UNIVERSITY OF CAPE TOWN

DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH
RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL
KLIPFONTEIN ROAD RONDEBOSCH
7700
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Undertaking research in the Department of Paediatrics and Child Health (DPCH)

Research done within the DPCH must undergo scientific review before commencement.
The purpose of this document is to outline the process of undertaking research in the DPCH and provide guidance regarding documentation required for protocol scientific review before submission to the faculty Human Research Ethics Committee (HREC).

Section A: Submission to the Department of Paediatrics & Child Health Research Office

1. Research protocols must be submitted to the Research Office which will send proposals for departmental review to ensure that only well-designed and scientifically sound research is submitted to the Faculty Human Research Ethics Committee (HREC). There are three types of Departmental Review:

    a. **Primary Review:** This review applies to new protocols that are being reviewed for the first time. It involves a detailed scientific evaluation of the study design, sample size, analysis plan, and measures for participant safety and confidentiality before submission to the HREC for ethical approval.

    b. **Sub-Study Review:** This review applies to secondary analyses of data from previously approved studies or to extensions of existing studies. It is generally faster, except when the new study introduces additional participant contact or risks that were not approved in the original study. Each sub-study is issued unique DRC and HREC numbers linked to the parent study.

    c. **Reciprocal Review**: This applies to protocols that have already been reviewed and approved by an external scientific and ethics committee (national, international, or pharmaceutical). The local principal investigator must submit a "local PI synopsis" to outline how the approved protocol will be adapted to the local context. This is a rapid review, focusing on local implementation, participant safety, and confidentiality.

    The minimum time allocated for departmental review is 2-3 weeks, though the process may take longer depending on reviewer availability. The Departmental Review Committee (DRC) does not conduct "expedited reviews"; this option is available only to the HREC after DRC approval. Researchers are encouraged to submit their proposals for departmental review well in advance of their targeted HREC submission date.

2. All submissions must be made to the research office:
    CONTACT:
    Geanine Hopley
    Departmental Research Office
    Department of Paediatrics and Child Health Faculty of Health Sciences
    University of Cape Town
    ICH Building, Red Cross War Memorial Children's Hospital
    geanine.hopley@uct.ac.za

3. The following documents are required by the research office, these must be submitted **electronically**

Form/Document	Purpose	Details
Cover Letter	Address DRC Chair	Sent with proposal submission - **Must include the full list of researchers** [#] - Must include 2-4 reviewer suggestions[*]
Protocol Synopsis	Plain Language Summary of the study	**Required by HREC.** Maximum 4 pages length
Full Research Proposal	For DRC review of the study	**Required by HREC**. **Should include (if applicable):** - Consent forms - Information sheet - Data collection tool - Budget - Contract
FHS013 Form	HREC Document outlining study details	**Required by HREC** - Signed (Student and/or PI) **If study for degree purposes, Supervisor must be the PI.**[‡]
Form A	Application for research with minors	Required application for ministerial consent when conducting research with minors.

Research should be collegial and collaborative; research proposals including patients from a sub-specialty discipline, unit or clinical area should have a senior staff member from that area as a collaborator or co-investigator.

* Suggested reviewer cannot be someone involved in the study, and should also be an expert in the field with an appropriate qualification. While the researcher's reviewer suggestions will be considered, the DRC Chair will allocate reviewers and may choose people other than those recommended by the researcher. **Please note that anonymity between researcher and reviewer should be maintained.**

‡ **PhD research proposals** need to be presented at **DPCH Postgraduate Support Forum** or a departmental seminar; PhD supervisor to confirm that the proposal has been presented. Contact the postgraduate administrator, Melissa Williams (melissa.williams@uct.ac.za) for the details of PhD support forum meetings.

4. If external funding is involved, please see process to follow on the UCT Research Support Hub page (which includes who to contact for assistance with any queries around the eRA application process). Note that all external funding applications must link with the departmental research finance team to assist with / review the budgeting process.

Protocol Submission

- See above for required documentation.

DRC Review

- Minimum review time 2-3 weeks
- Reviewer may request further clarification/changes on proposal
- Once proposal is approved by reviewer, DRC Chair/Deputy Chair will sign FHS013**

DPCH HOD Approval

- DRC will submit signed FHS013 to Department of Paediatrics and Child Health HOD for approval**
- Research office will inform researcher once appoved by HOD. Reseacher may then submit proposal to HREC

HREC Approval

- See Section B
- HREC process detailed here: https://health.uct.ac.za/home/human-research-ethics
- **HREC approvals and reference numbers must be forwarded to DRC Research Office. Research study may not proceed unless UCT ethics approval has been forwarded to DRC**

Institutional Approvals

- Research taking place within health facilities requires institutional and departmental consents
- This can only be applied for after HREC approval of study
- See Section C and D for details

Funding

- Contact Research Office for details of applying for internal funding awards
- **External Funding**: Follow processes on **UCT Research Support Hub page** regarding the eRA application.
- Note that all external funding applications must link with the departmental research finance team to review the budgeting process.

** **NOTE:** DRC and HOD signatories may not be study investigators in the proposal.

Section B: Submission to the Faculty of Health Sciences Human Research Ethics Committee (FHS HREC)

- The submission process can be reviewed here: : http://www.health.uct.ac.za/fhs/research/humanethics/forms/
- Proposal submissions are to be emailed to hrec-submissions@uct.ac.za as a single PDF file.
- Invoice queries: hrec-payments@uct.ac.za
- Researchers must ensure that they check the Administrative Forms web page to make certain that they are using the current version of the forms.

Please see the accompanying document "HREC types of applications and approvals for studies from DPCH

Section C: Application to conduct research within health facilities

- Obtain approval from the relevant hospital administration and/or **National Health Research Database** website for applications to do health research within health facilities.
- **Research conducted at Red Cross Hospital:**
  Researchers are required to apply for institutional consent through the Hospital Research Review Committee. Contact the administrative office, rxh.researchrequests@westerncape.gov.za for application forms. Only after the approval from hospital management has been obtained can research be conducted at Red Cross War Memorial Children's Hospital.
- **Research conducted at Groote Schuur Hospital:**
  Contact the GSH Research Committee for research to be conducted at Groote Schuur Hospital. GSHResearch.Request@westerncape.gov.za

Section D: Obtaining Permission to Access UCT Staff or Students As Part of Research Activities

- Researchers are reminded that permission to access UCT staff or students is required from the relevant authorities before commencing recruitment: further information is available here

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HREC: types of applications and approvals for studies from DPCH

All forms are updated frequently: download current version from UCT Health Sciences HREC website:
Human Research Ethics | University of Cape Town (uct.ac.za)

1) ***All research involving human participants needs HREC approval*** (usually via FHS013), unless a specific waiver has been provided by the chair of the HREC. Any publication by the PI /other author that emanates directly from the initial or ongoing HREC approved data collection may use the same HREC number.
2) HREC approval must be obtained **before** starting any research-related activities. This includes data collection and/or analysis.
3) Study amendments:
    a. A study must have ***staff amendment*** if new investigators join the team / there is a leadership change in the research team. **FHS007**
    In general, an amendment is ***not needed*** to add new co-investigator/s for every author on every publication, as long as PI remains the same, as the PI has ethical responsibility for the study conduct).
    b. A study must have a ***study amendment*** form submitted if there is a ***change in data collection:*** new specimens, interviews, change in frequency of follow up visits, extending duration of follow up, etc. **FHS006**
4) A "sub study" needs a new HREC number and approval
    a. A sub study may involve ***new analysis / specimens / interviews / procedures*** that were not covered by the original parent study protocol (ie instead of submitting a study amendment: can add the new specimens as a sub study)
    b. A sub study is often for a ***student analysing a small aspect of a larger already-approved study,*** or a novel aspect of a larger ongoing study.
5) ***Postgraduate research students*** must all submit a research protocol and FHS013 (new or updated) for review and approval.
    a. *Where a student is doing research towards their postgraduate degree within an approved umbrella study:*
        i. *If the student was already listed as an investigator prior to registering for the degree, and the study is now being used for degree purposes, then an updated FHS013 must be submitted together with a staff amendment, noting the changed roles of investigators.*
        ii. *If a student is joining an approved study as a new investigator, the student should submit a full HREC application as a sub-study linked to the umbrella study.*
        iii. *If data have already been collected, and secondary analysis is being done towards the postgraduate degree, this study should be submitted as a sub-study with a new application* .
6) ***Case reports***: 3 or fewer patients: needs HREC approval (using the case report application form-FHS035) and signed informed consent. (if 4 or more patients then needs full protocol application: FHS013)

7) Registering ***a patient database*** or biorepository needs HREC approval (FHS020) and regular renewal (usually every three years)***.***
    a. ***Every new protocol / sub-study emanating from the database/repository requires new HREC number*** (and a new full protocol application).
8) ***Undergraduate student*** projects need a different protocol application (shorter than the full protocol application; using FHS 021)
9) HREC approval ***needs to be up to date:*** needs annual ***progress report and renewal*** **(FHS016)** of all studies while they are still ongoing. (Eg MMed projects need annual review every year until study closure: a journal reviewer may request more data / extra analysis of existing data, so the study needs to be kept current until the publication is accepted.)
10) ***Study closure report*** **(FHS010)** to be submitted at the end of all research activities.
11) ***Ministerial consent for non-therapeutic research with minors*** (FORM A) is required. 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" This includes secondary analyses of routinely collected data and retrospective descriptive studies.
12) ***Research that does not require HREC approval***: as per UCT "Policy for the responsible conduct of research" Nov 2020:

    https://uct.ac.za/sites/default/files/media/documents/Policy_Responsible_Conduct_Research_March2022.pdf

    "Research involving secondary de-identified or coded data sets, where the researcher does not have access to identifying information; research on information in the public domain (if legally compliant with applicable privacy legislation) and observational research in public spaces where individuals do not have an expectation of privacy, generally does not require research ethics approval. However, some social media research has ethical implications that requires researchers to act responsibly and seek advice from a REC if necessary."

    Researchers should ***seek advice from UCT HREC*** before starting the research, and ***obtain explicit waiver of HREC approval***.

13) Even if a project (eg systematic review) does not require HREC approval, it is considered best practice ***to pre-register the protocol*** in a recognised online database, eg PROSPERO (PROSPERO (york.ac.uk)) or OSF (OSF | Sign in)

For more information see:

1) UCT HREC home page: Human Research Ethics | University of Cape Town (uct.ac.za)
2) UCT Office for Research Integrity: Office of Research Integrity | University of Cape Town (uct.ac.za)
3) UCT guideline for risk-based ethical review of research (human participants)
4) UCT authorship guideline: https://uct.ac.za/sites/default/files/content_migration/uct_ac_za/39/files/Policy_Authorship_Practices.pdf