DkIT Research Ethics Committees
Standard Operating Procedures (SOPs)
These are adapted from the model SOPs developed by the Association of Research Ethics Committees (2013).

1. **Terms of Reference.**

   Background

   The Research Ethics Structures at DkIT are illustrated in Figure 1. The responsibility to ensure ethical research practice in DkIT rests with Academic Council. The Institute Ethics Committee (IREC) acts on behalf of Academic council to review proposed research and to monitor and review the Research Ethics Policy. The IREC sits within the Research Office and reports to Academic council via the Research Sub-Committee. Each School operates a Research Ethics subcommittee (SREC) to review research within the School on behalf of the IREC.

   1.1. Ethical approval and permission to conduct research are separate. The IREC or a subcommittee may provide or withhold ethical approval for proposed research. However this is not the same as permission to conduct research within DkIT and/or to contact DkIT staff and/or students with regard to research participation. The Human Resources Manager must provide permission to contact staff and the Registrar (or designated Officer) must provide permission to contact students.   In the case of proposed research where potential participants are limited to a single School, the relevant Head of School or nominee must give permission.

   1.2. Accordingly the terms of reference for the IREC are:

   (i)   to review all research involving human participants or animals conducted by individuals employed by DkIT or registered as students with DkIT that does not fall within the remit of any of the SRECs.

   (ii)   to consider all proposed research where DkIT can be seen as a 'gatekeeper', i.e. external research that proposes to recruit DkIT staff and students as participants. As per 1.1.1, permission to conduct the research within DkIT must be obtained from an appropriate authority.

   (iii)   to ensure that ethics review is independent, competent and timely;

   (iv)   to protect the dignity, rights and welfare of research participants;

   (v)   to consider the legitimate interests of other individuals, bodies or communities associated with the research;

   (vi)   to consider the safety of the researcher(s);

   (vii) to make informed judgements of the merit of proposals, or to ensure that such   judgements have already been made;

   (viii) to make informed recommendations to the researcher if the proposal is found to be wanting in some respect;

   (ix)   to develop and oversee implementation of the DkIT Research Ethics policy;

   (x)   to monitor and report to Academic Council on this implementation.

   1.3   The terms of reference for the School Ethics Committees are:

(i)   to review all proposed research involving human participants or animals[1] conducted by individuals who members of staff in the relevant school or are registered students of that school

(ii)   to ensure that ethics review is independent, competent and timely;

(iii)   to protect the dignity, rights and welfare of research participants;

(iv)   to consider the legitimate interests of other individuals, bodies or communities associated with the research;

(v)   to consider the safety of the researcher(s);

(vi)   to make informed judgements of merit of proposals, or to ensure that such judgements have already been made;

(vii)   Where research has been ethically approved elsewhere it this will be noted and the application will not be considered for approval. However, where the proposed research seeks to recruit DKIT staff or students as participants, the SRECs may require amendments to the proposal, or reject it, if this is deemed necessary to comply with DkIT Research Ethics Policy.

(vii)   To monitor activities and report on these to the IREC

(viii)   To nominate a representative to sit on the IREC.

2.   Constitution of the IREC

2.1   The IREC membership will be multidisciplinary. It will normally include:

Both men and women; one member nominated by each of the SRECs; at least one member knowledgeable in law and/or ethics; at least one Research Centre representative; at least one member who brings a non-academic perspective on ethics, such as a counselor, librarian, student advisor, child protection officer etc.; a student representative.

2.2   The SREC membership will include representatives from each department and research centre (where relevant) within the School. Membership will be constituted to ensure that there is broad expertise and experience in the range of research methodologies and methods typically reviewed by the SREC.

2.3   Members of the IREC will be appointed by Academic Council. The Chair, Vice-Chair and Secretary will be elected by the IREC. SREC members will be nominated by the relevant Head of School. He or she will Chair the SREC or appoint a nominee.

2.4   A quorum will require that at least half the members plus the Chair or Vice-Chair be present.

3.   Business procedures for IREC and SRECs.

3.1   Meeting schedules will be agreed and published at the beginning of each academic year. Each committee will meet at least three times per year and once each semester. Committees may meet more frequently if this is required.

3.2   Members are required to declare any conflict of interest or potential perception of conflict of interest regarding an application. Members should not be involved in the review of any applications that they themselves are associated with. This includes the supervision of undergraduate and postgraduate research.

3.3.   REC discussions are confidential.

3.4   Applicants may be invited to discuss their application at the discretion of the REC where this is felt necessary to ensure the integrity of the review.

3.5   Decision making is by consensus.

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[1] If proposed research involves live animals this is must be approved by the Institute Animal Care and Use Committee (IACUC) and written evidence of this approval must be included as part of the application.

4. **Documentation.**

4.1 Each member of the REC will receive all relevant documentation pertaining to each application they are involved in reviewing.

4.2 Each REC will determine how this documentation is provided.

4.3 Copies of all documentation will be retained by the Chair and stored in accordance with DkIT policy. Other members should delete electronic copies of handover hardcopies for shredding.

4.4 The minutes of each meeting will show: members present; others present; apologies and non-attendances; record of decisions.

5. **Applications**

5.1 Applications must include: A signed application form, completed in full; the proposed protocol; an outline of ethical issues and how they will be addressed; a copy of the information given to participants, any advertisements; participant consent forms; copies of tools including questionnaires, interview schedules and letters of access where required.

5.2 Applications proposing to include work on live animals must be made using the Animal Research Application form. All such applications are reviewed initially by the Institute Animal Care and Use Committee (IACUC). The proposed protocol must be approved by the IACUC before an application is made to the relevant REC and the statement of approval must be included as part of the application.

5.3 Proposed research that is being conducted in partial fulfillment of the requirements for the MA/PG Diploma or PG Certificate in Learning and Teaching (MALT) will be considered by a sub-committee of the IREC convened as required for this purpose. This sub-committee will co-opt members of the MALT course team.

6. **Decisions**

6.1 There are five decisions available to the committee
- Approval
- Approval on condition of further information, clarification or revision.
- Reject
- Refer to another committee with or without advice

6.2 Communication of decision

The Chair will notify applicants in writing. This communication will include
- The title of the proposed research; applicant name; REC title; date of meeting at which application was considered; statement of decision; duration of approval and signature of Chair.
- Where approval is conditional the communication will explain the reasons for the decisions, detail the information, clarification and/or revisions required and the date by which these should be submitted.
- Decisions pertaining to research proposed in fulfilment of MALT requirements (see 5.3) will also be communicated to the Chair of the relevant SREC.

6.3 Mechanism for considering further information, clarification or revision

6.3.1 Applicants should submit the information requested by the date indicated in the notification of decision.

6.3.2 If the additional information, clarification or revision is very straightforward and/or minor, the Chair or Vice-Chair will approve if it is satisfactory. In the case of substantial revision or major amendments the Chair will ask a subgroup of members to review the additional information to determine if the conditions for approval have been met.

7. **Proportionate or expedited review**

A researcher/applicant may request that an ethics application be considered under the Fast-track review process. This means that the application would receive an expedited review outside of the normal ethics committee meeting cycle and thus will not require a meeting of the full REC. Should a Fast-track be granted, the time from submission to approval may be approximately one month, depending on time taken to resolve amendments and clarifications.

7.1 The applicant must contact the Chair of the REC and provide a justification in writing for the Fast-track consideration. Possible justifiable reasons include:
- Tight time frames (e.g. Summer Studentships);
- Funding reasons;
- Ethical approval necessary for grant application or grant registration;
- Application is very low risk;
  Approval has been granted elsewhere.

7.2 The Chair decides if a Fast-track is justified. If permission is granted an application should then be completed as per the normal application process outlined in section 5.

7.2.1 The Chair assigns a minimum of three reviewers from the REC to each Fast-track application and notifies the reviewers of their assigned review as soon as possible.

7.2.2 A response from the three committee reviewers should be provided within one week if possible.

7.2.3 Applicant then receives feedback from the Chair, normally within ten working days of submission.

8. Appeals

8.1 An Appeal Committee will be convened on a case-by-case basis. The Committee will include 3 members of one of the RECs or an external REC and will not include the original members of the REC that made the original decision. The committee will include at least one member with knowledge of the research area in question.

8.2. Applicants should make submit written notice of their intention to appeal within 15 working days of the receipt of the REC decision. The reasons for challenging the decision of the REC must be clearly defined in the notice and based on one or more of the following grounds:
- Criteria used for ethical review
- Material fact pointing to unfairness of decision
- Procedural error pointing to unfairness of decision

8.3 The appeal will be heard in a timely manner and normally within 14 working days of receipt of notice of appeal.

8.4 The appellant may attend before the Appeal Committee in person.

8.5 The final decision by the Appeal Committee will be communicated in writing within 5 working days of the Appeal Committee meeting.

9. Reference

Association of Research Ethics Committees (2013). *A framework of policies and procedures for university research ethics committees*. Association for Research Ethics. Available http://s3.spanglefish.com/s/21217/documents/independent-membership/12-11-13-framework-complete.pdf