38/916 amended

THE UNIVERSITY OF HONG KONG

Human Research Ethics Committee

Operational Guidelines and Procedures

I. The University's Ethical Committee Structure

1. As stipulated in the University's *Policy on Research Integrity* (http://www.rss.hku.hk/index.php/integrity/rcr/policy), all members of the University are under an obligation to comply with the highest standards of professional conduct. All research conducted by staff and students of the University involving human participants and the use of vertebrate animal subjects must be referred to the appropriate ethics committee:

   - the Institutional Review Board of the University of Hong Kong/Hospital Authority of Hong Kong West Cluster ("HKU/HA HKW IRB"), based in the Faculty of Medicine, receives for review any research protocols involving human participants and submitted by Principal Investigators (PI) who are academic/research staff of the Faculties of Medicine and Dentistry;

   - the Human Research Ethics Committee (HREC) receives for review any research protocols involving human participants submitted by Principal Investigators from the academic/research staff and students from Faculties other than Medicine and Dentistry; and

   - the Committee on the Use of Live Animals in Teaching and Research (CULATR) which reviews research protocols involving living animals.

II. Ethical Reviews of Research Projects Involving Human Participants

2. The IRB handles ethical reviews of clinical research protocols conducted at the University of Hong Kong, while the HREC handles reviews of non-clinical research protocols involving human participants. A cross-referral mechanism has been established to enable the committees to refer applications beyond their remit to each other for review.

3. The following guidance notes on how to obtain ethical approval from the HREC are intended to provide the necessary information for PIs to complete the application form for ethical approval. The application form, together with background information, the terms of reference, and current membership of the HREC, can be downloaded from the HREC section of the Research Services website (the "website" hereafter) at http://www.rss.hku.hk/integrity/ethics-compliance/hrec.

III. Who Should Apply for Ethical Review by the HREC

4. Staff members and students from non-clinical faculties, who are the PI of a research project which involves human participants in research investigations (including secondary data analysis) should submit an application for ethical approval to the HREC or the Faculty-based Research Ethics Committee (REC), as appropriate. All research, qualitative or quantitative, is covered, regardless of whether the research is funded by internal/external grants or even unfunded. Details on various types of review and guidelines on whether to apply to the HREC or REC will be covered in the following sections.

5. Researchers from Faculties other than Dentistry and Medicine but whose research protocol may involve clinical research, should submit their applications in the first instance to the HREC for consideration. The Chairman will determine, on behalf of the HREC, whether the research protocol should be referred to the IRB for consideration. Similarly, the IRB will receive and refer applications outside the scope of clinical studies to the HREC for consideration.

6. The responsibility for seeking compliance with the basic ethical principles and procedures rests with the Principal Investigator who should clearly indicate in his/her research proposal if it is necessary to seek ethical clearance.

7. When HKU staff or students engage (other than as research participants) in research projects led by other universities/organizations that involve human participants in the research investigations, if any part of the data collection is organized through or in the name of HKU, the responsible person from HKU (including staff and students) should seek ethical approval from HKU. For research projects without any HKU staff and students participating as PIs or Co-Is that involve human research participants in HKU, the PI of the project should seek ethical approval from HKU to ensure that the human research participants in HKU are well protected.

8. Exemption from ethical approval will only apply to anonymous surveys for improving teaching and learning (not for research) which are exclusively for the University's internal usage.

IV. Research Work Conducted by Students

9. The University's *Policy on Research Integrity*, which requires all members of the University (including students) to ensure that the design of projects takes account of any relevant ethical guidelines, is made available for information of all Research Postgraduate and Taught Postgraduate students in the *Graduate School Handbook* and the *Postgraduate Handbook (Coursework Programmes)* respectively.

Declaration of Awareness to Seek Ethical Clearance

10. All postgraduate students admitted since September 1, 2006 are required to sign a declaration form upon first registration at the University to acknowledge their awareness of the requirement to comply with ethical clearance requirements. Research postgraduate (RPg) students are asked to indicate in their annual progress report form if ethical approval is required for the research involved in his/her proposed thesis. RPg students will be required to submit documentary evidence to show that the relevant ethical approval has been obtained for research work on their theses when they submit their detailed scheme of research and the candidate's progress report, for purposes of confirmation of candidatures.

Research Postgraduate (RPg) Students

11. All RPg students are responsible for seeking ethical approval for their research projects with their supervisor and Head of Department endorsing the application before submission to the HREC.

Taught Postgraduate (TPg) and Undergraduate (Ug) Students

12. TPg students are required to submit their ethical application, with endorsement of their supervisor, to the Faculty-based Research Ethics Committee or its delegate(s) who should be an independent party for approval. Ug students are assumed to be less experienced in judging if ethical clearance should be sought for their assignments, so the supervisor/tutor in charge is given responsibility for determining if each student's project needs ethical clearance and for completing the necessary application for ethical approval on the students' behalf, for submission to the Head of Department/Dean of Faculty (for unitary Faculties).

V. Ethical Guidelines for Research involving Human Participants

13. Every PI should be aware of the basic ethical principles set out in the University's *Policy on Research Integrity* and the *Belmont Report* which constitutes the ethical principles underpinning research involving human participants. The *Policy* document and a four-page summary of the Belmont Report can be downloaded from the website. Researchers should, in particular, note the following principles when conducting non-invasive, behavioral type of research within the purview of the HREC:

    - minimal risk and risk proportionate to research benefit;
    - informed consent;
    - no undue influence and inducement to participate;
    - protection of vulnerable research participants;
    - protection of research involving deception of participants;
    - ensuring the confidentiality and security of research and personal data; and
    - compliance with the Law.

Sources of Data

14. All research that involves collecting new data from human participants and/or using pre-existing personal data[1] is subject to ethical clearance. Collection of new data from human participants covers all forms of collection process, e.g. experimental procedures/retreatment/intervention, focus group, telephone/internet survey, observation, personal interviews, or self-administered questionnaire, etc. Usage of pre-existing data refers to retrieving readily available personal data from existing documents/records for secondary analysis, irrespective of whether or not the data are publicly available[2], whether or not the data originally collected are intentionally for research purpose, and whether the personal data from existing documents/records will be extracted for secondary analysis. For example, using students' assignments for research analysis means to use pre-existing data from a private source that were originally collected for non-research purposes.

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[1] As defined by the Personal Data (Privacy) Ordinance, "personal data" means any data (a) relating directly or indirectly to a living individual; and (b) from which it is practicable for the identity of the individual to be directly or indirectly ascertained; and in a form in which access to or processing of the data is practicable.

[2] "Publicly available" means that the general public can obtain the data. Sources are not considered "publicly available" if access to the data is limited to researchers.

Risk Assessment

15. To ensure that participants' interests and rights are protected, PIs are required to undertake "Risk Assessment" in completing the ethical application. For which, PIs should consider carefully if the research study will involve any possible risks which could induce greater than minimal physical and/or psychological stress/pain/discomfort to participants. Under normal circumstances, participants should not be exposed to risks which are greater than minimal risks[3]. In case that there are risks, PIs should inform participants clearly about the type and what degree of the risk they may be undertaking, and what measures will be taken to minimize the risk, and what remedial support will be given to participants at risk. PIs should safeguard participants' privacy and confidentiality. PIs should let participants know how their provided data will be deployed in the research, identifiable or anonymous[4], and how and how long the data will be safely kept. PIs should also assess if there is any potential conflict of interest that needs to be declared and addressed.

Informed Consent

16. Respect for persons requires that participants, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them; the informed consent process is the instrument to provide this opportunity[5]. Researchers must accordingly obtain appropriate informed consent, and shall:

    a) give the research participant sufficient information about the study and how the study may affect the participant;

    b) deliver the information in a comprehensible manner, using a language readily understandable by the research participant; and

    c) assure the voluntary capacity of the participant by providing sufficient opportunity to consider whether or not to participate, and minimizing the possibility of coercion, undue influence, or harassment.

17. The process of obtaining informed consent has two components:

    a) providing the person who is being recruited to become a research participant with the information necessary to give informed consent by means such as an Information Sheet, and obtaining the consent to participate in the research; and

    b) documenting that informed consent has been obtained by means of an Informed Consent Form. Standard templates of Informed Consent Form can be downloaded from the website.

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[3] As defined by the IRB in its Standard Operation Procedures (2005), "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test.

[4] Anonymous data: Data without personal identifier (e.g. name, ID card, DNA profile). Data is anonymous when there is no possible way to identify the participants from the data collected. Data are not anonymous if procedures, such as accessing a computer database, will identify the participant. For most specific cases, the omission of names and other personal identifiers as HKID/Passport numbers, is sufficient to qualify data as anonymous.

[5] Section 6 (Informed Consent of Human Subjects of Research) of the IRB's *Standard Operating Procedures* (2005).

The basic rule of human participant research is that both components of the informed consent process shall be completed.

Recorded Consent Other Than Written Consent

18. Other than written consent, online/email recorded response can also serve as a means of obtaining informed consent as long as it is in response to a proper information sheet. Also, when conducting research where seeking written consent is not practical (e.g. illiterate respondents) or too sensitive, audio-recorded oral consent might be less of a privacy risk than written consent and can be considered as an alternative to written consent. In either case, please submit a full justification and an information sheet together with your application for ethical approval.

Waiver of the Requirement of Recorded Informed Consent

19. Research participants must normally give recorded informed consent to any use of their personal data unless existing personal data is being used for the purposes for which they were collected or a directly related purpose.

    In case that any forms of recorded consent are not practical and that the new data to be collected are without personal identifiers[6], the Committee may waive the requirement of written informed consent for the following types of research study:

    a) The research that involves no greater than minimal risk to the participants, and cannot practicably be carried out, if informed consent were to be obtained in advance, provided that the rights and welfare of the participants will not be adversely affected; in this instance, arrangements shall be made to provide pertinent information to the participants as soon as practicable and not later than immediately after their participation;

    OR

    b) The research project is to be conducted by or subject to the approval of government officials and is designed to study, evaluate, or otherwise, examine:

        i) public benefit of service programmes;
        ii) procedures for obtaining benefits or services under those programmes;
        iii) possible changes in or alternatives to those programme or procedures; or
        iv) possible changes in methods or levels of payment for benefits or services under those programmes; and

    c) The research could not practicably be carried out without the waiver or alteration.

Pre-existing Data

20. Users of existing documents or records containing personal data must complete the "Existing Data" section of the application form. This requires providing full details on the types of personal data to be used, and any appropriate informed consent forms or Personal Information Collection Statements from the original data collection process. It also requires an explanation of how this research is consistent with the purpose and use specified when the data were originally collected, as otherwise PIs must seek informed consent from participants again if they wish to use pre-existing data with personal

[6] Personal identifier can be direct or indirect. Direct personal identifiers are, e.g. name, address, ID card numbers, medical record numbers, etc., while indirect identifier is, e.g. assigned code that can make a subject reasonably identifiable.

identifiers for a new purpose.

Pilot Studies

21. There is a need to seek consent before obtaining data in pilot studies on the grounds that the informed consent form could be tested and be refined for use in any subsequent study.

Parental Consent and Student Assent

22. The best practice should be to seek written consent from parents and to obtain assent from students themselves for research involving children under 18, even in cases where children were able to decline participation. The assent forms should be written in an easily comprehensible manner at children's reading level, in order to facilitate their decision making on participating. For research with only minimal risk (including privacy risk), the following principles will determine if passive parental consent[7] can be used in place of written parental consent for participants who are children under 18. PIs seeking approval of passive parental consent should provide a full justification and an information sheet.

For School-based Research

23. a) for school based studies of children below Primary, active consent of parents is normally required;

    b) for school based studies of children in Primary (i.e. 5 years old and above), parental passive consent is normally sufficient for studies involving minimal risk, provided that only anonymous and non-sensitive data will be collected; and

    c) for school based studies of children in Secondary (i.e. 11 years old and above), parental passive consent is normally sufficient for studies involving minimal risk.

For Adolescent Research Outside School

    d) for studies of adolescents aged 16 or above, parental consent is not normally required on the basis that they are mature minors.

For Studies of University Students

    e) parental consent is normally not required for research projects involving no greater than minimal risks, even if the university students are aged 17 or below, on the understanding that they should be able to make their own decisions. For further details on dealing with the affairs of student minors, researchers should refer to the University's Guidance Note - Students under the age of 18 (document 155/813).

Privacy and Confidentiality of Data

24. To comply with the *Personal Data (Privacy) Ordinance*, researchers must maintain the confidentiality of data related to individual research participants. Except by public observation, researchers should clearly indicate the purpose of the collection of data and the method to ensure the confidentiality of collected data. Researchers must also avoid use of any personal identifiers such as individual names and addresses in their research reports which could lead to the human participants being identified.

25. The minimum retention period for research data and records is three years after publication or public release of the research to ensure that there are no problems with

[7] Passive parental consent means that parents are fully informed of the right to refuse participation by their children. Parents/guardians must be given reasonable time (e.g. 2 weeks), to object to the child's participation. Student assent is still required even if passive parental consent is used.

consent, fabrication and falsification. PIs are strongly advised to remove all personal identifiers for long term retention of their research data, in order to minimize privacy risks. Data with personal identifiers must not be kept beyond 5 years after publication unless there is explicit written consent from the participants to retaining the data with personal identifiers preserved, such as in oral histories. Anonymised data and records should be retained for as long as they are of continuing value to the researcher and the wider research community.

Security

26. Participants should be assured that the information collected will not be publicly disclosed in a way that specific person can be identified unless expressly consented to, and that every precaution will be taken in relation to the storage, use and disposition of data, for example, locking up raw data. For private sensitive data, PIs are suggested using indirect identifiers and keeping the direct identifiers separate from the data. Measures should be taken to ensure the integrity, prudence and competence of persons having access to data.

Benefits

27. Prospective participants should not be adversely induced by financial reward or be pressured to participate in research. All reimbursement of expenses, such as traveling expenses, should be commensurate with standard practice and be reasonable.

For Studies Involving External Parties

28. If an external party is involved in co-organizing the research project (e.g. in recruitment or data collection), a formal contract/letter of agreement or consent form should be signed before commencement of the project, and such document should be submitted together with the ethical application. Alternatively, an authorized representative of the external organization can participate in the research project as a co-investigator.

VI. Types of Review

29. The HREC conducts three types of review i.e. expedited review, double review and full review. In general, for a research protocol which involves only minimal risks to human beings, an expedited review may be conducted to shorten the review process, subject to the Chairman's discretion. If not, the application will go through double review or full review by the Committee.

30. Expedited Review

    Projects involving no greater than minimal risk will normally be considered by the Chairman (or another member of the Committee as recommended by the Chairman) under "expedited review".

31. Double Review

    Research that does not fulfill the description of minimal risks will normally require double review by at least two members of the Committee.

32. Full Review

    If the applicant does not agree with the changes asked for, the reviewers do not agree in their assessments, or there is an important matter of principle, the application will receive a full review by the Committee.

VII. Procedures to be Followed when Applying for Ethical Review by the HREC

33. Research protocols submitted by staff members and RPg (i.e. MPhil and PhD) students will be scrutinized by the HREC. For Faculties of Education and Social Sciences, they each have their own mechanism in place to preview the ethical applications at Faculty level before they are submitted to the HREC. Ethical applications submitted by TPg students will be vetted by the Faculty Research Ethics Committees (the "RECs"). Faculties which do not have an ethics committee may have designated its Faculty Higher Degrees Committee/Faculty Research Committee to discharge such a function. Please consult your Faculty Office for details.

34. Heads of Departments (or Deans of unitary Faculties) or their delegates are responsible for the vetting of undergraduate students' applications. Please refer to the appended flowchart on the procedures for submitting applications for ethical approval by the HREC.

Obtaining Prior Ethical Approval

35. It is the responsibility of the PI to make sure that ethical approval has been obtained prior to any data collection/analysis taking place. Supervisors of RPg students are also responsible for ensuring that their students have obtained such ethical approval before starting data collection. Failure to obtain necessary ethical approval will cause rejection of research grant applications, and may require recollection of data. In addition, a letter of warning will be issued to the PI concerned, and if necessary, the Chairman of the HREC may refer the case to the Chairman of the University Research Committee for possible disciplinary action.

Deadlines for Submission

36. There is no deadline for applications for ethical clearance. The processing time from submission of application to notification of approval will normally take not more than 3 weeks, provided that the submitted application form is properly completed with all required documents attached. In addition, Principal Investigators of RGC GRF and ECS proposals are cautioned particularly to submit their applications for ethical approval by not later than end of February, as in accordance with the RGC's ruling, where such ethical approval is required but has not yet been obtained by the RGC deadline (normally set on April 30), the application will be regarded as being withdrawn.

Documents to be Completed and Submitted

37. The application form, the standard templates of informed consent form (and deception: post-debriefing consent form) can be downloaded from the website. Please enclose copies of full research proposal including any questionnaire and/or interview script and informed consent form together with your completed application form, and submit to the Secretary, Human Research Ethics Committee, c/o Research Services, Registry.

VIII. The Outcome of the Review

38. The Committee will normally notify the applicant in writing of the result of application within 3 weeks' time from receipt of his/her duly completed application with all required documents. Research cannot begin until the protocol has been approved by the Committee.

Approved:

39. A letter of approval will be issued to the PI with indication of the ethics approval period granted, which normally shall not be more than four years, unless an extension has been

granted. An HREC reference number will be assigned to each approved project and indicated in the letter of approval. The PIs are required to include the HREC reference number in all materials sent to potential and actual participants.

40. To improve transparency of the ethics approval process and allow general public to search for research projects with ethical approval granted by the Committee, the project title/abbreviated project title provided by the PI in the application form, HREC reference number, ethical approval period, and name and department of the PI of all research projects approved by the HREC with effect from April 1, 2015 will be posted on a public website (http://www.rss.hku.hk/integrity/ethics-compliance/hrec-approved-projects) maintained by the Research Services until the expiry date of the ethical approval period.

Conditionally Approved:

41. The approval letter is issued with comments/concerns to be satisfactorily addressed.

If Approved is Not Given:

42. The Committee will specify its comments/recommendations on the notification to the PIs of protocols which are not approved.

Reconsideration of Decision:

43. The Committee will further consider the resubmitted proposals according to the Committee's recommendations.

IX. Progress Monitoring

44. The PIs of all active research projects are required to report to the Committee any amendments and new information on the project. Any deviation from the study protocol or compliance incident that has occurred during a study and may adversely affect the rights, safety or well-being of any participant or breaches of confidentiality should be reported to the HREC within 15 calendar days from the first awareness of the deviation/incident by the PI. PIs may also be required to submit a final completion report on the request of the Committee. The report form can be downloaded from the website.

45. Ethical approval is time-limited, normally to be granted initially for four years. Should extension of such ethical approval be needed, the PI has to apply for such extension well before the initially approved expiration date on a prescribed form, and justifications for such extension must be provided in the application.

X. How to Maintain Ethical Standard in Research

Right to Appeal

46. The RECs or the Faculty Higher Degrees Committee/Faculty Research Committee as appropriate can refer special cases requiring advice to the HREC for ethical review. The Heads and Deans can refer special cases requiring advice to the RECs or its equivalent committee or HREC for ethical clearance. All applicants have a right to appeal, and to refer cases with doubts or problems to the HREC for further review.

47. The ethics committees established by the self-funded units of the University, such as the HKU SPACE, the Versitech, can also refer special cases of appeal to the HREC for informal advice.
48. A statement informing participants of their right as research participants to contact

HREC directly if they have any concerns or questions should also be provided on all recruitment materials, consent forms, information sheets, and debriefing notes for dispatch to all research participants. All recruitment materials and consent forms must include a readily reachable contact of the PI or relevant personnel of the study for participants' enquiries about details of the study (normally a telephone number for studies conducted in Hong Kong, and an email address for overseas studies), the HREC's contact number for enquiries about participants' rights and the HREC reference number assigned to each approved project as indicated in the letter of approval. For surveys conducted by telephone and/or self-administered questionnaire, full contact information of the HREC and also the PI concerned must be provided before data collection starts (but can be after selection of a respondent).

Annual Report by Heads/Deans

49. The Head or Dean as appropriate will be invited to submit an annual statistical report on the number of approved applications/re-submissions and any acute incidents which have occurred, to the HREC by the end of the academic year.

XI. Contact information

50. Enquiries may be directed to:

- Professor J.H. Bacon-Shone, Chairman of the HREC
  Tel: 3921 2600; Email: johnbs@hku.hk

- Miss Annie Ngai, Head, Research Services
  Tel: 2859 1911, Email: anniengai@hku.hk

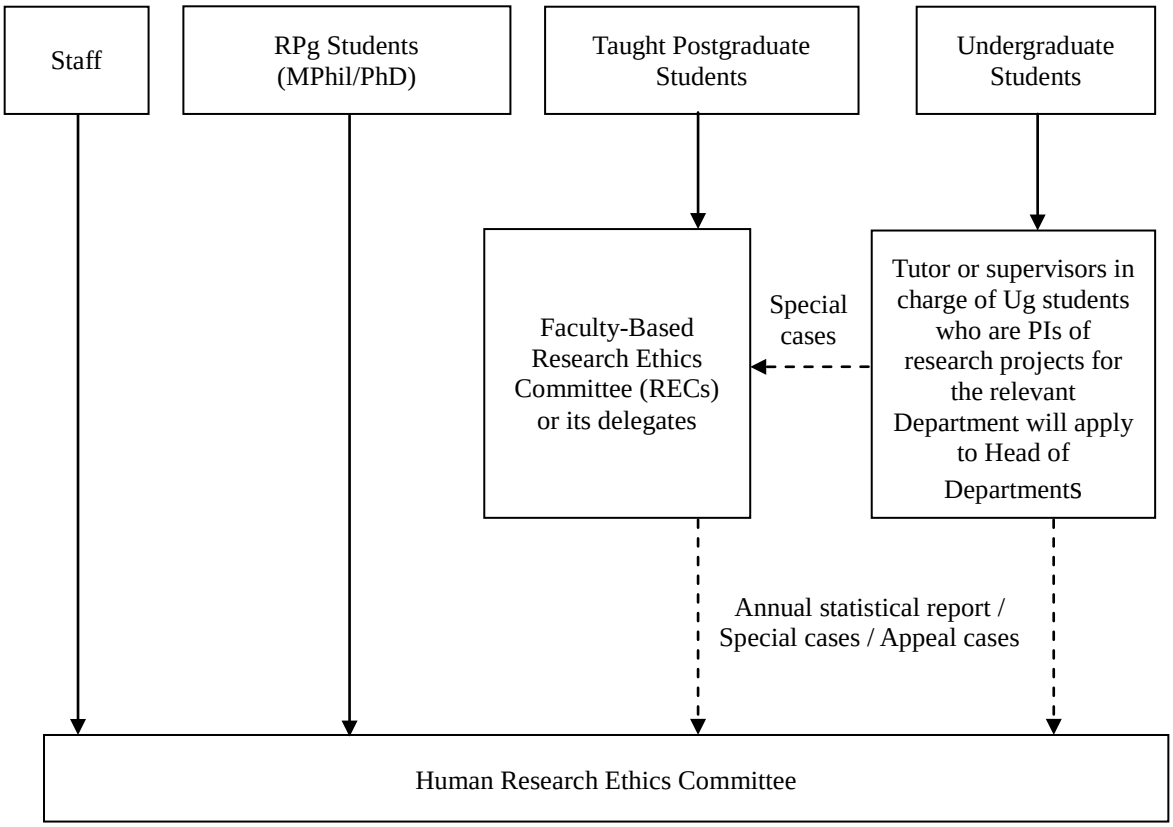
- Ms. Kate Yip, Assistant Registrar, Research Services
  Tel: 2241 5266; Email: kkkyip@hku.hk

June 2017

Human Research Ethics Committee (HREC)

Procedures for Applications for Ethical Approval

Please read carefully the Operational Guidelines and Procedures of the HREC regarding the Section on Who Should Apply for Ethical Review before completing the application form.



→ *For RPg Students/Staff:*
Complete the HREC application form for ethical approval, and send it to the HREC, c/o the Research Services, Registry, 9/F, Knowles Building, the University of Hong Kong.

For TPg Students:
As advised by the Faculty, please complete either the HREC application forms or the relevant application form and send it to your Faculty Office.

For Ug Students:
As advised by your Department, please complete the HREC application form or the appropriate application form with your Tutor/Supervisor as the Principal Applicant, and send it to the Head of your Department/Dean of the Faculty.

⇢ The Heads of Departments and the RECs or its delegates can refer special cases to the HREC. The TPg/Ug students can appeal to HREC for a further review on their research protocols.

July 2015