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

**HEALTH SCIENCES RESEARCH ETHICS COMMITTEE**

# PREPERATION GUIDE: NEW APPLICATIONS RIMS POSTGRADUATE AND OTHER RESEARCH (Excluding Contract Research)

All applications must be approved by the Health Sciences Research Ethics Committee (HSREC) BEFORE research is conducted / continued.

a. **New applications** must be submitted to the HSREC on RIMS https://ufs.rims.ac.za/ no later than the submission dates for 2017 listed below in order to be tabled at the next meeting.

b. **All subsequent submissions** (amendments, reports, notifications, etc.) – please contact HSREC Administration to determine whether you should submit on RIMS or in hard-copy at the office.
   - Agenda closes for all new matters **7 working days prior** to the meeting.

c. HSREC Administration reserves the right not to accept applications for review that are submitted in hard copy at the HSREC office if RIMS should have been used.

***IMPORTANT NOTE:*** *Late and incomplete submissions will stand over until the next meeting. Please contact HSREC Administration to arrange for a consultation if needed.*

| SUBMISSION DATES 2017 | MEETING DATES 2017 |
|---|---|
| 20 JANUARY 2017 | 31 JANUARY 2017 |
| 17 FEBRUARY 2017 | 28 FEBRUARY 2017 |
| 15 MARCH 2017 | 28 MARCH 2017 |
| 12 APRIL 2017 | 25 APRIL 2017 |
| 19 MAY 2017 | 30 MAY 2017 |
| 15 JUNE 2017 | 27 JUNE 2017 |
| 14 JULY 2017 | 25 JULY 2017 |
| 18 AUGUST 2017 | 29 AUGUST 2017 |
| 14 SEPTEMBER 2017 | 26 SEPTEMBER 2017 |
| 20 OCTOBER 2017 | 31 OCTOBER 2017 |
| 24 NOVEMBER 2017 | 05 DECEMBER 2017 |

| HSREC ADMINISTRATION CONTACT DETAILS: | | |
|---|---|---|
| The Chair: Health Sciences Research Ethics Committee<br>Dr SM Le Grange<br>For Attention: Mrs M Marais<br>Block D, Room 104,<br>Francois Retief Building<br>Po Box 339 (G40)<br>Nelson Mandela Drive<br>Faculty of Health Sciences<br>University of the Free State<br>Bloemfontein<br>9300 | Mrs M Marais<br>*Head: Administration*<br><br>Mrs J du Plessis<br>*Administration* | 051-401 7795<br><br>051-401 7794 |
| | Fax number | 051-4444359 |
| | Email | ethicsfhs@ufs.ac.za |
| | Office hours | 07h45 – 16h30 |

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

- Geraldine Meyers**:** meyersgj@ufs.ac.za, 051 401 9398
- Willem Kilian: kilianw@ufs.ac.za; 051 401 3682
- Maricel Van Rooyen: vanrooyenm2@ufs.ac.za, 051 401 9451

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**SUBMISSION REQUIREMENTS:**

# Electronic submission on **RIMS**

(PLEASE SEE SUBMISSION REQUIREMENTS AND GUIDANCE BELOW)

## A. CREATING YOUR USER PROFILE

- Kindly send the following details to the RIMS office to enable them to create your user profile. Contact details provided on the previous page. Please specify if you are a CUT/UFS student/UFS employee/External Researcher:
    - Full names and surnames:
    - Staff/ student number
    - Email addresses
    - Department
    - Telephone numbers
- You will receive a confirmation email from the RIMS office with all the details you need to log in.
- Kindly change your password:
    - 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/staffnumber
    - 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.

## B. ELECTRONIC APPLICATION

- Please refer to the Ethics Application Manual available on the HSREC webpage for generic guidance on how to complete the e-form.
- The Documents Checklist and Ethical Risk Assessment Checklist must be completed. This is mandatory.
- Investigator declaration of conflict of interest for ALL investigators must be signed on the **RIMS Postgrad and Other Research Investigator Declaration** template (available on our webpage or from HSREC Administration) and uploaded to RIMS at the end of the e-form. The application will not be accepted by the system if this has not been done.
- All researchers as well as their main supervisor (if applicable) must sign this form **prior** to the RIMS application process being started.

**IMPORTANT NOTE:** Signatures are **mandatory**. Applications will **not** be accepted for review if all required signatures have not been obtained.

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**C. DOCUMENTS CHECKLIST FOR ALL NEW APPLICATIONS (CASE STUDIES/SERIES DOCUMENTS CHECKLIST TO FOLLOW)**

The following items appear on the Documents checklist. Please see below for guidance.

Please keep all the documents mentioned below separate, and only upload the requested document under each section.

**1. Cover Letter**

- If the new application forms part of a sub-study, the main study's ethics reference number must be quoted.
- An example of a cover letter can be requested from HSREC Administration.

**2. Study protocol**

- Include page numbers, version numbers and dates on protocol.

**NOTE:** Only upload the protocol at this stage. All other supporting documents will be uploaded at subsequent sections of the Documents Checklist.

**3. Investigator's brochure and other related material**

Only for Contract research/clinical trials (All contract research/clinical trial submissions will remain status quo until further notice. RIMS roll-out scheduled for 2017)

**4, 5 Questionnaires and/or other measuring tools/instruments**

- The questionnaire(s) 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 in English, Afrikaans, Sesotho or other applicable languages. Questionnaires must be available in the main language(s) of the research setting.

- **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.

**6. Recruitment material/ Advertisement(s)**

If an advertisement for potential study subjects will be used, it must include the following information:

- Advertisement in its final form (logo etc.) must be presented to the HSREC
- Note condition/disease under discussion in the research proposal in layman's terms
- Category participants: Age, etc.
- Which method will be used, e.g. questionnaires
- Remuneration for transport and inconvenience
- Any costs payable by participant
- Contact person's name and cell phone number
- For further enquiries also note office hours, if applicable
- Voluntary participation and participant may withdraw at any time
- Patients currently on treatment will participation in the research study in conjunction with the treating physician
- Time duration of study

**7. Material Transfer Agreement**

If any samples will be transferred between labs, this needs to be included in your application.

**8. Budget**

- 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, 10, 11, 12, 13 Letters of approval to conduct research**

**IMPORTANT NOTES**:

- If permission has been requested but not been granted by the time of submission, include the **letter of request** in

this application.

- Feedback on a letterhead of the institution and the name (printed) of the person granting approval has to appear together with the signature and must be submitted to the Ethics Committee in order to obtain final approval before conducting a study.

**The following letters of approval must be submitted:**

- **Head of Academic Department**
- **Institutional permission (other than public healthcare facilities)**
- 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** ethical approval has been granted. Please contact HSREC Administration for more information.
- 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.
- Approval must be obtained from the **UFS authorities** if research is to be conducted among students, lecturers or other role-players on campus at the University of the Free State. **Approval form: UFS authorities (HSREC17) must be used for this purpose. You can download it from the HSREC webpage, or contact HSREC Administration. Important note regarding the use of the HSREC17: All signatories' signatures must be on the same form in the end.**
    - If research is to be conducted in a specific faculty, permission must be obtained from the Dean of the specific faculty and the Head of the School involved as indicated on the HSREC17 form. A copy of the protocol together with a cover letter must be attached to the HSREC17 form before it is submitted to the Dean of the specific faculty and the Head of the School for approval purposes.
    - If research is to be conducted in the Faculty of Health Sciences, permission must be obtained from the Dean of the Faculty of Health Sciences and the Head of the School involved as indicated on the HSREC17 form. A copy of the protocol and the HSREC Application form must be attached to the HSREC17 form before it is submitted to the Head of the School and the Dean for approval purposes.
    - Where research involves **ANY** UFS students, the consent of the Dean: Student Services as indicated on the HSREC17 form must also be obtained. A copy of the protocol must be attached to the HSREC17 form before it is submitted for approval purposes.
    - When research is to be conducted among students, lecturers or other role-players on campus at the University of the Free State permission must be obtained from the Vice-rector: Research as indicated on the HSREC17 form. A copy of the protocol must be attached to the HSREC17 form in order to obtain approval.
    - A progress report must be sent to the HSREC and Vice-rector: Research after completion of the study.
    - PLEASE CONTACT HSREC ADMINISTRATION FOR GUIDANCE ON THE ABOVE PROCESS (HSREC17: PERMISSION FROM UFS AUTHORITIES).
- If your project is conducted at a school, consent/permission has to be obtained from the following:
    - Department of Education
    - Principal and Teacher
    - Parent/guardian
    - Learners

**The following must be mentioned in the letter:**

- Project/trial/study title
- Name and contact details of the researcher
- Brief description of the project/trial/study
- The relevant department/ward and whether patients and/or files are involved
- Number of patients, records/files, samples involved
- Duration of the study
- Whether the results of the project will be published and/or presented at a meeting/congress

**14, 15 Participant Information and Consent/Assent Form (ICF)**

**NOTE**: 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.

The following must be mentioned in the **INFORMATION LEAFLET AND INFORMED CONSENT**:

- Purpose of the study (explanation in lay terms)
- Potential advantages of the study for the patient and the other persons
- Risks and foreseeable discomfort for the patient/subject
- That the patient/subject may withdraw from the study at any time

That participation is voluntary

- Alternative methods for treatment available?
- Nature of preparations (+ placebo) in use
- That information obtained will be treated as confidential
- That insurance has been taken out to protect subjects
- The name of the contact person
- The reversibility or irreversibility of side-effects
- 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
- Serious adverse effects
- Dotted line for signature and date
- That results may be published and/or presented at a meeting/congress
- That no costs will be payable by the participant
- Remuneration for patient/participant?
- 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.
- Time that participant will have to give up to participate in the study
- 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.

**KINDLY NOTE:** 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.

**16. Evaluation Committee approval: Masters (excluding M.Med.) and Doctoral degrees**

**17. Insurance certificate (Contract/Clinical trials)**

**18. Letter requesting permission from the relevant provincial department**

- 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** ethical approval has been granted. Please contact HSREC Administration for more information.
- Please upload the cover letter that you are planning to submit to the Provincial Department.

**19. Letter requesting permission from the Head Master of a school**

- Only necessary if research is to be conducted at schools, see points 9, 10, 11, 12 and 13
- Please upload the cover letter that you are planning to submit to the School(s).

**20, 21, 22 Short Curriculum Vitae (CV) of all investigators**

Submit a short CV for the principal investigator, co-investigators, and sub-investigators (where applicable)

- **Each CV should not comprise more than 2 pages.**

If the study is for degree purposes, a supervisor CV must also be included.

**23. Approval by a Biostatistician**

Please note the following when the Department of Biostatistics, Faculty of Health Sciences (Prof G Joubert Tel. 051-4013117, Ms. M Nel Tel. 051-401 3116, Mr. FC van Rooyen Tel. 051-401 3114, Dr J Raubenheimer Tel 051-401 3115), CR de Wet Building, UFS will be assisting you with the protocol:

- 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.
- 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.

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.

**24. Main supervisor GCP (Good Clinical Practice) certificate**

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.

**25. Researcher or main supervisor's professional registration**

**26. NHREC Registration form**

Only for contract research/clinical trials

**27. MCC application / approval letter**

Only for contract research/clinical trials

**D. DOCUMENTS CHECKLIST FOR ALL NEW CASE STUDIES/SERIES**

The following items appear on the Case Report/Series Documents checklist. Please see below for guidance.

Please keep all the documents mentioned below separate, and only upload the requested document under each section.

**1. Cover Letter**

- If the new application forms part of a sub-study, the main study's ethics reference number must be quoted.
- An example of a cover letter can be requested from HSREC Administration.

**2. Abstract**

- Include page numbers, version numbers and dates.

**NOTE:** Only upload the abstract at this stage. All other supporting documents will be uploaded at subsequent sections of the Documents Checklist.

**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).**

***NOTE**: 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, if applicable**

**12. Letter requesting permission from the relevant provincial department**

- If research is/was conducted in **public healthcare facilities**, approval from the Provincial Department of Health must be obtained. Note that this can only be applied for **after** ethical approval has been granted. Please contact HSREC Administration for more information.

  Please upload the cover letter that you are planning to submit to the Provincial Department.

**13. Letter requesting permission from the Head of Dept./Head of the School of Medicine/Nursing/Allied Health Professions**

## E. 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.

**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 ethical approval, a lay term summary 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)

Examples of what Lay terms should describe:
o Where the study will be conducted
o What population will be included in the study
o What method will be used
o What treatment will be administered to participants
o What control method will be used

**POST SUBMISSION GUIDANCE**

**RESPONDING TO THE COMMITTEE'S FEEDBACK**

**IMPORTANT NOTE: Please refer to the RIMS manual for more information (the system will send it automatically to your provided email address): *How to respond when the Ethics Committee asks for Modifications required on an Application***

- The submission deadlines are approximately **7 working days** prior to the HSREC meetings. Feedback will only be provided to applicants **after** the meeting.
- From **3-7 working days** after the meeting, HSREC Administration will forward comments via RIMS from the Committee to your provided email address. You will receive a system generated notification from RIMS.
- Response to modifications by email will not be accepted. Please respond in RIMS.
- Copy or restate the question or concern and then provide a detailed and thoughtful response. Incomplete responses are likely to trigger a repeat query from the reviewer.
- Address all points and queries, using examples, references and hard data where necessary.
- If the Committee's feedback is unclear or ambiguous, contact HSREC Administration and request clarification. If you disagree with a comment or recommended change, provide your rationale.
- If the response requires revisions to the protocol, recruitment materials and/or information sheets/ consent forms, revise the documents accordingly, submit **electronic** copies **via RIMS** with changes highlighted in bold/color/italics so the evaluators can immediately determine where and what changes have been made. Include a summary of changes in your response.
- Proofread the final versions for grammatical, typographical and formatting errors.
- **NOTE**: Only RIMS correspondence will be accepted when responding to the HSREC's comments after submission of the application. You are welcome to contact HSREC Administration of you have any questions/concerns.
- Feedback from the meeting will be communicated to researchers within **7 working days** after the meeting. You are welcome to contact the office for any information.