HSREC Preparation Guide: Application for Ethics Clearance

Health Sciences Research Ethics Committee

Version 07.01

February 2019

UNIVERSITY OF THE
FREE STATE
UNIVERSITEIT VAN DIE
VRYSTAAT
YUNIVESITHI YA
FREISTATA

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HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Contents

General notes

The Health Sciences Research Ethics Committee (HSREC) uses an online ethics review management system, *Research Information Management System (RIMS)* to manage the application and review process.

The purpose of this document is to provide researchers with the information needed to comply with the administrative requirements of an ethics application to the HSREC. **Please read the whole document.**

The HSREC cannot grant retrospective approval in cases where data collection has commenced or is completed. Please ensure that you submit an application for ethics review well in advance.

Applications will only be accepted on RIMS (https://rims.ufs.ac.za/)

a) HSREC Administration reserves the right to not accept applications for review that are submitted in any other format.
b) New applications and all other subsequent submissions (amendments, reports, notifications, etc.) must be submitted to the HSREC on RIMS no later than the submission deadlines listed below.
c) Please note: RIMS has a scheduled maintenance window every Monday from 16:00 – 22h00. The system will not be available during this time. When logging in again on the next day, please press F5 for the page to refresh.
d) The HSREC advises anyone who is awaiting the outcome of an ethics application to check their junk/spam e-mail folder. If these e-mails are sent to the junk/spam folder, please unmark it as spam/junk.
e) Researchers are welcome to make an appointment with HSREC Administration for consultation prior to starting their application process. Please see contact information above.

RIMS-compatible browsers

Submission deadlines and meeting dates

IMPORTANT NOTE: Meeting the submission deadline does not guarantee the submission will be incorporated into a specific HSREC meeting agenda or review cycle. Some submissions might roll over to the next available HSREC meeting. Late and incomplete submissions will automatically roll over until the next review cycle and meeting. Please contact HSREC Administration to arrange for a consultation if required.

SUBMISSION *DEADLINES 2019	MEETING DATES 2019
09 JANUARY 2019	29 JANUARY 2019
06 FEBRUARY 2019	26 FEBRUARY 2019
06 MARCH 2019	26 MARCH 2019
03 APRIL 2019	23 APRIL 2019
08 MAY 2019	28 MAY 2019
05 JUNE 2019	25 JUNE 2019
10 JULY 2019	30 JULY 2019
07 AUGUST 2019	27 AUGUST 2019
11 SEPTEMBER 2019	01 OCTOBER 2019
09 OCTOBER 2019	29 OCTOBER 2019
06 NOVEMBER 2019	26 NOVEMBER 2019

*Applications may be submitted on a rolling basis, but no later than the deadlines listed above.

Contact details for HSREC Administration and the RIMS Office

HSREC ADMINISTRATION CONTACT DETAILS:		
The Chair: Health Sciences Research Ethics Committee Dr SM le Grange For Attention: Mrs M Marais Block D, Room 104, Francois Retief Building PO Box 339 (G40) Nelson Mandela Drive Faculty of Health Sciences University of the Free State Bloemfontein 9300	Mrs J du Plessis HSREC Coordinator *Undergraduate, Honours and M.Med Research* Ms MA Mulondo HSREC Coordinator *Postgraduate/Other and Contract Research* Mrs M Marais *Head: HSREC Systems, Administration and Operations*	+27 51 401 7794 +27 51 401 7795 +27 51 401 7387
	Email	ethicsfhs@ufs.ac.za
	Office hours	07:45-16:30

For all RIMS system related questions/concerns/creation of user profiles, please contact the RIMS office:

RIMS CONTACT DETAILS:		
Physical Address: Johannes Brill Building 111 Directorate Research Development RIMS IB 57 University of the Free State Bloemfontein 9300	Mr W Killian *RIMS Administrator* Mrs A Smith *RIMS Administrator (Tuesday, Wednesday and Thursday)* Mr Mpho Mashamba *RIMS Administrator* Mrs M Van Rooyen *RIMS Project Manager*	+27 51 401 3682 killianw@ufs.ac.za +27 51 401 9398 SmithAM@ufs.ac.za +27 51 401 9398 mashambaml@ufs.ac.za +27 51 401 9451 vanrooyenm2@ufs.ac.za
	Office hours	07:45-16:30

WHO TO CONTACT FOR HELP

Enquiries about the HSREC application and review process:	Contact the HSREC Coordinators
Experiencing technical difficulties with RIMS:	Contact the RIMS Administrators

Review Fee Structure

GENERAL INFORMATION:

- HSREC has a graded administrative fee structure in place, which is revised annually.
- **Student projects for degree purposes, self-funded projects and projects funded solely from a University of the Free State Departmental budget are exempt from fees.**
- **IMPORTANT NOTE:** HSREC reserves the right to not review a research application, or to withhold an HSREC letter if invoicing details have not been submitted to HSREC Administration with the application

INDUSTRY-SPONSORED CLINICAL TRIALS		
Item	**Description**	**HSREC Review Fee (incl. VAT)**
New application	Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project	R12 206,14
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R9 154,61
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification	R1 098,54
Protocol amendment - Major	Relaxation of inclusion criteria; relaxation of exclusion criteria; change in objectives / rationale of study; change in the study design and number of participants; relaxation of standards for data analysis; any change to the protocol that requires full committee approval	R2 441,23
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis / results	R1 525,77
Informed consent / Information Leaflet amendment	Any change to the content of the original informed consent form / information leaflet	R1 220,62
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R1 220,62
Additional investigator	Any additional investigator (per investigator)	R610,30
Administrative changes	Name changes; additional sites; typographical changes; other administrative changes	R610,30
External Administrative Charge	General Admin required by HSREC e.g. copying of lost trial documentation, protocols etc.	R610,30
Expedited / Urgent review of documentation		R610,30

*Administrative Fees for the process of SAEs / Progress Reports / Safety Reports / Investigators' Notifications are incorporated in the pricing structure

INTERNATIONAL GRANT FUNDED RESEARCH		
Item	**Description**	**HSREC Review Fee (incl. VAT)**
New application	International grant funded research (Total project budget > R1m)	R9 154,61
New application	International grant funded research (Total project budget R500 000 to R1m)	R4 272,15
New application	International grant funded research (Total project budget R100 000 to R500 000)	R2 441,23
New application	International grant funded research (Total project budget < R100 000)	R1 098,55
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R1 098,55
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification	R915,68
Protocol amendment - Major	Relaxation of inclusion criteria; relaxation of exclusion criteria; change in objectives / rationale of study; change in the study design and number of participants; relaxation of standards for data analysis; any change to the protocol that requires full committee approval	R1 098,55
Protocol amendment - Minor	Tightening of inclusion criteria; tightening of exclusion criteria; changes in the Investigator's Brochure; changes in the background information; extension of study period; budget change or change to the contract; minor technical amendments; other changes that do not affect study design or analysis / results	R732,37
Informed consent amendment	Any change to the content of the original informed consent form	R732,37
Participant / Recruitment material	This includes all material to be handed out to participants, all forms of advertising and blanket approvals.	R732,37
Additional investigator	Any additional investigator (per investigator)	R488,25

*Administrative Fees for the process of SAEs / Progress Reports / Safety Reports / Investigators' Notifications are incorporated in the pricing structure

NOTES:

- No Pro-Forma Invoices will be generated. Invoices will be generated after submission
- Purchase Order numbers (where applicable) must be provided with the application
- Please quote invoice number on electronic payments, and **send proof of payment to** ethicsfhs@ufs.ac.za
- Application documents must clearly indicate VAT numbers and to whom the invoice must be made out

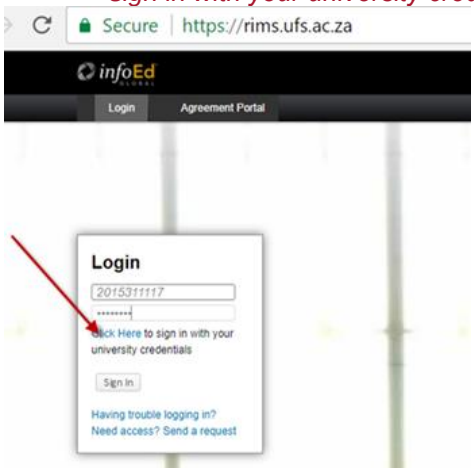
Getting started

RIMS login

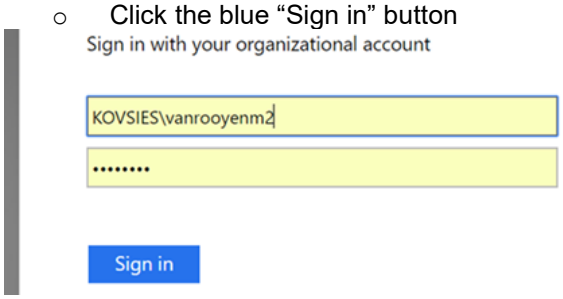
Please take note that the login for RIMS has changed. *Single sign-on* has been activated, which means that UFS students and staff should now use their own **university credentials** to access the system.

Steps to login:

- Clear the history and cache of your browser (Firefox/Chrome/Safari). **Please note:** *Do not use Microsoft Edge or Internet Explorer to access RIMS.*
- Click on the RIMS Web Portal link at https://www.ufs.ac.za/ufsresearch, or type the following URL in your browser's address bar: https://rims.ufs.ac.za
- Login steps for students and staff of the UFS:
  - Visit the RIMS Login page at https://rims.ufs.ac.za, then click on the blue link *('Click Here to sign in with your university credentials'*) as indicated below



  - University credentials: See screenshot below for example
  - Click the blue "Sign in" button



- If you forgot your password, please reset it by following the link below: https://selfservice.ufs.ac.za

- ***Login for external users (not a UFS student or staff member)***
  - **Do NOT select the option:** *('Click Here to sign in with your university credentials')*
  - Login with the original RIMS login details from the landing login screen.
  - For **new** external applicants please follow the instructions below to obtain a RIMS user profile:
    - Please e-mail the following details to the RIMS office for the creation of this profile (contact information provided above):
      Specify if you are a CUT/External Researcher
      Full names and surnames:
      Staff/ student number
      Email addresses
      Department
      Telephone numbers

    - The researcher will receive a confirmation email from the RIMS office with all the details required to log in.

    - To change the standard RIMS password, see instructions below:

      - Login to RIMS with the username and password given by the RIMS office
      - Click on MY PROFILE
      - Scroll down
      - Below the Research Interest Summary block, you will see Username UFS_student or your staff number
      - Please click on the SET button, next to your username
      - Please type in your new password, and confirm the new password
      - Click on SUBMIT
      - Click on Close
      - Scroll back up to the top of the page
      - Click on 'SAVE'
      - After you have done this, you can log out and try to Login with your new password

- **IMPORTANT NOTE:** Please ensure that your email address displays correctly in RIMS **before** completing your application. Incorrect email addresses will result in HSREC comments/decisions not reaching you. If incorrect, contact the RIMS office to update.

- RIMS Manuals: Please refer to the following RIMS manuals when applying for research ethics clearance (available on the HSREC webpage):
  - How to apply for ethics clearance on RIMS (RIMS01)
  - How to make modifications that are required on a RIMS (RIMS02)
  - How to respond when an Application has received Conditional Approval (RIMS03)
  - How to submit a Health Sciences Historical Application (RIMS04)

- The Investigator Declaration and Conflict of Interest statements
  - All researchers as well as their main supervisor (if applicable) must sign this form prior to the RIMS application process being initiated in the system. A signed document is a **mandatory** upload on the application form at the time of submission. A project will not be accepted for review if this signed document is not included.
  - Forms
    i. HSREC 18 form for Undergraduate and honours research (Appendix 2)
    ii. HSREC 19 form for Postgraduate/Other/Contract research (Appendix 3)
    iii. HSREC 22 for Case studies/series (Appendix 4)

- Notes on lay term summaries: Simple, clear language must be used (maximum Grade 8 reading level) and all medical and technical terms have to be explained. Include a paragraph on the ethical considerations of the project.

- **Definition**: To put something in lay terms is to describe a complex or technical issue using words and terms that the average individual (someone without professional training in the subject area) can understand, so that they may comprehend the issue to some degree.
- When submitting any research protocol for ethics approval, a lay term summary generated by the principal investigator must be included. This is a summary of the study in lay terms which is included in the agenda for notification of all members of the HSREC amongst which there are some who do not have medical background.
- A summary of the research protocol in lay terms must be included in the application form (no more than 750 words)
- A **mandatory** section regarding the ethical considerations of the project must be included in the lay term summary.
- Examples of what lay terms should describe:
    i. Where the study will be conducted
    ii. What population will be included in the study
    iii. What method will be used
    iv. What treatment will be administered to participants
    v. What control method will be used

- Permission from UFS authorities:
    - Approval must be obtained from UFS Authorities if research is to be conducted among students, lecturers and/or other role-players at the University of the Free State. This request for permission is completed in RIMS as a separate electronic application (Gatekeeper's Approval – Student/Staff Participation) **after** the HSREC grants conditional approval to a project.
    - Once the Gatekeeper's Approval letter is received by the researcher via RIMS, the letter must be uploaded to the RIMS HSREC application as a response to conditional approval.
    - Please contact HSREC Administration for guidance on the above process if anything is unclear.

- Completing the application on RIMS: Who is responsible
    - Postgraduate/Other research: The student/researcher is regarded as the Principal Investigator, and should complete the application
    - Undergraduate research: The student (s) supervisor is regarded as the Principal Investigator, however it is not the supervisor's responsibility to complete the application. If research will be conducted in groups, the group leader is responsible for completing the application. A field exists on the application form for supervisor details.

Application documents

Undergraduate and Honours research

The following documents should be prepared for submission to the HSREC.

- Some items in this list might not be applicable to a project, please select the N/A option on the form.

1. Cover letter
    a. Draft a letter addressed to the Chairperson of the HSREC. Contact details provided at the beginning of this document.
    b. If the new application is part of a main study, please quote the main study's ethics number in this letter.

2. Study protocol
    a. Please upload the final protocol with exclusion of the appendices (this will be uploaded separately, please ensure that all appendices are saved as separate documents). Ensure that all track changes have been finalised.

3. Questionnaires
    a. The questionnaire(s) can be submitted in either English and must be written in layman's terms. Once the requested changes, if any, have been made, the HSREC may request submission of translations in English, Afrikaans, Sesotho or other applicable languages. Questionnaires must be available in the main language(s) of the research setting.
    b. Please include the following introductory wording into questionnaires where **anonymous** participation in a study is relevant: "You have been asked to participate in a research study. Please note that by completing this questionnaire you are voluntarily agreeing to participate in this research study. You will remain anonymous and your data will be treated confidentially at all times. You may withdraw from this study at any given moment during the completion of the questionnaire. The results of the study may be published." In such cases signing an Informed Consent Form is not required but an Information Leaflet must still be available.
    c. Please note that standardised questionnaires may not be translated.

4. Other measuring tools/instruments

5. Recruitment material/advertisement(s)
    a. If an advertisement for potential study subjects will be used, it must include the following information:
        i. Advertisement in its final form (logo etc.) must be presented to the HSREC
        ii. Note condition/disease under discussion in the research proposal in layman's terms
        iii. Category participants: Age, etc.
        iv. Which method will be used, e.g. questionnaires
        v. Remuneration for transport and inconvenience
        vi. Any costs payable by participant
        vii. Contact person's name and cell phone number
        viii. For further enquiries also note office hours, if applicable
        ix. Voluntary participation and participant may withdraw at any time
        x. Patients currently on treatment will participation in the research study in conjunction with the treating physician
        xi. Time duration of study

6. Budget
    a. If the study budget is already part of the protocol, please save a copy of the complete budget (break it down) and upload it here, as it is mandatory. The application form cannot be saved if the budget has not been provided here

7. Permission letter from the applicant's Head of Department / Head of School of Nursing, if applicable
    a. If this letter is not submitted with the initial application, the project will not be taken in for review, but sent back to the researcher.
    b. The researcher's head of academic department must sign a letter printed on a letterhead confirming the researcher's project title.
    c. Do not submit a letter requesting permission from the HOD. It must be a final letter.

8. Approval requested from the School Research Committee, if applicable

9. Permission letter from the Vice Rector: Research at UFS for research to be done among students and/ or employees of the UFS
    a. Note: This permission can only be obtained after receiving conditional approval from the ethics committee for your research by submitting a Gatekeepers application on RIMS

10. Permission letter from the institution where the study will be conducted
    a. This letter should be from the institution where research will be conducted, excluding institutions falling under the jurisdiction of the Free State Department of Health.
    b. If permission is still awaited, the researcher should upload the letter of request.

11. Approval from Radiation Committee
    a. Studies that involve radiation and humans (patients, employees or public) need to be evaluated by the Radiation Control Committee for exposure calculations and approval. Upload the permission letter from the Radiation Control Committee here (if applicable).

12. Informed Consent and Information Document for adults in the languages common to the research area
    a. The ICF can be submitted in either English or Afrikaans and must be written in layman's terms. Once the requested changes, if any, have been made, then the committee may request the researcher to submit translations. ICF must always be available in the main languages of the research setting.
    b. The following should be mentioned in the information leaflet and informed consent (where applicable):
        i. Purpose of the study (explanation in lay terms)
        ii. Potential advantages of the study for the patient and the other persons
        iii. Risks and foreseeable discomfort for the patient/subject
        iv. That the patient/subject may withdraw from the study at any time
        v. That participation is voluntary
        vi. Alternative methods for treatment available?
        vii. Nature of preparations (+ placebo) in use
        viii. That information obtained will be treated as confidential
        ix. That insurance has been taken out to protect subjects
        x. The name of the contact person
        xi. The reversibility or irreversibility of side-effects
        xii. Number of studies that have so far been conducted with this substance on animals and also the number of persons that have been exposed to it
        xiii. Serious adverse effects
        xiv. Dotted line for signature and date
        xv. That results may be published and/or presented at a meeting/congress
        xvi. That no costs will be payable by the participant
        xvii. Remuneration for patient/participant?
        xviii. In prospective ongoing studies where invasive procedures or new drugs are investigated, for an unregistered indication, the information leaflet and informed consent must be combined in one document. Participants of prospective drug or interventional (invasive) studies must receive a copy of the informed consent and information leaflet to ensure access to the document at all times. Study participants must initial on each page of the document to confirm that they have familiarised themselves with the contents.

The study participant and investigator obtaining the consent must both sign in full, print their names and indicate the date on the last page of the consent document.

xix. Time that participant will have to give up to participate in the study

xx. Whether the product will be made available to participants on completion of the study and if so, whether there are any cost implications for the participant.

13. Assent form for minors
    a. When children participate in research studies, an assent form together with an Information Leaflet (with the above information explained at the level of the children involved) must be available apart from the Informed Consent document that needs to be signed by the parents/legal guardian.
    b. **Note**: For "Non-therapeutic" health research with minors, as part of the statutory requirements, Form A (NHREC Operational Guidelines for Ministerial Consent: v19 Feb 2015 – included in this document) must be completed and must accompany your application. Non-therapeutic research is classified as research that includes interventions that do not hold the prospect of direct health-related benefit to the participant but may produce results that contribute to generalisable knowledge. This form must be uploaded on the application form.

14. Letter requesting permission from the relevant provincial department
    a. Submit a cover letter addressed to the provincial department. You may use the same letter you addressed to the HSREC, and change the address appropriately.
    b. If research is to be conducted in public healthcare facilities, approval from the Provincial Department of Health must be obtained. Note that this can only be applied for **after** the HSREC has granted **conditional approval** pending the submission of this permission. Do not apply for gatekeeper permission with any other approval status (e.g. modifications required).
        - Gatekeepers are the owners of the data
    c. If research is to be conducted in Schools, the following steps should be taken:
        - Complete (fully) the Department of Education (DOE) application form. The application must clearly state:
            i. Who is going to the school
            ii. What will they do
            iii. What will happen to the results.
        - Submit to DOE at the same time that you submit to the HSREC.
        - Only one person per project must communicate with the DOE contact person.
        - After completion of the project, results must be communicated to the DOE contact person.
    d. If research is to be conducted in another province/country, the responsibility lies with the researcher to ascertain the appropriate permission required and inform the HSREC thereof.

15. Student(s) CV(s)
    a. Undergraduate student groups: Mention full names, Student no, course, language, ID no and cell phone number

16. Main Supervisor's CV
    a. This should be an abridged CV.

17. Co-supervisor's CV
    a. This should be an abridged CV.

18. Sub/ Co-Investigator (s) CV(s)
    a. This should be an abridged CV.

19. Approval letter from a Biostatistician
    a. Please note the following when the Department of Biostatistics, Faculty of Health Sciences (Prof G Joubert Tel. +27 51 401 3117, Ms. M Nel Tel. +27 51 401 3116,

Mr. FC van Rooyen Tel. +27 51 401 3114, Mr M Mamba Tel +27 51 401 3115, CR de Wet Building, UFS) will be assisting you with the protocol:

b. In cases where protocols are submitted for the first time, these should be handed in at the Department of Biostatistics one month prior to the submission date of the HSREC.
c. Protocols already verified by the Department of Biostatistics and which only need to be finally approved must be submitted to the Department of Biostatistics 2 weeks before the submission date of the HSREC.
d. Please note that, if the Department of Biostatistics, UFS is involved in analysing data, a letter of approval issued by the Department of Biostatistics must be uploaded here.

20. Main supervisor attended a Good Practice (GCP) course
    a. In the case of all intervention trials, such research protocols will be evaluated on merit and the risk will determine the need for the researcher to produce a current GCP certificate or attend a GCP course. The reviewers will evaluate the necessity for the researcher to attend a GCP course. The reviewers will make the appropriate recommendations to the HSREC. The final decision regarding the necessity to provide a GCP certificate of attendance of a GCP course will be taken at the HSREC meeting.

21. Professional Registration
    a. Main supervisor's proof of current registration must be submitted (e.g. HPCSA, Nursing Council, etc.)

22. Any other documents not mentioned above that need to be uploaded

Postgraduate/Contract/Other Research

The following documents should be prepared for submission to the HSREC.

- This list **excludes** case studies/series. A separate list has been created in this document for this research type.
- Some items in this list might not be applicable to a project, please select the N/A option on the form.

1. Cover letter
    a. Draft a letter addressed to the Chairperson of the HSREC. Contact details provided at the beginning of this document.
    b. If the new application is part of a main study, please quote the main study's ethics number in this letter.
    c. Contract research: Cover letter listing all submitted documents with version numbers and version dates

2. Study protocol
    a. Please upload the final protocol with exclusion of the appendices (this will be uploaded separately, please ensure that all appendices are saved as separate documents). Ensure that all track changes have been finalised.

3. Investigator's brochure and other related material
    a. Applicable to contract research/clinical trials.

4. Questionnaires
    a. The questionnaire(s) can be submitted in either English and must be written in layman's terms. Once the requested changes, if any, have been made, the HSREC may request submission of translations in English, Afrikaans, Sesotho or other applicable languages. Questionnaires must be available in the main language(s) of the research setting.
    b. Please include the following introductory wording into questionnaires where **anonymous** participation in a study is relevant: "You have been asked to participate in a research study. Please note that by completing this questionnaire you are voluntarily agreeing to participate in this research study. You will remain anonymous and your data will be treated confidentially at all times. You may withdraw from this study at any given moment during the completion of the questionnaire. The results of the study may be published." In such cases signing an Informed Consent Form is not required but an Information Leaflet must still be available.
    c. Please note that standardised questionnaires may not be translated.

5. Other measuring tools/instruments

6. Recruitment material/advertisement(s)
    a. If an advertisement for potential study subjects will be used, it must include the following information:
        i. Advertisement in its final form (logo etc.) must be presented to the HSREC
        ii. Note condition/disease under discussion in the research proposal in layman's terms
        iii. Category participants: Age, etc.
        iv. Which method will be used, e.g. questionnaires
        v. Remuneration for transport and inconvenience
        vi. Any costs payable by participant
        vii. Contact person's name and cell phone number
        viii. For further enquiries also note office hours, if applicable
        ix. Voluntary participation and participant may withdraw at any time
        x. Patients currently on treatment will participation in the research study in conjunction with the treating physician
        xi. Time duration of study

7. Material transfer agreement
    a. If any samples will be transferred between labs, this needs to be included in your application.

8. Budget
    a. If the study budget is already part of the protocol, please save a copy of the complete budget (break it down) and upload it here, as it is mandatory. The application form cannot be saved if the budget has not been provided here.

9. Permission letter from the applicant's Head of Department / Head of the School of Nursing, if applicable (excluding MMED as HOD will sign the Departmental Evaluation Committee Report)
    a. If this letter is not submitted with the initial application, the project will not be taken in for review, but sent back to the researcher.
    b. The researcher's head of academic department must sign a letter printed on a letterhead confirming the researcher's project title.
    c. Do not submit a letter requesting permission from the HOD. It must be a final letter.

10. Approval requested from the School Research Committee, if applicable

11. Permission letter from the Vice Rector: Research at UFS for research to be done among students and/ or employees of the UFS
    a. Note: This permission can only be obtained after receiving conditional approval from the ethics committee for your research by submitting a Gatekeepers application on RIMS

12. Permission letter from the institution where the study will be conducted
    a. This letter should be from the institution where research will be conducted, excluding institutions falling under the jurisdiction of the Free State Department of Health.
    b. If permission is still awaited, the researcher should upload the letter of request.

13. Approval from Radiation Committee
    a. Studies that involve radiation and humans (patients, employees or public) need to be evaluated by the Radiation Control Committee for exposure calculations and approval. Upload the permission letter from the Radiation Control Committee here (if applicable).

14. Informed Consent and Information Document for adults in the languages common to the research area
    a. The ICF can be submitted in either English or Afrikaans and must be written in layman's terms. Once the requested changes, if any, have been made, then the committee may request the researcher to submit translations. ICF must always be available in the main languages of the research setting.
    b. The following should be mentioned in the information leaflet and informed consent (where applicable):
        i. Purpose of the study (explanation in lay terms)
        ii. Potential advantages of the study for the patient and the other persons
        iii. Risks and foreseeable discomfort for the patient/subject
        iv. That the patient/subject may withdraw from the study at any time
        v. That participation is voluntary
        vi. Alternative methods for treatment available?
        vii. Nature of preparations (+ placebo) in use
        viii. That information obtained will be treated as confidential
        ix. That insurance has been taken out to protect subjects
        x. The name of the contact person
        xi. The reversibility or irreversibility of side-effects
        xii. Number of studies that have so far been conducted with this substance on animals and also the number of persons that have been exposed to it
        xiii. Serious adverse effects
        xiv. Dotted line for signature and date
        xv. That results may be published and/or presented at a meeting/congress

xvi. That no costs will be payable by the participant
xvii. Remuneration for patient/participant?
xviii. In prospective ongoing studies where invasive procedures or new drugs are investigated, for an unregistered indication, the information leaflet and informed consent must be combined in one document. Participants of prospective drug or interventional (invasive) studies must receive a copy of the informed consent and information leaflet to ensure access to the document at all times. Study participants must initial on each page of the document to confirm that they have familiarised themselves with the contents. The study participant and investigator obtaining the consent must both sign in full, print their names and indicate the date on the last page of the consent document.
xix. Time that participant will have to give up to participate in the study
xx. Whether the product will be made available to participants on completion of the study and if so, whether there are any cost implications for the participant.

15. Assent form for minors
    a. When children participate in research studies, an assent form together with an Information Leaflet (with the above information explained at the level of the children involved) must be available apart from the Informed Consent document that needs to be signed by the parents/legal guardian.
    b. **Note**: For "Non-therapeutic" health research with minors, as part of the statutory requirements, Form A (NHREC Operational Guidelines for Ministerial Consent: v19 Feb 2015 – included in this document) must be completed and must accompany your application. Non-therapeutic research is classified as research that includes interventions that do not hold the prospect of direct health-related benefit to the participant but may produce results that contribute to generalisable knowledge. This form must be uploaded on the application form.

16. Evaluation Committee approval: Masters, M.Med and Doctoral degrees
    a. The final signed Evaluation Committee report must be submitted at the time of application to the HSREC. If this document has not been submitted, the project will not be taken in for review.

17. Insurance Certificate
    a. Applicable to contract research/clinical trials.

18. Letter requesting permission from the relevant provincial department
    a. Submit a cover letter addressed to the provincial department. You may use the same letter you addressed to the HSREC, and change the address appropriately.
    b. If research is to be conducted in public healthcare facilities, approval from the Provincial Department of Health must be obtained. Note that this can only be applied for after the HSREC has granted conditional approval pending the submission of the outstanding permissions. Do not apply for permission with any other approval status (e.g. modifications required).
    c. For more information, visit the National Health Research Database webpage (NHRD).
    d. If research is to be conducted in Schools, the following steps should be taken:
        - Complete (fully) the Department of Education (DOE) application form. The application must clearly state:
            i. Who is going to the school
            ii. What will they do
            iii. What will happen to the results.
        - Submit to DOE at the same time that you submit to the HSREC.
        - Only one person per project must communicate with the DOE contact person.
        - After completion of the project, results must be communicated to the DOE contact person.

e. If research is to be conducted in another province/country, the responsibility lies with the researcher to ascertain the appropriate permission required and inform the HSREC thereof.

19. Principal Investigator's CV
a. This should be an abridged CV.

20. Supervisor's CV (only for student research)
a. This should be an abridged CV.

21. Sub/Co-investigator CV(s)
a. This should be an abridged CV.

22. Approval letter from a Biostatistician
    a. Please note the following when the Department of Biostatistics, Faculty of Health Sciences (Prof G Joubert Tel. +27 51 401 3117, Ms. M Nel Tel. +27 51 401 3116, Mr. FC van Rooyen Tel. +27 51 401 3114, Mr M Mamba Tel +27 51 401 3115, CR de Wet Building, UFS) will be assisting you with the protocol:
    b. In cases where protocols are submitted for the first time, these should be handed in at the Department of Biostatistics one month prior to the submission date of the HSREC.
    c. Protocols already verified by the Department of Biostatistics and which only need to be finally approved must be submitted to the Department of Biostatistics 2 weeks before the submission date of the HSREC.
    d. Please note that, if the Department of Biostatistics, UFS is involved in analysing data, a letter of approval issued by the Department of Biostatistics must be uploaded here.

23. Attended a Good Clinical Practice (GCP) Course
a. In the case of all intervention trials, such research protocols will be evaluated on merit and the risk will determine the need for the researcher to produce a current GCP certificate or attend a GCP course. The reviewers will evaluate the necessity for the researcher to attend a GCP course. The reviewers will make the appropriate recommendations to the HSREC. The final decision regarding the necessity to provide a GCP certificate of attendance of a GCP course will be taken at the HSREC meeting.

24. Professional Registration
a. Researcher and/or supervisor's proof of current registration must be submitted (e.g. HPCSA, Nursing Council, etc.)

25. NHREC Registration form
a. Applicable to contract research/clinical trials.

26. SAHPRA application / approval letter
a. Applicable to contract research/clinical trials.

Case studies/series

The following documents should be prepared for submission to the HSREC.

- Some items in this list might not be applicable to a project, please select the N/A option on the form.

1. Cover letter
    a. Draft a letter addressed to the Chairperson of the HSREC. Contact details provided at the beginning of this document.
    b. If the new application is part of a main study, please quote the main study's ethics number in this letter.

2. Abstract

3. Relevant accredited scientific publication

4. Patient data

5. Anonymous laboratory data or imaging material

6. Photograph to be published

7. Adult Patient Consent form

8. Child Assent form

9. Parental / Guardian consent form is required if there is a Child Assent form

10. Clear declaration if consent was not obtained including which measures were taken to seek consent from participant(s).
    a. If Informed Consent cannot be obtained from the patient, next of kin, etc. (due to death, lost to follow up, etc.) then the Clinical Head/Chief Executive Officer of the Institution must give consent.

11. Letter requesting permission from the institution where this case report/series will be conducted (other than public healthcare facilities), if applicable

12. Letter requesting permission from the relevant provincial department
    a. Submit a cover letter addressed to the provincial department. You may use the same letter you addressed to the HSREC, and change the address appropriately.
    b. If research is to be conducted in public healthcare facilities, approval from the Provincial Department of Health must be obtained. Note that this can only be applied for **after** the HSREC has granted **conditional approval** pending the submission of this permission. Do not apply for gatekeeper permission with any other approval status (e.g. *modifications required*).
        - *Gatekeepers are the owners of the data*
    c. If research is to be conducted in Schools, the following steps should be taken:
        - *Complete (fully) the Department of Education (DOE) application form. The application must clearly state:*
            i. Who is going to the school
            ii. What will they do
            iii. What will happen to the results.
        - *Submit to DOE at the same time that you submit to the HSREC.*
        - *Only one person per project must communicate with the DOE contact person.*
        - *After completion of the project, results must be communicated to the DOE contact person.*

    d. If research is to be conducted in another province/country, the responsibility lies with the researcher to ascertain the appropriate permission required and inform the HSREC thereof.

13. Permission letter from the Head of Department / Head of the School of Medicine/ Nursing/ Allied Health Professions, if applicable
    a. If this letter is not submitted with the initial application, the project will not be taken in for review, but sent back to the researcher.
    b. The researcher's head of academic department must sign a letter confirming the researcher's project title.
    c. Do not submit a letter requesting permission from the HOD. It must be a final letter.

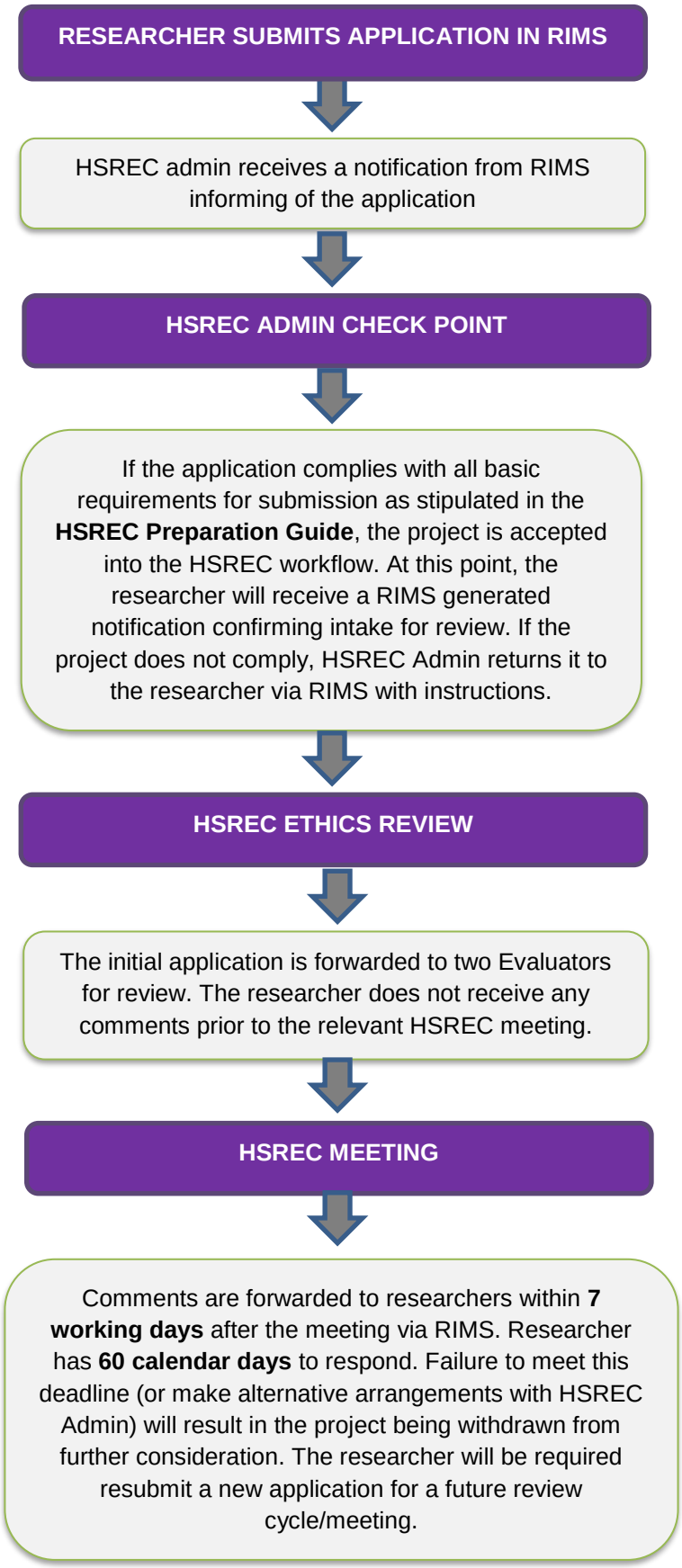
14. Principal Investigator CV
    a. This should be an abridged CV

15. Supervisor's CV (only for student research)
    a. This should be an abridged CV

16. Sub/ Co-Investigator (s) CV(s)
    a. This should be an abridged CV

17. Professional Registration
    a. Researcher and/or supervisor's proof of current registration must be submitted (e.g. HPCSA, Nursing Council, etc.)

What to expect after initial application submission



How to respond to comments from the HSREC

Possible review outcomes from a full convened meeting of the HSREC

Approval

a) The application is approved. Research activity may be conducted within the constraints (if any) established by the HSREC. No changes or additional information are required, and all of the applicable criteria for HSREC approval are met.
b) Final ethics clearance is valid for one year from the date of approval.
c) The official **ethics number** of the project is allocated.
d) **Response required from researcher:** Submission of progress report as specified in the final approval letter

Conditional approval

a) The HSREC has determined that the applicable criteria for approval have been met, based on the assumption that specific conditions will be met by the researcher and subsequently verified.
b) The application does not need to be presented at the next meeting, and can be granted final approval between meetings
c) The research activities under review cannot begin.
d) The project has not been allocated an official **ethics number** at this point, only a RIMS generated reference number which cannot be used as an ethics number.
e) **Response required from researcher**:
    - The HSREC requires as a condition of approval that the investigator: (1) make specified changes; (2) confirm specific assumptions or understandings on the part of the HSREC; and/or (3) provide additional or revised information or documents such that, based on the assumption that the conditions are satisfied, the applicable criteria for approval would be met and required determinations would be made.
    - Write a letter of response to the HSREC including a summary of changes (if applicable), and upload to RIMS as part of the response to conditions.
    - It is **very important** to highlight all changes made in documentation in order for the review to be finalised. Failure to comply with this request will delay approval.
    - Please note: All documents must be uploaded to/replaced on the Documents Checklist. Documents submitted in any other location in RIMS will not be reviewed. Non-compliance to this request will result in the application being returned to the researcher to load the documents in the correct place.
    - The researcher has 60 calendar days to respond to the *Conditional Approval* determination, as stipulated in the official letter from the HSREC. If the deadline cannot be made, please inform HSREC Admin providing adequate justification.
        i. Failure to meet this deadline (or make alternative arrangements with HSREC Admin) will result in the project being withdrawn from further consideration. The researcher will be required resubmit a new application for a future review cycle/meeting.

Modifications required

a) The HSREC is unable to approve the research because it cannot make the determinations required for approval (i.e., the applicable criteria for HSREC approval have not been met.) The HSREC defers the item for further review after changes and/or additional information have been provided by the researcher.
b) The application does not need to be presented at the next meeting, and can be granted conditional/final approval between meetings
c) The research activities under review cannot begin.
d) The project has not been allocated an official **ethics number** at this point, only a RIMS generated reference number which cannot be used as an ethics number.
f) Response required from researcher:

- Clarification, revised documents and/or additional information are required from the investigator in order to determine that the applicable criteria for HSREC approval are met.
- Use the Summary of Changes template (loaded onto RIMS as part of the Documents Checklist) to draft your response to the HSREC. This is a mandatory form. Responses received without this form will be sent back to the researcher.
- Please note: All documents must be uploaded to/replaced on the Documents Checklist. Documents submitted in any other location in RIMS will not be reviewed. Non-compliance to this request will result in the application being returned to the researcher to load the documents in the correct place.
- It is **very important** to highlight all changes made in documentation in order for the review to be finalised. Failure to comply with this request will delay approval.
- The researcher has 60 calendar days to respond to the *Modifications Required* determination, as stipulated in the official letter from the HSREC. If the deadline cannot be made, please inform HSREC Admin providing adequate justification.
    i. Failure to meet this deadline (or make alternative arrangements with HSREC Admin) will result in the project being withdrawn from further consideration. The researcher will be required resubmit a new application for a future review cycle/meeting.

Modifications required - Held over

a) The HSREC is unable to approve the research because it cannot make the determinations required for approval (i.e., the applicable criteria for HSREC approval have not been met.) The HSREC defers the item for further review after changes and/or additional information have been provided by the researcher.
b) The application will be presented at the next meeting for an updated determination.
c) The research activities under review cannot begin.
d) The project has not been allocated an official **ethics number** at this point, only a RIMS generated reference number which cannot be used as an ethics number.
e) Response required from researcher:
- Clarification, revised documents and/or additional information are required from the investigator in order to determine that the applicable criteria for HSREC approval are met.
- Use the Summary of Changes template (loaded onto RIMS as part of the Documents Checklist) to draft your response to the HSREC. This is a mandatory form. Responses received without this form will be sent back to the researcher.
- Please note: All documents must be uploaded to/replaced on the Documents Checklist. Documents submitted in any other location in RIMS will not be reviewed. Non-compliance to this request will result in the application being returned to the researcher to load the documents in the correct place.
- It is **very important** to highlight all changes made in documentation in order for the review to be finalised. Failure to comply with this request will delay approval.
- The researcher has 60 calendar days to respond to the *Modifications Required: Held over* determination, as stipulated in the official letter from the HSREC. If the deadline cannot be made, please inform HSREC Admin providing adequate justification.
    i. Failure to meet this deadline (or make alternative arrangements with HSREC Admin) will result in the project being withdrawn from further consideration. The researcher will be required resubmit a new application for a future review cycle/meeting.

Rejected/Disapproved

a) The applicable criteria for HSREC approval are not met, and the HSREC is not willing to re-consider the item.
b) An item is disapproved rather than deferred when the HSREC believes that it is very unlikely that:
- The applicable criteria for approval will be met even with substantial changes and/or additional information; or

- It is not possible to obtain (or the researcher is unwilling to provide) the substantial changes or additional information that would be necessary to meet the criteria for approval.

c) No actions proposed in the application may be initiated.
d) The HSREC generally does not disapprove an item until there has been at least one attempt to work with the investigator to find mutually acceptable changes (i.e., at least one review with a Modifications Required decision) that will allow the HSREC to determine that the criteria for approval have been met
e) The project has **not** been allocated an official **ethics number** at this point, only a RIMS generated reference number which cannot be used as an ethics number.
f) **Response required from researcher:** None, the application is closed. The researcher may submit a new application after considerable updates have been made.

Subsequent submissions and reporting requirements on HSREC approved research

Definition

- Subsequent submissions refer to any and all applications, notifications, reports, etc., submitted to the HSREC for approval or notification after final approval has been granted for the initial application.
- All subsequent submissions and reports will only be accepted if submitted via RIMS. Hard copy and email submissions will not be accepted.

Paper vs electronic initial applications and RIMS

- All projects with an initial application **already on RIMS**
  - Log into RIMS and locate the relevant record. Choose the type of submission from the dropdown list. Electronic application forms have been created to accommodate all subsequent submissions. Please refer to page 16 of the 'How to apply for ethics clearance on RIMS' manual available on the HSREC webpage.
- All projects with an initial **paper** submission
  - Researchers require RIMS user profiles. If one has not been created, please contact the RIMS office (contact details at the start of this document)
  - Refer to the 'How to submit a Health Sciences Historical Ethics Clearance Application' RIMS manual (available on the HSREC webpage) for guidance on how to submit an historical application. This will enable you to submit your subsequent submissions (amendments, reports, notifications, etc.) on RIMS.

Progress and final reports

- Ethics approval is valid for one year from the date of approval on the official final approval letter. An annual progress report must be submitted to the HSREC before the ethics approval expiry date, so that the submission can be reviewed and the project re-approved for the next year. No research may continue without this process and re-approval.
- The progress report should contain sufficient information to allow the reviewer to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered.
- HSREC policy requires researchers to formally inform HSREC when a study is completed. A study is considered active while analysis of any data (human or other data) collected or resulting from the study is ongoing.

Amendments

- HSREC review and approval is required in advance of implementing any changes (amendments) to a protocol. Amendment applications may be submitted at any time after the study has been granted final approval.
- The changes made to applications as a response to HSREC comments (and prior to final approval of the initial application) are not considered an amendment, but part of the initial review.
- All applications for an amendment must include a letter to the HSREC with the rationale or justification for the proposed change(s). The justification for an amendment must clarify how it will change the study, how it will affect risks to participants and what safeguards will be introduced to protect participants from additional risks. If the revision requires a change in the informed consent process, a revised consent form must be submitted with the amendment.
- Submission requirement: please submit the updated documents in track changes or highlighted, in order for the review to take place. If the changes are not indicated/justified, the amendment will not be reviewed, but returned to the researcher.

  Minor amendments do not change the risk benefit profile of the study in any way.

  Examples of typical minor amendments:
  a) Additional investigators or study sites

b) Small changes in the Informed Consent
c) Change in background information or update of literature review
d) Extension of period of study
e) Other changes that do not affect study design and will not affect study outcomes or results
f) Administrative changes
g) Stricter inclusion or exclusion criteria

Major or substantive amendments require a change(s) to the study methodology or procedure that may result in an alteration of the risk benefit profile of the study.

Examples of typical major or substantive amendments:

a) Change in study aims, objectives or design
b) Resulting changes to consent documents
c) Additional study procedures
d) Easing of inclusion or exclusion criteria

Unexpected Problems and Adverse Events

- The HSREC requires researchers to promptly notify the HSREC of the following information and events, for any HSREC approved research:
    - Unexpected problem;
    - Unexpected adverse medical device effect;
    - Adverse Events and Serious Adverse Events;
    - Serious non-compliance by researcher (or allegation of serious non-compliance);
    - Continuing non-compliance (or allegation of continuing non-compliance);
    - Emergency deviation from HSREC-approved procedures made without prior HSREC review to eliminate an apparent immediate hazard to a subject or others;
    - Continuation of research procedures after HSREC approval has lapsed, because the procedures are of direct benefit to individual subjects or withholding the research intervention (if any) may increase risks to subjects;
    - Breach (or risk of breach) of subject confidentiality or privacy;
    - Complaint of a subject that cannot be resolved by the study team;
    - Audit, inspection, compliance-related inquiry, or safety-related inquiry from a regulatory agency;
    - New information that has implications for the risks of the research

When to report Unexpected Problems or Adverse Events: Table 1 on the next page includes a list of information and events that need to be reported as well as the timelines.

Table 1: HSREC required reporting timelines for unexpected problems or adverse events

Information or Event	When to report
Unexpected problems	All unexpected problems that increase the risk of harm to participants or others must be reported to the HSREC **within seven calendar days** after the investigator first learns of their occurrence
Fatal and life-threatening, unexpected adverse drug reactions	All fatal and life-threatening adverse drug reactions in clinical trials must be reported to the HSREC **as soon as possible but not later than seven calendar days** after the investigator first learns of their occurrence.
Serious and unexpected non-fatal adverse drug reactions	All serious unexpected drug reactions that are not fatal or life-threatening must be reported to the HSREC **as soon as possible but not later than fifteen calendar days** after first learning of their occurrence.
Expected adverse drug reactions	All adverse drug reactions that are expected but are judged to be occurring at a significantly higher frequency or severity than expected must be reported to the HSREC **within fifteen calendar days** after the investigator first learns of their occurrence. The basis for these assessments must be included in the investigator's report.
Serious and unexpected adverse device effects	All unexpected adverse device effects must be reported to the HSREC **as soon as possible but not later than seven calendar days** after first learning about their occurrence
New information that might impact the conduct of a clinical trial	Other unexpected adverse events, regardless of severity, that may alter the balance of risks and benefits in a study and as a result warrant consideration of substantive changes in the overall conduct of a clinical trial must be reported to the HSREC **within three calendar days** of first learning about their occurrence. The report could include individual case reports or a major safety finding from other sources.
Early termination or cancelation of studies	The termination is immediately reported in writing.

Table 2: Timelines for Reporting Protocol Violations/Deviations and Study Exceptions

Information or Event	When to report
Major protocol violations/deviations	The Principal Investigator must report major protocol deviations to the HSREC **within seven calendar days** of first hearing of the incident
Minor protocol violations/deviations	If the principal investigator determines the deviation is **minor** and has **no impact** on the study or welfare of participants, **no further action** is necessary and the **deviation can be reported in the next annual progress report.**
Study exceptions	All study exceptions must receive HSREC approval **prior** to initiation and must be **listed** in the subsequent progress report.

Appendix 1: HSREC Criteria of Approval

The list below is used by HSREC reviewers when evaluating projects.

REVIEW CRITERIA – to be used by reviewers			
1. Introduction, specific aims, literature review	**YES**	**NO**	**N/A**
Is the literature review adequate?	☐	☐	☐
Are the study aims and objectives clearly specified?	☐	☐	☐
Is there adequate preliminary data to justify the study?	☐	☐	☐
Are adequate references provided?	☐	☐	☐
Is there appropriate justification for this study protocol?	☐	☐	☐
Why is it important to conduct this study? Will it add important knowledge to the field?	☐	☐	☐
Is this study worth doing in this particular setting?	☐	☐	☐
2. Scientific design	**YES**	**NO**	**N/A**
Is the scientific design adequate to answer the study question(s)?	☐	☐	☐
Is the scientific design adequately described and justified?	☐	☐	☐
Does the study involve a placebo? If so, is the need for placebo adequately justified? Could the study be done without a placebo?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Are study aims and objectives achievable in the given time frame?	☐	☐	☐
Do the principal and co-investigators have appropriate academic and clinical credentials and experience to conduct this study?	☐	☐	☐
2.1 Qualitative research:			☐ **N/A**
Does the researcher have experience in conducting qualitative research?	☐	☐	☐
Does the researcher demonstrate an understanding of the qualitative paradigm and method chosen?	☐	☐	☐
3. Selection of participants ☐ **N/A**	**YES**	**NO**	**N/A**
Is the choice of participants appropriate for the study question?	☐	☐	☐
Is the rationale for the proposed number of participants reasonable?	☐	☐	☐
Is participant selection equitable?	☐	☐	☐
Are inclusion and exclusion criteria clearly stated and reasonable?	☐	☐	☐
Is the inclusion of children, pregnant women or other vulnerable groups adequately justified?	☐	☐	☐
Are adequate safeguards in place to protect the rights and welfare of these vulnerable groups?	☐	☐	☐
Can the study be done without involving vulnerable populations?	☐	☐	☐
Will the study target or exclude a particular ethnic or language group?	☐	☐	☐
3.1 Qualitative research:			☐ **N/A**
Is the method of sample selection appropriate and clear?	☐	☐	☐
If the sample size cannot be delineated before the study begins, are a rationale and plan provided?	☐	☐	☐
Has the researcher clearly described how they will determine when adequate sampling (saturation) has occurred?	☐	☐	☐
Has the study population been involved in previous research and/or is the study population currently involved in research to the extent that the current study may present a significant additional burden?	☐	☐	☐

4. Recruitment strategy ☐ N/A	YES	NO	N/A
Are the methods for recruiting participants clearly explained and appropriate?	☐	☐	☐
Is the location, setting and timing of recruitment acceptable?	☐	☐	☐
Are screening procedures prior to recruitment acceptable?	☐	☐	☐
Will any potential participants be in a dependent relationship with the researcher/recruiter? (e.g. Student/lecturer, employee/employer, patient/doctor)	☐	☐	☐
Has the researcher taken steps to ensure that the participant's decision to enrol will not be inappropriately influenced by this relationship?	☐	☐	☐
5. Research procedures ☐ N/A	**YES**	**NO**	**N/A**
Are the rationale and details of research procedures described in sufficient detail?	☐	☐	☐
Are the research procedures acceptable and in keeping with study aims and objectives?	☐	☐	☐
Is there a clear distinction between research procedures and standard clinical practice and/or standard care?	☐	☐	☐
Are the proposed tests/measurements appropriate, valid and reliable to answer the study question in the local context?	☐	☐	☐
Is there a clear description of plans to inform participants of specific research results e.g. Incidental findings, clinically relevant findings?	☐	☐	☐
Are those performing the research procedures adequately trained?	☐	☐	☐
6.Risk-benefit assessment ☐ N/A	**YES**	**NO**	**N/A**
Are risks (Physical, psychological, social, and economic) and benefits (to individuals and/or community) adequately: • Identified; • Evaluated; and • Described?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Do risks and benefits stated in the protocol match those described in the informed consent form?	☐	☐	☐
Are potential risks minimised?	☐	☐	☐
Are potential benefits maximised?	☐	☐	☐
Will counselling or support services be available, if required?	☐	☐	☐
Are potential benefits realistically described and not over emphasised?	☐	☐	☐
Are risks reasonable in relation to anticipated benefits?	☐	☐	☐
Are risks reasonable in relation to importance of anticipated knowledge gained?	☐	☐	☐
Is the risk/benefit ratio acceptable for proceeding with the research?	☐	☐	☐
Is the population from which study participants are drawn likely to benefit from the research?	☐	☐	☐
7. Clinical drug/device trial ☐ N/A	**YES**	**NO**	**N/A**
Has the national drug regulatory authority approval been obtained, if required?	☐	☐	☐
Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing?	☐	☐	☐
Is the use of placebo adequately justified from both a scientific and an ethical perspective?	☐	☐	☐
Are there adequate provisions for safety monitoring including a DSMB?	☐	☐	☐
8. Data analysis and statistical analysis ☐ N/A	**YES**	**NO**	**N/A**
Are the plans for data and statistical analysis defined and justified?	☐	☐	☐
Has the sample size and selection been adequately justified?	☐	☐	☐
8.1 Qualitative research: ☐ N/A	**YES**	**NO**	**N/A**

Is it clear and well-motivated why or how qualitative data collection methods are the most appropriate for analysis?	☐	☐	☐
Is there clarity in the analytic approach?	☐	☐	☐
Does the description of the analytic approach indicate how this will allow the researcher to pursue their objectives?	☐	☐	☐
Has the researcher adequately described how they intend to go about coding and analysis?	☐	☐	☐
9. Compensation and costs for subjects ☐ N/A	**YES**	**NO**	**N/A**
Are there adequate plans to avoid out-of-pocket expenses and costs to participants?	☐	☐	☐
Is the amount or type of compensation or reimbursement reasonable and well justified?	☐	☐	☐
If children or adolescents are involved who receives compensation and is this appropriate?	☐	☐	☐
10. Privacy and confidentiality ☐ N/A	**YES**	**NO**	**N/A**
Are there adequate measures to protect the privacy and ensure the confidentiality of the research subjects?	☐	☐	☐
Does the protocol describe site-specific measure to protect privacy?	☐	☐	☐
Does the protocol describe how written records, audio or videotapes, and digital recordings will be secured, for how long, and whose responsibility?	☐	☐	☐
For focus groups, are participants informed that confidentiality cannot be guaranteed as group members may disclose what we discussed outside the research setting?	☐	☐	☐
Are activities that could potentially result in notification e.g. Abuse, neglect, potential for harming self or others, addressed in the protocol and IC form?	☐	☐	☐
11. Process of obtaining informed consent and assent ☐ N/A	**YES**	**NO**	**N/A**
Is the process adequately described? Or has a waiver of informed consent or waiver of documentation of informed consent been requested and adequately justified?	☐	☐	☐
Are all required elements of informed consent contained in the ICF?	☐	☐	☐
Is the language level appropriate?	☐	☐	☐
Does the process minimise the potential for undue influence?	☐	☐	☐
Does the process provide sufficient time, privacy and an adequate setting for participants to decide?	☐	☐	☐
Will the ICF be translated into all required languages?	☐	☐	☐
Is assent required?	☐	☐	☐
12. Other ☐ N/A	**YES**	**NO**	**N/A**
Is the investigator and research team adequately qualified to carry out/supervise the research?	☐	☐	☐
Does the PI have 'human subjects protection training' /GCP?	☐	☐	☐
Is the budget adequate?	☐	☐	☐
Are there any administrative deficiencies with the application, such as missing documents?	☐	☐	☐
Has a material/data transfer agreement been submitted if required?	☐	☐	☐
13. At the end of the study ☐ N/A	**YES**	**NO**	**N/A**
Will post trial treatment be available?	☐	☐	☐
Will communities and participants be informed of significant findings?	☐	☐	☐
Will findings be disseminated more broadly e.g. publishing, presenting etc.?	☐	☐	☐

Appendix 2: Undergraduate/Honours Student Research Investigator Declaration

*Note: Complete and upload to RIMS application form if applicable. **DO NOT** modify this form.*

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV HEALTH SCIENCES GESONDHEIDSWETENSKAPPE

HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

UNDERGRADUATE/HONOURS STUDENT RESEARCH INVESTIGATOR DECLARATION

1.1 MAIN SUPERVISOR DETAILS	
Title, Initials, Surname:	
Department/Institution:	
Phone:	
Email address:	

1.2 What is your role in this research? [✓]			
Principal investigator	☐	Co-investigator	☐
Sub-investigator	☐	Supervisor	☐
Other: Specify			☐

PROJECT TITLE *(maximum 250 characters for database purposes)*

2. MAIN SUPERVISOR STATEMENT OF CONFLICT OF INTEREST

The **Main Supervisor** is expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, 'immediate family' means the Principal Investigator's spouse or domestic partner and dependent children. **Please tick ✓ all that apply.**	
2.1 No conflict of interest declared:	☐ N/A
Neither I, nor any member of my immediate family, have any interest related to this research (e.g. financial interest in the sponsor of the research or intervention being tested.)	☐
Neither I, nor any member of my immediate family, have a proprietary interest in the product being tested in this research (e.g. patent, trademark, copyright, licensing agreement).	☐
Neither I, nor any member of my immediate family, have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of sponsor-investigator.	☐

2.2 Conflict of interest declared:	☐ N/A
As Supervisor of this research **I am aware of a potential conflict of interest**. Please describe and provide a plan to manage the conflict of interest in the space below:	☐

3. DECLARATIONS AND SIGNATURES

Note: This application will not be processed unless all the required declarations and signatures are completed and have been submitted.

3.1 Student(s)

My/our signature(s) confirm that:

i. Information in this application is true and accurate.
ii. I/we will begin the research only after HSREC approval is obtained.
iii. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
iv. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.

Name		Signature		Date	
Name		Signature		Date	

Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	

.

3.2 Main Supervisor			
My signature confirms that: i. The application is ready for submission for ethics clearance. ii. Information in this application is true and accurate. iii. The research has scholarly merit. iv. The level of risk inherent in the study is commensurate with the student researcher(s)'s experience and the extent of oversight that I will provide. v. I have time, training, experience and resources to oversee this research. vi. The student researcher has adequate training and resources to complete the research in the allocated timeframe. vii. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study. viii. The research will begin only after HSREC approval is obtained. ix. I accept full responsibility for the conduct of this research and the protection of participants' rights and welfare. x. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures. xi. I will ensure that the research undergoes continuing review as required by the HSREC, including annual progress reports, protocol amendments and a final closing report at the end of the research. xii. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HSREC. xiii. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave.			
Signature of Main Supervisor		Date	
Print name			

Note: *The Main Supervisor and student researcher(s) are jointly responsible for the ethical conduct of this research from inception to dissemination of findings*

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

HEALTH SCIENCES RESEARCH ETHICS COMMITTEE
POSTGRADUATE/ CONTRACT/OTHER RESEARCH INVESTIGATOR DECLARATION

The principal investigator, supervisor, as well as all sub- & co-investigators (where applicable) must sign this declaration.

1.1 INVESTIGATOR DETAILS AND ROLE IN THIS RESEARCH	
Title, Initials, Surname:	
Department/Institution:	
Phone:	
Email address:	

1.2 What is your role in this research? [✓]			
Principal investigator	☐	Co-investigator	☐
Sub-investigator	☐	Supervisor	☐
Other: Specify			☐

PROJECT TITLE *(maximum 250 characters for database purposes)*

2. STATEMENT OF CONFLICT OF INTEREST

The **Principal Investigator** is expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, 'immediate family' means the Principal Investigator's spouse or domestic partner and dependent children. **Please tick ✓ all that apply.**	
2.1 No conflict of interest declared:	☐ N/A
Neither I, nor any member of my immediate family, have any interest related to this research (e.g. financial interest in the sponsor of the research or intervention being tested.)	☐
Neither I, nor any member of my immediate family, have a proprietary interest in the product being tested in this research (e.g. patent, trademark, copyright, licensing agreement).	☐
Neither I, nor any member of my immediate family, have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of sponsor-investigator.	☐
2.2 Conflict of interest declared:	☐ N/A
As Principal Investigator of this research **I am aware of a potential conflict of interest**. Please describe and provide a plan to manage the conflict of interest in the space below:	☐

3. DECLARATIONS AND SIGNATURES

Note: This application will not be processed unless all the required declarations and signatures are completed.

3.1 Principal investigator			
My signature confirms that: i. Information in this application is true and accurate. ii. I will begin the research only after written HSREC approval is obtained. iii. I accept full responsibility for the conduct of this research and the protection of participants' rights and welfare. iv. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures. v. I will provide progress reports to the HSREC as requested, including a final closing report at the end of the research. vi. I will notify the HSREC in writing if any change to the research is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants' safety. vii. I will notify the HSREC in writing immediately if any adverse event or unanticipated problem occurs during the research. viii. I will allow an audit of my research if requested by the HSREC. ix. I have the time, training, experience and resources to oversee this research. x. I will endeavour to publish and disseminate the findings of the study.			
Signature of Principal Investigator		Date	
Print name			

3.2 Student Main Supervisor (if research is for a qualification) ☐ N/A

My signature confirms that:

i. The application is ready for submission for ethics clearance.
ii. Information in this application is true and accurate.
iii. The student researcher has adequate training and resources to complete the research in the allocated timeframe.
iv. The research has scholarly merit.
v. The level of risk inherent in the study is commensurate with the student researcher's experience and the extent of oversight that I will provide.
vi. I have time, training, experience and resources to oversee this research.
vii. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study.
viii. I will ensure that the research undergoes continuing review as required by the HSREC, including annual progress reports, protocol amendments and a final closing report at the end of the research.
ix. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HSREC.
x. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave.

Signature of Supervisor		Date	
Print name:			

Note: *The main supervisor and student researcher are jointly responsible for the ethical conduct of this research from inception to dissemination of findings.*

3.3 Co-supervisor(s) ☐ N/A

My/our signature(s) confirm that:

i. Information in this application is true and accurate.
ii. I/we will begin the research only after HSREC approval is obtained.
iii. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
iv. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.

Name		Signature		Date	
Name		Signature		Date	

3.4 Collaborating Investigator(s) ☐ N/A

My/our signature(s) confirm that:

i. Information in this application is true and accurate.
ii. I/we will begin the research only after HSREC approval is obtained.
iii. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
iv. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.

Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	

*Note: Complete and upload to RIMS application form if applicable. **DO NOT** modify this form.*

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV HEALTH SCIENCES GESONDHEIDSWETENSKAPPE

HEALTH SCIENCES RESEARCH ETHICS COMMITTEE
CASE REPORT/SERIES: INVESTIGATOR DECLARATION

The principal investigator, supervisor, as well as all sub- & co-investigators (where applicable) must sign this declaration.

1.1 INVESTIGATOR DETAILS AND ROLE IN THIS RESEARCH	
Title, Initials, Surname:	
Department/Institution:	
Phone:	
Email address:	

1.2 What is your role in this research? [✓]			
Principal investigator	☐	Co-investigator	☐
Sub-investigator	☐	Supervisor	☐
Other: Specify			☐

Title of Case Report/Series

2. STATEMENT OF CONFLICT OF INTEREST

The Principal Investigator is expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, 'immediate family' means the Principal Investigator's spouse or domestic partner and dependent children. **Please tick ✓ all that apply.**	
2.1 No conflict of interest declared:	☐ N/A
Neither I, nor any member of my immediate family, have any interest related to this research (e.g. financial interest)	☐
Neither I, nor any member of my immediate family, have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of-investigator.	☐

2.2 Conflict of interest declared:	☐ N/A
As Principal Investigator of this research **I am aware of a potential conflict of interest**. *Please describe and provide a plan to manage the conflict of interest in the space below:*	☐

3. DECLARATIONS AND SIGNATURES

3.1 Principal investigator

My signature confirms that:

xi. Information in this application is true and accurate.
xii. I accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
xiii. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures.
xiv. I will endeavour to publish and disseminate the findings of this case report/series.

Signature of Principal Investigator		Date	
Print name			

3.2 Student Main Supervisor (if research is for a qualification) ☐ N/A

My signature confirms that:

i. The application is ready for submission for ethics clearance.
ii. Information in this application is true and accurate.
iii. The research has scholarly merit.

Signature of Principal Investigator		Date	
Print name			

Note: *The main supervisor and student researcher are jointly responsible for the ethical conduct of this research from inception to dissemination of findings.*

3.3 Co-supervisors ☐ N/A

My/our signature(s) confirm that:

v. Information in this application is true and accurate.
vi. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
vii. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.

Name		Signature		Date	
Name		Signature		Date	

3.4 Collaborating Investigators					☐ N/A
My/our signature(s) confirm that: v. Information in this application is true and accurate. vi. I accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.					
Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	
Name		Signature		Date	

Appendix 5: Example of Cover Letter
Note: Customise to be project specific and upload to RIMS Document Checklist

[RESEARCHER ADDRESS]
[DATE]

The Chair: Health Sciences Research Ethics Committee
Dr SM le Grange
For Attention: Mrs M Marais
Block D, Room 104,
Francois Retief Building

PO Box 339 (G40)
Nelson Mandela Drive
Faculty of Health Sciences
University of the Free State
Bloemfontein
9300

Dear Dr SM le Grange,

PROJECT TITLE: [INSERT TITLE]

Enclosed please find the above research protocol for your evaluation and approval.

[PLEASE DELETE THIS SENTENCE. MENTION ANY OTHER DETAILS FOR NOTIFICATION BY THE HSREC THAT WAS NOT INCLUDED IN THE PROTOCOL OR APPLICATION FORM]

Yours faithfully,

_____
[INSERT NAME AND SIGNATURE OF RESEARCHER]

Email address
Cell phone number

*Appendix 6: Example of Head of Department permission letter – **must** be printed on the Department letterhead.*
Note: Customise to be project-specific and upload to RIMS Document Checklist

The Chair: Health Sciences Research Ethics Committee
Dr SM le Grange
For Attention: Mrs M Marais
Block D, Room 104,
Francois Retief Building

PO Box 339 (G40)
Nelson Mandela Drive
Faculty of Health Sciences
University of the Free State
Bloemfontein
9300

[DATE]

Dear Dr SM le Grange,

[STUDENT NAME AND NUMBER]
[PROJECT TITLE]

I, [HOD NAME] hereby grant [STUDENT NAME] permission to conduct the above-mentioned research project. The research will be completed in accordance with myself as Head of Department of [ENTER DEPT NAME] and [ENTER STUDENT SUPERVISOR NAME] as supervisor of this study.

Yours faithfully,

_____
[HEAD OF DEPT NAME AND DATE]

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL
HEALTH
RESEARCH ETHICS
COUNCIL

Private Bag X828, PRETORIA, 0001, Cnr Struben and Thabo Sehume Street
Tel: +27 (0) 12 395 8124/8113 Fax: +27 (0) 12 395 9249

MINISTERIAL CONSENT
FOR NON-THERAPEUTIC HEALTH RESEARCH WITH MINORS:
OPERATIONAL GUIDELINES
2015

1 PURPOSE

To provide guidance to health Research Ethics Committees (RECs) and health researchers regarding Ministerial Consent for 'non-therapeutic' health research with minors.

2 BACKGROUND

1. Section 71(3)(a)(ii) of the National Health Act (NHA) requires the Minister of Health to consent to 'non-therapeutic' health research with minors, after considering whether four criteria are met (see Appendix 1).
2. The Minister may delegate authority, in terms of s 92(a), to any person in the employ of the state, a council, board or committee established in terms of the Act to give this consent.
3. The Minister has delegated authority to provide Ministerial Consent for 'nontherapeutic' health research with minors to RECs who have been found to be compliant with the audit and have achieved full registration with the NHREC. Correspondence in this regard was sent to relevant RECs on 14 October 2014. As further RECs become fully registered, their authority to exercise the delegated power will be communicated by the NHREC through the Secretariat.
4. Regulations for research with human participants, published on 19 September 2014 (R 719; see Appendix 2), contain Form A that sets out the four criteria to be met for the additional review of 'non-therapeutic' health research with minors. Proper use of Form A should provide adequate evidence that these reviews are performed appropriately by RECs (see Appendix 3).

3 RECOMMENDATIONS FOR ***RESEARCHERS***

1. Researchers should consider carefully whether their planned research involving minors holds out the prospect of direct benefit to participants ('therapeutic' research); or whether it holds out no prospect of direct benefit to participants but holds out the prospect of generalisable knowledge ('non-therapeutic' research).
2. Researchers conducting 'non-therapeutic' research with minors must attach Form A to the application for ethics approval.

3. The content supplied in Form A should draw on relevant sections of the protocol or ethics application, for example, the sections that deal with the scientific justification for enrolling minors; how knowledge will be advanced by enrolling minors; the benefits to society in terms of knowledge gained by enrolling minors; and the potential risks to enrolled minors and risk minimisation.
4. Whether Ministerial Consent for 'non-therapeutic' health research with minors has been granted will be communicated, as part of the overall feedback about the application from the REC.

4 RECOMMENDATIONS FOR REGISTERED ***RECS***

1. RECs with delegated authority to grant Ministerial Consent must draw to the attention of researchers the following requirements:

a) That researchers must consider carefully whether their planned research involving minors holds out the prospect of direct benefit to participants ('therapeutic research'); or whether it holds out no prospect of direct benefit to participants but holds out the prospect of generalisable knowledge ('nontherapeutic research').
b) That 'non-therapeutic' research must meet four criteria to be eligible for Ministerial Consent.
c) That the ethics application for 'non-therapeutic' health research with minors must include Form A completed appropriately.
d) That where the REC judges that the research involves 'non-therapeutic' health research with minors, this view will be communicated to the researcher with a request to complete Form A accordingly.
e) That the content supplied in Form A should draw on relevant sections of the protocol or ethics application, for example, the sections that deal with the scientific justification for enrolling minors; how knowledge will be advanced by enrolling minors; the benefits to society in terms of knowledge gained by enrolling minors; and the potential risks to enrolled minors and risk minimisation.
f) That the outcome (whether consent for non-therapeutic health research with minors is granted) will be communicated by the REC, as part of the overall feedback about the application.
g) That 'therapeutic' health research with minors does not require this additional review but is reviewed in the usual way to ensure norms and standards are met.

2. RECs should only grant Ministerial Consent after review of the application leads to the decision to grant ethics approval, and the careful review of Form A satisfies the REC that the four criteria are met.
3. RECs should maintain specific records of such applications, and outcomes, for reporting purposes. A traceable link to each application must be maintained.
4. RECs may devise Standard Operating Procedures (SOPs) to integrate the additional review into the overall ethics review process to facilitate efficient use of time.

5 RECOMMENDATIONS FOR NON-REGISTERED RECs

1. Two types of REC might not be registered with the NHREC.
2. The first type is an REC that reviews health research but has not been granted delegated authority because it is not (yet) fully registered with the NHREC. RECs that fall into this category are urged to complete the registration process as soon as possible.
3. The second type is an REC that does not review 'health research' with human subjects and is – because of the remit of its review and oversight authority – not registered and is unlikely to seek registration. While such RECs are not required to address the issue of Ministerial Consent, they should carefully review non-health research including the justification for the involvement of minors.

6 CONCLUSIONS

1. It is hoped that the delegation of authority from the Minister to fully registered RECs to grant Ministerial Consent for 'non-therapeutic' research with children will resolve an important issue in the short-term, while appropriate law reform of section 71 is pursued in the medium term.
2. RECs and researchers are requested to send feedback to the NHREC about the process of granting Ministerial Consent and the adequacy of these operational guidelines, so that improvements can be made.

Appendix 1: CURRENT WORDING: S 71 OF THE NATIONAL HEALTH ACT

Research on or experimentation with human subjects

(1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted- *(a)* in the prescribed manner; and
(b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.

(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted- *(a)* if it is in the best interests of the minor; in such manner and on such conditions as may be prescribed;
with the consent of the parent or guardian of the child; and
if the minor is capable of understanding, with the consent of the minor.

(3) *(a)* Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted- (i) in such manner and on such conditions as may be prescribed;
(ii) with the consent of the Minister;
(iii) with the consent of the parent or guardian of the minor; and (iv) if the minor is capable of understanding, the consent of the minor.
(b) The Minister may not give consent in circumstances where- (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult; (ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors; (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;
(iv) the research or experimentation poses a significant risk to the health of the minor; or (v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

Appendix 2: CURRENT WORDING: S 7 OF THE REGULATIONS FOR RESEARCH WITH HUMANN PARTICIPANTS

Ministerial consent for non-therapeutic research with minors

7. Protocols for human participants' research that propose non-therapeutic research with minors must have ministerial consent in terms of section 71(3)(a)(ii) of the Act **or, where appropriate, consent from a delegated authority in terms of section 92(a) of the Act.**

a) Applications for ministerial consent must be made on Form A;
b) the application should be considered by the Minister or the delegated authority after the protocol is reviewed by a registered health research ethics committee to assess whether it meets the required norms and standards of the health research ethics committee;
c) in granting ministerial consent, relevant bodies or experts may be consulted;
d) the researcher must be notified of the outcome in writing within 60 days; and
e) the researcher may appeal the outcome including by approaching the National Health Research Ethics Council in terms of section 72 (6) (d) of the Act.

Appendix 3: Application for Ministerial Consent for Non-Therapeutic Research with Minors (Form A)

*Note: Complete and upload to RIMS application form if applicable. **DO NOT** modify this form.*

APPLICATION FOR MINISTERIAL CONSENT
FOR NON-THERAPEUTIC RESEARCH WITH MINORS

1. INSTRUCTIONS

1.1 This application form must be completed for all protocols that are classified as "non-therapeutic" and involve the participation of minors. *Non therapeutic research is defined in the regulations relating to research on human participants as "research that does not hold out the prospect of direct benefit but holds out the prospect of generalizable knowledge". Minors are defined as persons under the age of 18 by section17 of the Children's Act (No. 38 of 2005).*

1.2 This application form should be submitted with a copy of the protocol and supporting documents.

1.3 This application should be submitted to the Minister of Health or the delegated authority in terms of section 92(a) of the Act.

1.4 This application form should describe how 'non-therapeutic' research protocols with minors meet the conditions set out in section 71 (3)(b) of the Act (described below).

1.5 All sections of the form must be completed in full.

1.6 Ministerial Consent may be granted for non-therapeutic health research with minors when certain conditions set out in section 71 (3)(b) of the Act are met and these conditions are:

(a) The research objectives cannot be achieved except by the enrolment of minors;

(b) The research is likely to lead to an improved scientific understanding of conditions, or disorders affecting children;

(c) Any consent given to the research must be in line with public policy; and

(d) The research does not pose a significant risk to minors, and if there is some risk, the benefit of the research outweighs the risk.

2. INVESTIGATORS' DETAILS

Name of principal investigator	
Title of research protocol	
Institutional affiliation	
Postal Address	

Physical Address	
Email Address	
Phone	
Fax	
Date of Application	
Signature of Applicant	

3. APPLICATION

3.1 Condition 1: The research objectives cannot be achieved except by the participation of minors

Describe the scientific justification for the enrolment of minors. Explain why this research must be done with minors as participants:

3.2 Condition 2: The research is likely lead to an improved scientific understanding of certain conditions, diseases or disorders affecting minors

Describe how the research might, or aims to, advance knowledge affecting the health and welfare of minors as a class. Note that 'condition' is defined in the Regulations as 'physical and psychosocial characteristics understood to affect health' allowing that this research does not only involve children with an illness.

3.3 Condition 3: Any consent given to the research is in line with public policy

Consent given by authorised persons must be in line with public policy considerations. Describe how consent to the research will be in line with public policy or would be acceptable, for example, show how the research poses acceptable risks and promotes the rights of minors:

3.4 Condition 4: The research does not pose a significant risk to minors; and if there is some risk, the benefit of the research outweighs the risk.

Describe how the potential risks from the research procedures and/or intervention to minor participants will be minimised and describe any possible benefits from the research to society in the form of knowledge:

Appendix 8: Broad Ethical Principles for Ethics Review (DOH2015)

THREE BROAD ETHICAL PRINCIPLES

Beneficence and non-maleficence

- Maximise benefit and minimise harm, risks of harm posed by the research must be reasonable in light of anticipated benefits.
- Research design must be sound; researchers must be competent to carry out the proposed research activities.
- Research involving human participants should seek to improve the human condition. If the research cannot do this, then it is unlikely to be ethical.

Distributive justice (equality)

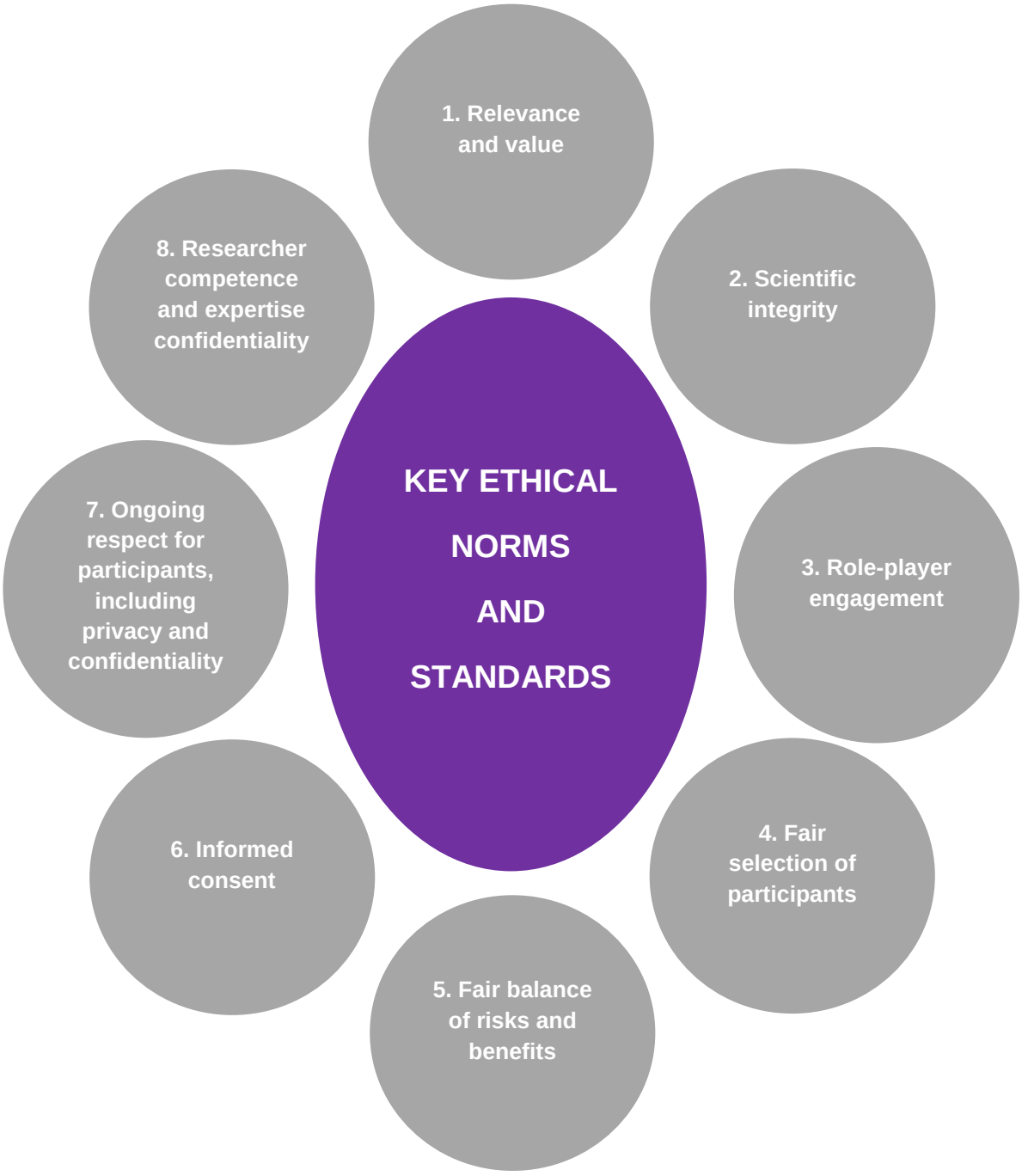
- Fair balance of risks and benefits amongst all role-players in research;
- Principle of equality is expressed in the research context.
- No segment of the population to be unduly burdened by the harms of research or denied the benefits of knowledge derived from it.
- Reasonable likelihood that the population from which participants are drawn will benefit from the research results, if not immediately, then in the future.

Respect for persons (dignity and autonomy)

- Persons capable of deliberation about their choices must be treated with respect and permitted to exercise self-determination.
- Persons who lack capacity/ diminished capacity protected against harm from irresponsible choices.
- Dignity, well-being and safety interests of all research participants are the primary concern
- Interests of participants should outweigh the interests of science and society. Consequently, involvement of persons or particular categories of people in the research should be justified in research proposals.
- Respect for persons means also that the interests of researchers must be considered. These include welfare and safety interests, authorship and intellectual property interests, and collegial and professional interests.

Appendix 9: Eight Key Ethical Norms and Standards for Ethics Review (DOH2015)

KEY ETHICAL NORMS AND STANDARDS



Version history

Version 07_Jan 2019	• Changes as per branding guidelines • Deadline of 30 days to respond to review comments from the HSREC was extended to 60 days • M.Med research added to list requiring Evaluation Committee reports • DOE-required steps were added to post- and undergraduate research sections as well as case report section. • MCC updated to SAHPRA • HSREC 17 form/requirements updated to reflect the new system • Updated dates for 2019 • Ethical considerations inclusion for lay terms summary • Inclusion of the mandatory Summary of Changes form when responding to comments from the HSREC. • Adjusted fees. • All documents must be uploaded to/replaced on the Documents Checklist. Documents submitted in any other location in RIMS will not be reviewed. Non-compliance to this request will result in the application being returned to the researcher to load the documents in the correct place. • Update of the RIMS login procedures for UFS students and staff – Single sign-on