## CHECKLIST FOR HREC TERMS OF REFERENCE

The following elements should be addressed in the Terms of Reference of all HRECs within the NSW public health system.

<table>
<thead>
<tr>
<th>Subject matter</th>
<th>Issues to be considered</th>
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<tr>
<td>Purpose &amp; function</td>
<td>*General principles about what the HREC aims to achieve and safeguard</td>
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<tr>
<td>Scope of responsibility</td>
<td>*The institutions, organisations and researchers for whom the HREC will provide ethical review</td>
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<td></td>
<td>*Type of research to be reviewed</td>
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<tr>
<td>Status of the HREC within the ISLHD</td>
<td>*Define under whose authority the HREC has been established</td>
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<td>*HRECs within the NSW public health system will normally be established under the authority of the ISLHD Chief Executive</td>
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<td>*There should be clear documentation stating what authorities have been delegated to the HREC from the Chief Executive</td>
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<tr>
<td>Accountability of the HREC</td>
<td>*The reporting requirements to the Chief Executive, NHMRC, NSW Privacy Commissioner, NSW Health and any other state and/or commonwealth agencies</td>
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<td></td>
<td>*The Terms of Reference and SOPs should be available to the public</td>
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<tr>
<td>Membership</td>
<td>This should at least cover the following aspects of HREC membership:</td>
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<tr>
<td></td>
<td>*Composition: including basic categories, quorum requirements including number of members and/or member categories, expert advice outside the HREC membership</td>
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<td></td>
<td>*Appointment: who appoints members, method of recruitment, procedure for selection, method of induction</td>
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<td></td>
<td>*Terms of appointment: duration of appointment, policy for renewal of appointment, disqualification procedure, resignation procedure, replacement procedure</td>
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<td></td>
<td>*Conditions of appointment: willingness to publicise name and profession, remuneration if any, confidentiality agreement, letter of appointment</td>
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<td></td>
<td>*Education and training for HREC members</td>
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<td>*Liability coverage for members</td>
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<td>Conduct of business</td>
<td>Procedures: the HREC should operate according to written standard operating procedures</td>
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<td></td>
<td>Meetings: frequency, dates, conflicts of interest, decision making, elements of review, recording of decisions</td>
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<td></td>
<td>Expedited review: nature of applications, amendments and other considerations that will be eligible for expedited review, quorum requirements, status of decisions</td>
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<td>Multi-centre research: mechanism(s) for the streamlining of review of multi-centre applications</td>
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<td>Fees: if charged, under what circumstances</td>
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<td>Records: records and registers to be kept, security of data, retention and disposal of files</td>
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<tr>
<td>Post approval responsibilities</td>
<td>Monitoring: how often, mechanism, conditions of approval</td>
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<tr>
<td>Complaints and review</td>
<td>Concerning conduct of a project: who to notify, how the complaint will be handled, response to the complainant</td>
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<td>Concerning review process: who to notify, how the complaint will be handled, response to complainant</td>
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<tr>
<td>Concerning rejection of application: who to notify, how the complaint will be handled, response to complainant</td>
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<tr>
<td><strong>Amendment to Terms of Reference</strong></td>
<td>Who, how and when amendments to the Terms of Reference can/should be made</td>
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</table>
University of Wollongong & Illawarra Shoalhaven Local Health District
HUMAN RESEARCH ETHICS COMMITTEE (HREC)

TERMS of REFERENCE
[Version 3 June 2012]

OBJECTIVES

1. The HREC objectives are:

   1.1. Protect the mental and physical welfare, rights, dignity and safety of participants of research.

   1.2. Facilitate ethical research through efficient and effective review processes.

   1.3. Promote ethical standards of human research.

   1.4. To review research in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007.

FUNCTIONS

2. The HREC functions are:

   2.1. To provide independent, competent and timely review of research projects involving humans in respect of their ethical acceptability.

   2.2. To provide ethical oversight, monitoring and advice for research projects involving humans.

   2.3. To prescribe the principles and procedures to govern research projects involving human subjects, human tissue and/or personal records.

   2.4. To ensure that the scientific evaluation of any proposal involving human subjects, human tissue and/or personal records is to an acceptable standard, in accordance with NSW Dept of Health policy on scientific review.

SCOPE OF RESPONSIBILITY

3. Research proposals involving humans will be reviewed by the HREC where the research involves patients, staff or students of the ISLHD or the University of Wollongong, including:

   - any institutions governed by ISLHD
   - any institutions governed by UOW

This term of reference does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided that such other
HREC is registered with the Australian Health Ethics Committee. For research involving the ISLHD, the HREC must be on the approved NSW Health HREC list available at http://www.health.nsw.gov.au/ethics/research/contactshrec.asp

4. The HREC may grant ethical approval for research undertaken by external institutions/organisations and researchers where an agreement exists between the ISLHD, the University of Wollongong and the external institution/organisation that defines the role of the HREC in providing ethical approval and ethical monitoring of the research and the role of the external institution/organisation in giving approval for the research to take place within its organisation. The agreement shall specify which party bears legal responsibility for the liabilities that arise from the ethical review conducted by the HREC, and shall also specify that the institution/organisation (not the ISLHD or the University of Wollongong) is responsible for liabilities arising from the conduct of the research.

5. Human research is research conducted with or about people, or their data or tissue (NHMRC NS 2007). This includes research on pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, medical records, epidemiological, social, and psychological investigations.

6. STATUS OF THE HREC WITHIN THE ISLHD AND THE UOW

6.1. The HREC is an advisory committee of the ISLHD and the University of Wollongong with responsibility for:
   - granting ethical approval;
   - withholding ethical approval; and
   - withdrawing ethical approval

   for research to be carried out within the institutions noted in paragraph 3.

6.2. The ISLHD Chief Executive or delegate is responsible for granting the ISLHD’s institutional approval for research to be conducted within its institution(s) giving due consideration to the advice of the HREC. (Note: The Chief Executive may not give approval for research to be conducted within the ISLHD’s institutions unless ethical approval has been granted by the HREC)

6.3. The UOW DVC(R) or delegate is responsible for granting the UOW’s institutional approval for research to be conducted within its institution(s) giving due consideration to the advice of the HREC. (Note: The DVC(R) may not give approval for research involving humans to be conducted within the UOW’s institutions unless ethical approval has been granted by the HREC)

ACCOUNTABILITY OF THE HREC

7. The HREC is accountable to the ISLHD Chief Executive through the Chief Executive’s nominee, the Area Director of Research Management, in the conduct of its business. The minutes of the H&HM HREC meeting shall be forwarded to the Area Director, following confirmation. A copy of all correspondence from the Ethics Unit to researchers on applications involving the ISLHD will be send to the ISLHD Research Directorate Office.

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1. NSW Health Circular No 2003/84 Model Policy for the Safe Introduction of New Interventional Procedures into Clinical Practice
Version 3 September 2012
8. The HREC is accountable to the DVC(R) and the URC (through the UEPC) of the University of Wollongong in the conduct of its business.

9. The HREC shall provide regular reports, at least on an annual basis, to the Chief Executive, the DVC(R) and the University Ethics Policy Committee, which will include information on membership, the number of proposals reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.

9. The HREC may from time to time bring to the attention of the Chief Executive/UEPC/DVC(R) or delegate issues of significant concern.

10. The HREC will provide reports:
    - to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC);
    - to the NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW);

11. The HREC Terms of Reference, Standard Operating Procedures and membership will be available upon request to the general public and will be posted on the University of Wollongong website.

MEMBERSHIP

12. Composition

12.1 The composition of each HREC shall be in accordance with the National Statement and shall include at least:
    - a chairperson;
    - at least two members who are lay people, one man and one woman, who have no affiliation with the ISLHD or UOW, and are not currently involved in medical, scientific, or legal work;
    - at least two members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
    - a member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
    - at least one member who is a minister of religion, or a person who performs a similar role in the community; and
    - at least one member who is a lawyer.

12.2 To ensure the membership will equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person.

12.3 For the purposes of holding a meeting of the HREC, a quorum shall exist when a representative of each of the categories designated in the National Statement (and specified in paragraph 1.21) is present. In circumstances where such core members cannot be present, they may provide written comments in lieu of attendance. However, in those circumstances, there must be at least 5 members physically present to achieve quorum, including one of each of the following categories: Chair/Deputy Chair, lay person,
researcher familiar with the types of proposals that are normally reviewed by the HREC.

12.4 The HREC shall be free to consult any person(s) considered by the HREC to be qualified to provide expert advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.

13. **Appointment**

13.1 The Chief Executive or DVC(R) or delegate shall appoint members of the HREC, in consultation with the HREC and other senior ISLHD and UOW officials, as deemed appropriate.

13.2 Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement.

13.3 A selection committee, consisting of the Chairperson, the Executive Officer and at least one other HREC member shall meet with prospective members, consult with the HREC members and make a recommendation to the Chief Executive and DVC(R) or delegate.

13.4 Appointments will allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

14. **Terms of appointment**

14.1 Members are appointed for a period of two years. The Chairperson, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive and DVC(R).

14.2 Reappointment is by application to the Chairperson of the HREC who will then make a recommendation to the Chief Executive and DVC(R).

14.3 Membership will lapse if a member fails without reasonable excuse or without notifying the Chairperson to attend three consecutive meetings of the HREC, unless exceptional circumstances exist. The Chairperson in writing will notify the member of such lapse of membership. Steps shall be taken to fill the vacancy of the lapsed member.

14.4 A member may resign from the HREC at any time upon giving notice in writing to the Chairperson. Steps shall be taken to fill the vacancy of the former member.

14.5 The Chief Executive and DVC(R) may terminate the appointment of any member of the HREC if they are of the opinion that:

- it is necessary for the proper and effective functioning of the HREC;
- the person is not a fit and proper person to serve on an HREC;
- the person has failed to carry out their duties as an HREC member.

14.6 Members will be provided with a letter of appointment which will include date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their
duties as a HREC member, HREC meeting attendance responsibilities and general responsibilities as a HREC member.

15. **Conditions of appointment**
15.1 Members must agree to their name and profession being made available to the public, including being published on the University of Wollongong Intranet.

15.2 Payments made to HREC members may only be made in relation to the following items and at the following rates and on the following basis:
- The Chair of each HREC will receive a payment equivalent to the annual FTE 0.2 rate of an Associate Professor position.
- provision of specialist knowledge to the Executive Committee of the HREC on a regular basis, where the person is not employed by the UOW or the ISLHD.
- Reimbursement of legitimate expenses incurred in attending HREC meetings or in otherwise carrying out the business of the HREC.

15.3 Members will be required to sign a statement undertaking:
- that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential;
- that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and
- that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.

16. **Education for HREC members**
16.1 Newly appointed members shall be provided with adequate orientation and documentaiton

16.2 Throughout their tenure, members shall be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC, at the expense of the ISLHD and the UOW.

17. **Sub-committees**
17.1 The HREC may appoint such sub-committees as it sees fit to carry out a scientific or technical review of a research proposal, or ethical review of minimal risk research, submitted to the HREC. The Chair of any such sub-committee will be appointed by the Chief Executive or DVC(R). Members of the sub-committee need not be members of the HREC.

18. **Liability coverage**
18.1 The ISLHD and the UOW provide indemnity for members of the HREC for any liabilities that arise as a result of the member exercising his or her duties as a member in good faith. Such indemnity is provided through the NSW Treasury Managed Fund and the UOW liability protections.

**CONDUCT OF BUSINESS**

19. **Procedures**
19.1 The HREC will perform its functions according to written standard operating procedures. These procedures shall be reviewed at least every three years and amended and updated as necessary. All HREC members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to changes thereto.
20. **Submissions, notifications and approvals**

20.1 All applications for ethical approval must be submitted to the Executive Officer of the HREC, by the relevant closing date, in writing in the format approved from time to time by the HREC and shall include such documentation as the HREC may specify.

20.2 Guidelines will be issued to assist applicants in their preparation of applications.

20.3 The HREC may request the applicant to supply any further information in relation to an application and/or request the applicant to attend a meeting of the HREC at which the application will be considered for the purpose of providing information to and answering questions from the HREC members.

20.4 The HREC will consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application is received by the relevant closing date. The Executive Office shall circulate the completed application and associated documents received with a meeting agenda to all members of the HREC at least 7 days prior to the next meeting.

20.5 The HREC may delegate consideration of certain scientific/technical matters to a HREC member or sub-committee of members. The HREC may also obtain expert scientific/technical advice, subject to paragraph 12.4.

20.6 The HREC may take into account the views or opinions of another HREC in relation to a research protocol.

20.7 The HREC will promptly notify the applicant in writing, advising whether the application, which it has considered, has received ethical approval and any conditions of that approval.

21. **Expedited review**

21.1 The HREC may establish an Executive, consisting of at least the Chairperson and two Committee Members. Where provided by the Operating Procedures, the Executive will undertake expedited review of research proposals between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other HREC members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next HREC meeting.

21.2 The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, annual reports, renewal requests, minor amendments and responses to review. The minutes of any such meetings will be tabled for ratification at the next HREC meeting.

22. **Multi-centre research**

22.1 To facilitate multi-centre research the HREC may:
- communicate with any other HREC;
- accept a scientific/technical and/or ethical assessment of the research by another NHMRC accredited HREC;
22.2 The HREC shall participate in the NSW Health Single Ethical and Scientific Review of Multi-Centre Research Scheme by requiring eligible protocols to be submitted to that Scheme.

22.3 The HREC will follow the ‘Standard Operating Procedures under the NSW Health model for single ethical and scientific review of multi-centre research.’

23. **Advocates and interpreters**

   23.1 The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.

   23.2 Where research involves the participation of persons unfamiliar with the English language, the HREC will require that the participant information sheet is translated into the participant’s language and that an interpreter is present during the discussion on the project unless there are special circumstances justifying the waiving of this requirement.

24. **Meetings**

   24.1 The HREC shall meet on a regular basis, which will normally be at monthly intervals.

   24.2 Meeting dates and agenda closing dates will be published.

   24.3 Any member of the HREC who has any interest, financial or otherwise, in a proposal or other related matter(s) considered by the HREC, should as soon as practicable declare such interest. If the member is present at a meeting at which the project is the subject of consideration, the member will withdraw from the meeting until the HREC’s consideration of the relevant matter has been completed. The member will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter. All declarations of interest and absence of the member concerned will be minuted.\(^2\)

   24.4 The HREC will endeavor to reach a decision concerning the ethical acceptability of a proposal by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the proposal, provided that the majority includes at least one layperson. Any significant minority view (i.e. 2 or more members) shall be noted in the minutes.

25. **Fees**

   25.1 A fee will be charged for applications submitted for assessment by the HREC in the following circumstances:

   - for the review of sponsored Clinical Trials
   - for the review of applications submitted by external organisations and not involving the staff, students or patients of the UOW or ISLHD.

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\(^2\) A discussion paper, prepared by the Health Ethics Branch, is currently in circulation

Version 3 September 2012
26. **Records**

26.1 The Executive Officer will prepare and maintain written records of the HREC’s activities, including agendas and minutes of all meetings of the HREC.

26.2 The Executive Officer will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the HREC.

26.3 Files shall be kept securely and confidentially in accordance with the requirements of Health Records and Information Privacy Act 2002.

26.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least 5 years from the date of completion of a project but for specific types of research, such as clinical research, 15 years shall apply.

26.5 The HREC will maintain a register of all the applications received and reviewed in accordance with the NHMRC National Statement.

**POST APPROVAL RESPONSIBILITIES**

27. The HREC will monitor approved projects in terms of compliance with the HREC’s ethical approval. In doing, the HREC so may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the HREC will require applicants to provide a report at least annually, and at completion of the study.

28. The HREC will, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of ethical approval of the project, including:

- proposed changes in the research protocol or conduct;
- unforeseen events that might affect continued ethical acceptability of the project;
- serious or unexpected adverse events; and
- if the project is abandoned for any reason.

29. The HREC may adopt any additional appropriate mechanism for monitoring, as deemed necessary.

**COMPLAINTS AND REVIEW**

30. **Complaints concerning the conduct of a project**

30.1 Any concern or complaint about the conduct of a project should be directed to the Ethics Manager. The Ethics Manager shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson of the HREC will investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then he/she can refer the complaint to the Chief Executive or DVC(R), or request the Chairperson to do so.

31. **Complaints concerning the HREC’s review process**

31.1 Any concern or complaint about the HREC’s review process should be directed to the attention of the Chairperson of the HREC, detailing it in writing. Complaints may also be made to the Chief Executive or DVC(R). The
Chairperson will notify the Chief Executive and DVC(R) of any complaints received by him/her, as soon as possible. The Chief Executive/DVC(R) will inform the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson’s investigation, then he/she can refer the complaint to the Chief Executive, DVC(R) or nominee, or request the Chairperson to do so. The Chairperson will provide to the Chief Executive and DVC(R) all relevant information about the complaint/concern. The Chief Executive and/or DVC(R) will determine whether there is to be a further investigation of the complaint. If it is decided there is to be a further investigation, then the Chief Executive and/or DVC(R) will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

31.2 In conducting its review, the panel shall be concerned with ascertaining whether the HREC acted in accordance with the National Statement, its Terms of Reference, the Standard Operating Procedures, or otherwise acted in an unfair or unbiased manner.

32. **Complaints concerning the HREC’s rejection of an application**

32.1 A person with a complaint about the HREC’s rejection of their application should bring the complaint to the attention of the Chairperson of the HREC, detailing the grounds of the complaint. Complaints may also be made to the Chief Executive or DVC(R). The Chairperson will notify the Chief Executive and DVC(R) of the complaint as soon as possible. The Chief Executive/DVC(R) will notify the Chairperson of any complaints received by him/her as soon as possible.

The Chairperson will investigate the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. If the complainant is not satisfied with the action taken by the HREC, then he/she can refer the complaint to the Chief Executive, DVC(R), or nominee, or request the Chairperson to do so. The Chairperson will provide to the Chief Executive and DVC(R) all relevant information about the complaint. The Chief Executive and/or DVC(R) will determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the Chief Executive and/or DVC(R) will convene a suitable panel to review the complaint, ensuring that both the complainant and the HREC are afforded the opportunity to make submissions.

The outcomes of this process may include:

- The complaint/concern is dismissed.
- The complaint/concern is referred back to the HREC for consideration, bearing in mind the findings of the panel.

Should the HREC be requested to review its decision, then the outcome of this review by the HREC will be final. In accordance with point 6.2, the panel,
DVC(R) or Chief Executive cannot substitute its approval for the approval of the HREC.

AMENDMENT TO THE TERMS OF REFERENCE

33. These Terms of Reference may be amended by following the procedure below:

For those proposals made by a HREC member:
- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The proposal shall be ratified if two thirds of the members agree to the amendment.
- The Chairperson shall send the amendment to the Chief Executive, UEPC and DVC(R) for review and approval if appropriate.

For those proposals made by the Chief Executive, UEPC or DVC(R):
- The Chief Executive/UEPC/DVC(R) will send the proposal to the HREC and seek the views of any relevant person.