been shared successfully.

Your Supervisor will now be able to login, read and share comments with you while you are working on your form as shown below:

| Re | search Ethi | ics Applica | tions Home Contact | is Help • | B | eta Test Moo | le | Ms Nicole Walker + |
|--------------------|------------------------|----------------|--------------------------|------------|------------|------------------|------------------|--|
| | Work Area 🔹 | * | Work Are | a | | | | |
| b 👫 | 24 | | | a | | | | WHEN YOUR SUPERVISOR |
| Home | Notifications | | General | | | | _ | LOGS IN IT WILL APPEAR IN THEIR SHARED FOLDER |
| | Actions • | | Notifications | Signatures | Transfers | Shared | | |
| Create Folde | r Delete Folder I | Create Project | 24 | 0 | 0 | 1 | | |
| O Delete Projer | t Duplicate Project | Transfer | Projects | | | | | |
| | | | Search Projects | | | | | |
| | | | Project Title | | Project ID | Owner | Date Created | Date Modified Transfer Status |
| | | | Enter project title here | | 74 | Miss A Applicant | 18/05/2017 16:33 | 18/05/2017 16:40 |



Tip: If you are working on your e-form and you want to stop and continue at a later stage, you have to SAVE the e-form information and click on SAVE button icon on the left panel. When you are ready to work on the e-form again, login and click on Filter questions again.

| Res | earch Et | hics Applica | tions Home Contacts Help - Beta Tesi | | Miss A Applicant 🗸 |
|----------|---|---|---|---|---|
| | Actions 🗸 | 4 | Health Research New Application For | HOVER OVER THE YELLOW ICON. IT SHOWS THAT YOUR SUPERVISOR IS CURRENTLY ON | Version: Version 1 |
| Previous | Next | Navigate | Application to the Health Research Ethics Committees (HRECs) | THIS PAGE AS WELL | Collaborators on this page are: Ms Nicole Walker |
| Print | Documents | Signatures | Application to the Health Research Ethics Committees (HRECs) only Make sure you are completeing the correct Research Ethics Committee Application Form (HRECs) | . This is an application to the Health Research Ethics Com | nittees |
| Save | Share | Collaborators | Please select the type of research you are applying for: Please click the Information (*7) icon to the right for the definition of Clinical and Health Research © Clinical Trial © Health Research | | 0 |
| | ONE C BEEN T CC BETWE YOUR | OMMENT HAS ADDED. KEEF RACK OF OMMENTS EN YOU AND SUPERVISOF | Study for Degree purposes | | O |
| | | | © Yes ⊛ No | | |

Click on the speech bubble icon to view your supervisor comment/s.

| Re | search Et | hics Applic | ations Home Contacts Help - | Beta Test Mode | Miss A Applicant + |
|----------|----------------|-----------------|--|---|-------------------------------|
| | Actions 🗸 | | ● Yes ● No | | 0 |
| Previous |) Next | Navigate | Will there be students working on this p | oject as part of the research team but NOT for degree purposes? | • |
| Print | 0 Documents |) Signatures | YesNo | | |
| Save | Share | Collaborators | ß | | |
| | | 1 Commente | Linked existing/main studies | 1. CLICK SPEECH ICON TO VIE | ON THE BUBBLE EW OR ADD |
| Check | s Submit | comments | Is this a sub-study (new research questi | on) linked to an existing/main study? | ENTS |
| | | | OR Are there any other Stellenbosch Univer | sity Ethics applications that are related to, or have a bearing on, this new application? | |
| | | | This includes any ethics applications tha REC: Humanities, REC: AUC or REC:BI | t have already been reviewed or are pending review at any of the 5 Stellenbosch Ethics Comn (E). | nittees (HREC1, HREC2, |
| | | | YesNo | | |
| | | | | | |
| | | | | | |

| Date Added | Owner | |
|-----------------------------------|-----------------------------------|--|
| Now | | |
| | You | |
| Thursday, May 18, 2017 at 5:22 PM | Ms Nicole Walker | |
| | Close | * |
| | Fhursday, May 18, 2017 at 5:22 PM | Chursday, May 18, 2017 at 5:22 PM Ms Nicole Walker |

You can add comments for your supervisor to view while working through your application form.

Keep track of the comments made between you and your supervisor by clicking on the speech bubble or comments button in the action panel.

| Res | search Et | nics Applica | ations Home Contacts Help + | Beta Test Mode | Miss A Applicant + |
|-----------------------|------------------|---|---|--|-----------------------------|
| | Actions 🗸 | | • Yes | | |
| Previous | Next | 1 Navigate | © No | | |
| Print | Documents | Signatures | Will there be students working on this pro Ves No | oject as part of the research team but NUT for degree purposes? | |
| Save | Share | Collaborators | | | |
| Completeness Check | Submit | 2 Comments | Linked existing/main studies | on) linked to an existing/main study? | \mathcal{Q} |
| | | | OR Are there any other Stellenbosch University | "Curves applications that are related to, or have a bearing on, this new application? | |
| | YOU BE SHA | R COMME EN ADDEI RED WITH SUPERVIS | AND HAS DAND I YOUR OR es No | t have already been reviewed or are pending review at any of the 5 Stellenbosch Ethic E). | s Committees (HREC1, HREC2, |
| | | | | | |

Adding your supervisor's details in the form:

| Res | earch Etł | nics Applica | ations Home Contacts | s Help v | Beta Test Mode | Ms Nicole Walker 👻 |
|-----------------------|-----------|---------------|------------------------|---------------------|---|--|
| | Actions 🗸 | , | Health Re | search N | ew ^{Application Form} | 0075 |
| I | | 1 | neurin Ne | Scuron N | | |
| Previous | Next | Navigate | Supervisor | | 1. TYPE IN YOUR | \odot |
| Print | Documents | Signatures | Supervisor's Details | | SUPERVISORS NAME OR EMAIL AND SELECT | |
| m | < | 52 | Xabiso Xesi(xabiso@sur | n.ac.za) | | |
| Save | Share | Collaborators | Title | First Name | Surname | YOUR SUPERVISORS DETAILS WILL AUTOMATICALLY |
| ~ | 1 | | Mr | Xabiso | Xesi | POPULATE IN THE FIELD |
| Completeness Check | Submit | | Organisation | | | |
| | | | Department | Geolo | JY | |
| | | | Faculty | Science | e | |

Information icon displays at a few questions for further description:

| Eile Edit | https://stell | enbosch.forms.ethica | alreviewmanager.com/Proje 🔎 👻 🚔 🖒 🔊 Research Ethics Applications 🛛 | | 6) (4 | ĝ 🙂 |
|-----------|-------------------------|----------------------|--|--|-------------------------------------|-----|
| Res | search Etl Actions ◄ | nics Applicat | tions Home Contacts Help + While any radioactive material be administered to the patient du | Beta Test Mode | fs Nicole Walker v | 0 |
| Previous |) Next | 1 Navigate | ⊖ Yes ⊛ No | | | |
| Print | Documents | Signatures | Biohazadous Materials | | | |
| Save | Share | Scollaborators | Will any Biohazadous Material be involved in the project? | Bioharadous Material refers to recumbent DNA molecules, vi fungi, parasites, bacteria and all other potentially biohazardous or products that are dangerous to both the experimental patien researcher. | iruses, s material at and the | ļ |
| Check | | | Medical Devices | WHEN AN INFORMATION ICC APPEARS YOU CAN CLICK OF FOR FURTHER EXPLANATION/DESCRIPTION O QUESTION | DF A | |
| | | | Will any Medical Device be tested during this investigation? O Yes No | | | |



Uploading a document and viewing a URL Link:

| Re | search Etl | hics Applicat | ions Home Contacts Help - Beta Test Mode M | s Nicole Walker 👻 |
|----------------------------|------------|---------------|---|-------------------|
| | Actions • | • | Participant Insurance | 0 |
| (Construction) Previous |) Next | ◀ Navigate | Procedure for acquiring participant insurance through Stellenbosch University: | |
| b Print | Documents | Signatures | All new research applicants should contact the financial planning and asset management office to register their new research proj Stellenbosch University insurance brokers. | ect with |
| Save | Share | Collaborators | Please contact: Mr Wium van Kerwel, Assistant Account Financial Planning and asset Management tel: 021 - 808 2809 fax: 021 - 808 3663 e-mail: wvankerwel@sun.ac.za | |
| Completene Check | ss Submit | | Confirmation of Registration I confirm that I have registered my research project with with the above WEBPAGE TA | VILL THER B |
| | | | Is the proivision of insurance compliant with SAGCP Section 4.11? See Section 9 "Participant Insurance" of Health Research Ethics (HREC) Standard Operating Procedures (SOP) | |
| | | | | |
| | | | No CLICK ON DELORD DOCUMENT TO SAVE A DOCUMENT IN YOUR | |
| | | | Upload Document | |



Please note that if you click on any of the links in this form it will open up in a separate webpage/tab so remember to check your open webpages to go back to the eform.

5. Signing and Submitting your application

Completing the declaration/signatures on the application form.

HREC New Application Form









6. Request Supervisor Signature (STUDENTS ONLY)

If you are a student conducting the study for degree purposes, you must request your supervisor's signature for his/her approval on the signature declaration page. You can request the signature of ONE supervisor ONLY, so if you have more than one supervisor, please contact your supervisors to confirm who will take responsibility for signing your ethics application.

HREC New Application Form





Please note:

Once you request your supervisor's signature, your application is now with your supervisor for sign off before it will be submitted to the HREC Office.

Always follow up with your supervisor to ensure that they have signed your application form if your application hasn't been submitted to the HREC Office yet.

Keep track of your application by checking the status:





Once your application has been submitted; you will receive a notification:

| Re | esearch Eth | ics Applic | cations Home Conta | cts Help - | | Beta Test | Mode | | Miss A Applicant 👻 | |
|-------------------|----------------------|-------------------|-----------------------------|-----------------------|-----------------|---------------------|---------------------|------------------|--------------------|------------|
| | Work Area ◄ | | Work Are | | | | | | | |
| Home | Notifications | - | General | | | | | | | |
| | Actions 🛩 | | Notifications | Signatures | Transfers | Shared | | | | |
| Create Folder | Delete Folder | Create Project | 1 | 0 | 0 | 0 | | | | |
| Delete Project | Duplicate Project | Transfer | Projects | | | | | | | |
| | | | Search Projects | | | | | | | |
| | | | Project Title | Proj | iect ID 🔷 🗸 Own | er 🗄 | Date Created | Date Modified | Transfer Status | \$ |
| | | | Enter project title here | ? 74 | Miss . | A Applicant | 18/05/2017 16:33 | 18/05/2017 17:46 | | |
| | | | Testing HREC Eform | 65 | Miss | A Applicant | 15/05/2017 13:30 | | | |
| | | | Showing 1 to 2 of 2 entries | | | | | | Previo | ous Next 🕨 |
| | | | | | | © Infonetica Ltd 20 | 017 Version 8.7.0.0 | | | |
| | | | | | | Terms and Conditio | ns Privacy Policy | | | |

Your application has now been submitted for further processing.

| Re | esearch Ethics Ap | Dlications Home Contacts Help + | Beta Test Mode | Miss A Applicant 👻 |
|------|--------------------|---|---|--------------------|
| | Work Area 🖌 | Notifications | | 0 |
| Home | 1 Notifications | Search | | |
| | | Start | | |
| | | Display Please note that only the specified number of notif |) 100 notifications fications will show after searching. | |
| | | m è é Message | Attachment Project Short Title | time . |
| | | Application received | None Enter project title here | 18/05/2017 🗙 |
| | | Back to Work Area | | |

7. Changes Requested or Response to Modifications:

Login and click on your project list.

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| Home Notifications | General | | | | | | | |
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| ate Folder Delete Folder Create Project | 8 | 0 | 0 | 0 | | | | |
| e Project Duplicate Transfer | Projects | | | | | | | |
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| | Project Title | | | Pro ID | ect Owner | Date Created | Date Modified ⁽⁾ | Transfer () Status |
| project to open it | This is your proj | ect title of your Res | earch project | 1234 | Ms A Teste | 15/11/2017 17:50 | 08/03/2018 12:09 | |
| | Showing 1 to 1 of 1 entries | | | | | | 剩 Pr | revious Next 🕨 |
| | | | © Infonetica I | Ltd 2018 Version 9.7.0.0 | | | | |
| | | | Terms and | Conditions Privacy Policy | | | | |

Make your necessary changes or modifications that have been requested, save and then sign to resubmit your application.

| Research Ethics Applications Home Contacts Help + | | | |
|--|--|---|------------------------------------|
| 😼 Work Area 🕶 | I | | |
| Home 8 Notifications | This is your project | t title of your Research project | |
| Actions • | | | |
| Project Create Form Comments | | | |
| Share Pint Correspond | Project Tree | title of your Research project | |
| | Form Status | Review Reference | Date Modified |
| | Response To Modifications | HREC1-2018- 1234 | 08/03/2018 12:09 |
| | Navigation Documents HREC New Applic | Signatures Collaborators Submissions Correspondence | Indence History |
| | Section | Questions | |
| Click on the questions and respond to the modifications by | Filter | Filter Questions Project Title Project Location Project Funding Project Sponsor Applicant/Principal Investigator Supervision(s) Stellenbosch Contacts | Non Stellenbosch Contacts Students |
| adjustments stipulated in the | Human Subjects Research Protection | Human Subjects Research Protection | |
| Modification Required letter you | Type of Study | Study Type | _ |
| received via email. | Research with Children Additional Documents | Research with Children Non-Therapeutic Research Paediatric Bloods Additional Documents | 8 |
| | Disclosures | Disclosures Participant Insurance Exporting Samples/Data Payment | ts Diagnostic Tests |
| | Declarations/Signatures | Head of Division/Department Applicant/Principal Investigator Supervi | sor(s) |
| | | © Infonetica Ltd 2018 Version 9.7.0.0 | |
| | | Terms and Canditions Privacy Policy | |
| | | | |

nrk Area 👻 Work Area 141 Ħ General Actions 🛩 Notifications Transfers Shared Signatures 141 0 4 2 • Projects ct Duplicate Transfer Project Search Projects Image: Project ID - Owner Image: Date Created Image: Date Modified Image: Transfer Status Image: Date Modified Image: Transfer Status Image: Date Modified Image: Da Project Title Nicole Testing 15032018 Nicole Testing NW testing (2) 6448 Miss Nicole Walker 20/02/2018 09:19 20/02/2018 10:42 HREC Test of Amendment 6397 Miss Nicole Walker 14/02/2018 09:37 15/02/2018 14:57 6397 Wilds Niccie Wilker 14/02/2016 04:37 15/02/2016 (4:37) 6348 Miss Niccie Wilker 09/02/2018 10:58 15/02/2018 15:21 changing contact detail field 6221 Miss Nicole Walker 24/01/2018 11:94 22/05/2018 10:27 6164 Miss Nicole Walker 16/01/2018 08:37 NW Testing form Testing Animal Notification form Testing reviewers 18 July 2017 13/07/2017 10:16 Miss Nicole Walker 13/07/2017 10:16 641 NW Testing applicant signature 640 Miss Nicole Welker 13/07/2017 09:52 13/07/2017 09:57 NW Testing case report Miss Nicole Walker 12/07/2017 17:44 12/07/2017 18:41 638 630 Miss Nicole Walker 12/07/2017 10:37 12/07/2017 10:47 Title of project TEST NW Testing number 2 627 Miss Nicole Walker 12/07/2017 09:45 12/07/2017 09:46 12/07/2017 09:45 Miss Nicole Walker 12/07/2017 08:19 Miss Nicole Walker 10/07/2017 08:10 Click on your roject to open it 12/07/2017 08:20 NW Testing with coordinators 12 July 2017 624 Testing Health Free Testing 582 Miss Nicole Walker 09/07/2017 23:13 08/03/2018 10:38 Testing statuses please ignore the test project Miss Nicole Walker 07/07/2017 15:02 561 07/07/2017 15:03



8. Creating a Sub form (i.e. Progress Report, Amendment)



PLEASE NOTE:

All Health forms are prefixed with HREC, so ensure that you select the correct before completing.

NW Testing form

| HREC New Appli HREC Annu | ication Form | Clinical Trial /Health & Student Research Your sub-form has now been created |
|--|---|--|
| Form Status | Review Reference | Date Modified |
| Not Submitted | N/A | 08/03/2018 11:40 |
| Navigation Docume | ents Signatures | Collaborators Submissions Correspondence History |
| Navigation Docume HREC Annual /Health & Stud | Progress Rep dent Research | Collaborators Submissions Correspondence History Correspondence< |
| Navigation Docume HREC Annual /Health & Stud Section | Progress Rep dent Research | Collaborators Submissions Correspondence History Oort/Final Report: Clinical Trial Questions |
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| Navigation Docume HREC Annual /Health & Stuck Section SECTION A: REPORT AND STU SECTION B: INVESTIGATOR D | Progress Rep dent Research | Collaborators Submissions Correspondence History Cort/Final Report: Clinical Trial Show Inactive Sections Questions Report and Study Type Investigator details Complete the form and |
| Navigation Docume HREC Annual /Health & Stuck Section SECTION A: REPORT AND STU SECTION B: INVESTIGATOR D SECTION C: RESEARCH PROJ | ents Signatures Progress Rep dent Research JDY TYPE ETAILS ECT DETAILS | Collaborators Submissions Correspondence History Cort/Final Report: Clinical Trial Show Inactive Sections Questions Report and Study Type Investigator details Research Project details Complete the form and sign/request |
| Navigation Docume HREC Annual /Health & Stud Section SECTION A: REPORT AND STU SECTION A: REPORT AND STU SECTION C: RESEARCH PROJ SECTION D: PROJECT FUNDIN | ents Signatures Progress Rep dent Research JDY TYPE ETAILS FECT DETAILS NG | Collaborators Submissions Correspondence History Cort/Final Report: Clinical Trial Show Inactive Sections Complete the form and sign/request signatures Signatures |
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| Navigation Docume HREC Annual /Health & Stuck Section SECTION A: REPORT AND STU SECTION F: SUMMARY OF PRO SECTION F: SUMMARY OF PRO SECTION H: REPORT OCI NOM | ents Signatures Progress Rep dent Research JDY TYPE ETAILS IECT DETAILS IG JORESS SE EVENTS COMPLIANCE | Collaborators Submissions Correspondence History Cont/Final Report: Clinical Trial Show Inactive Sections Questions |
| Navigation Docume HREC Annual /Health & Stuck Section SECTION A: REPORT AND STU SECTION A: REPORT AND STU SECTION A: REPORT AND STU SECTION B: INVESTIGATOR DI SECTION D: PROJECT FUNDIN SECTION F:SUMMARY OF PRO SECTION H: PROTOCOL NON-C SECTION H: ATTACHMENTS | ents Signatures Progress Rep dent Research JDY TYPE ETAILS IECT DETAILS IG SGRESS SE EVENTS COMPLIANCE | Collaborators Submissions Correspondence History Cort/Final Report: Clinical Trial Show Inactive Sections Complete the form and sign/request signatures Serious Adverse Events Protocol non-compliance (Please attach details) Correspondence |



Creating another sub-form or more than one sub-form:

PLEASE NOTE:

YOU NEED TO ENSURE THAT YOU CLICK ON YOUR MAIN APPLICATION FORM IN ORDER TO BE ABLE TO CREATE MORE SUB FORMS. YOU WILL NOT BE ABLE TO CREATE A SUB FORM IF YOU CLICK ON AN EXISTING SUB-FORM.

9. Definitions of <u>ACTIONS</u> in Panel:



Previous: This button will take you to the previous page in your application.

Next: This button will take you to the next page in your application

Navigate: This button will always take you to the beginning of your project where you will be able to view all sections/pages.

Print: This button allows you to print your application or save it in a PDF version.

Documents: This button will display all the documents saved in your application which you have uploaded.

Signatures: This button you can view any signatures that may have been requested.

Save: This button can be used before moving to the next page after completing a section or page or if you can't complete your form but wish you come back to continue with it at a later stage then save before logging out.

Share: This button allows you to share your project with your supervisor. Allowing him read and write access.

Collaborators: This button will allow you to view the collaborators.

Completeness Check: This button will run a check on you application to see whether it's complete or whether any mandatory questions are incomplete.

Submit: This button is used once you have completed your application and your supervisor is happy to approve it.

10.Definitions of statuses:

Scheduled Full Review: To be used by ethics admin staff only. The application needs to be reviewed by the full ethics committee and cannot be reviewed via expedited procedures.

Scheduled Expedited Review: To be used by ethics admin staff only. The applicant has requested an expedited review and no major risks are involved in the study, making it possible to review it via expedited procedures.

Acknowledged: This status is used for submissions other than new applications, i.e. serious adverse events, etc. These submissions are acknowledged by the committee/expedited review. This status is also used by the coordinator to acknowledge receipt of an application.

Approved: The proposal and all attachments can be approved and no changes are required.

Approved with stipulations: The proposal can be approved and the study can start, but the approval has stipulations attached to it, either in the form of very minor changes that do not need to come back to the committee or the project cannot commence until additional approvals have been obtained (e.g. WCED or PGWC).

Modifications required: Significant changes need to be made to the research proposal prior to approval. The approval can either be finalised by the primary reviewer and Chairperson and need not go back to the full committee or in more serious cases, the proposal must be reviewed at the next committee meeting. This status can also be used for expedited review.

Rejected/Disapproved: The application for ethics approval is rejected completely due to noncompliance with minimum ethics considerations.

Suspended: The study has been suspended, for whatever reason, either by the committee or by the researcher. It could continue if circumstances change, with the approval of the ethics committee.

Deferred: The proposal is referred back to the primary investigator (PI) to rewrite and resubmit. This status is mostly used for proposals reviewed by full committee review.

Terminated: The study has been terminated permanently either by the REC, but more often by the sponsor or researcher.

No Quorum: To be used by ethics admin staff only. Not enough voting members were present at the meeting to reach a quorum; the proposal will have to be reviewed and ratified at a next meeting.

Referred to convened REC: A submission was reviewed via expedited procedures but after careful review, it is decided that it should rather be scheduled for a full committee review.

Referred to other ethics committee: To be used by ethics admin staff only. The application was submitted to the Health ethics office and should actually be reviewed by the REC: Humanities committee or vice versa.

Expired: To be used by ethics admin staff only. The approval or request for modifications has expired.