Imperial College Research Ethics Committee (ICREC) and Science, Engineering and Technology Research Ethics Committee (SETREC)

Modus Operandi

This modus operandi applies to each of ICREC and SETREC.

a. Quorum

A meeting shall be quorate if at least 4 members of the Committee are present (including a minimum of 2 lay members and a minimum of 2 College Members), one of whom must be either the Chair or Deputy Chair.

If the Chair is not present, the Deputy Chair shall take the role and powers of the Chair for the duration of that meeting.

If no quorum is present, the meeting shall proceed, but any decisions reached will be subject to subsequent ratification by such other members of the Committee as required so that any decision is reached and/or ratified by a minimum of 2 lay members and a minimum of 2 College Members.

b. Membership

Each Committee is composed of a minimum of 4 College Members and a minimum of 4 lay members. The Head of Research Governance and Integrity or Research Governance Manager at the College shall ex-officio act as a supernumerary member of the Committee, and such person shall be treated as a College Member for the purposes of section a of this modus operandi

The Chair shall be a lay member and the Deputy Chair shall be a College Member.

c. Researcher Representation

A Postgraduate Research Student, or a Postdoc Researcher, shall also be invited to join the Committee. They will not form part of the quorum for the meeting.

d. Term of Office

The Term of Office for Committee Members (excluding the ex-officio member) shall be 3 years, renewable up to twice, with a maximum term of 9 years.

e. Head of Department Approval

Before a proposal is sent to ICREC/SETREC for ethical review, it will be sent to the Head of Department (HOD) of the Principal Investigator (PI) involved.

At this stage, the HOD, his/her nominee or a committee set up by him/her for the purpose of reviewing certain types of proposals has the right to sign off the ethics of the proposal as low-risk without the need for ICREC/SETREC review if he/she feels the research:

* Involves the collection or study of existing data, documents or records which are publicly available (non-NHS sources)
* Involves the use of existing data, documents or records where participants cannot be identified in any way
* Involves the use of educational tests, surveys, interview procedures or observations of public behaviour where participants cannot be identified in any way, and where they are at no risk of adverse treatment through participation (e.g. criminal investigation)
* Has no controversial ethical aspects
* Has already received ethical approval from another body (for example, if the Imperial College researcher is a Co-Investigator, and the Principal Investigator has gained approval from his/her own university).

If the research involves anything else, the proposal must be sent to ICREC/SETREC for review by the Committee.

If the HOD signs off a proposal, it will pass to the Research Governance and Integrity Team (RGIT) for a full ethics review. The RGIT can override the HoD's decision and can send the proposal to ICREC/SETREC for review by the Committee.

f. Chair's Action

Chair's Action is defined as a decision taken by the Chair and one other Committee Member. The Chair can only take action if:

1. An ICREC/SETREC meeting is cancelled and, following email consultation with members, it is felt that a proposal can be given a favourable opinion or a favourable opinion subject to conditions before the next meeting.
2. The Committee, following their review of a proposal, asked for amendments or additional information, but gave the Chair and one other Committee member the power to give a favourable opinion to the proposal subsequently once those amendments had been made or the information had been provided.

g. Monitoring of Proposals

PIs, once a favourable opinion is given, have the obligation to report to the Committee:

* Any exceptions, adverse or unforeseen events which occur during the research
* Any relevant or material changes to the protocol or personnel
* Any external information likely to have a bearing on the research in question

The Committee has the power to initiate a review of the ethical favourable opinion at any time it sees fit.

Committee opinion lasts for five years; any project longer than five years must then be resubmitted for ethics review.

h. Specialist Advice

If necessary, the Committee can invite a specialist to give information on a proposal. Any such individuals will be invited for that proposal only and shall not participate in the final decision of the Committee.

i. Presence of Principal Investigators

All PIs whose proposals are being discussed shall be invited to attend the meeting to give explanations/clarification if necessary, although the Ethics and Research Governance Coordinator can filter these before a meeting. The named PI must attend; they can bring any other relevant people as appropriate. For the avoidance of doubt, the PI must attend where proposals are student projects where the named PI is the supervisor.

If a PI is unable to attend they may request in writing to the Ethics and Research Governance Coordinator to send a member of staff on their behalf. If a decision is not able to be made without the PI's presence, the study will be deferred to the next month or until the PI can attend.

PIs and any person attending with the PIs shall be present in the room only for the question/answer session and shall not participate in the final decision of the Committee. Video or phone conference can be made available if necessary.

j. Declaration of Interest

Committee members must provide details of their interests for an ICREC/SETREC Members' Register, which will be held by the Ethics and Research Governance Coordinator and updated at least on an annual basis. If any member has a financial or personal interest in any proposal or project sponsor under scrutiny, the Chair will decide whether the interest disqualifies the member from discussion. If this proves to be the case, that member cannot participate in any final decision.

k. Frequency of Meetings

At present, each Committee shall meet a minimum of six times a year according to a published schedule. Papers for the meeting must be circulated to the members no less than 7 days before the meeting and must be received by the Ethics and Research Governance Coordinator no less than 21 days before the meeting.

In normal circumstances, all proposals will be discussed at the next available meeting. However, in any situation deemed extraordinary, proposals can be dealt with in one of the following ways:

* An emergency meeting, with the same quorum requirements;
* By email correspondence or teleconference to discuss the specific proposal. At least 4 members (including the Chair), comprising a minimum of 2 lay members and a minimum of 2 College Members, must contribute to the discussion; the decision can be devolved to an extraordinary sub-committee of no less than 2 people approved by the whole Committee; or
* Chair's Action can be recommended by the Committee.

l. Modification of Proposals

If a proposal requires modification before it is approved by ICREC/SETREC, the revised application will normally be sent to the next available meeting. However, if this is deemed unsuitable or unnecessary by the Committee, one of the following options can be proposed:

* Chair's Action;
* teleconference or email approval by Committee members (on the same basis as referred to in section k of this modus operandi); or
* a meeting of an extraordinary sub-committee of no less than two people.

m. Process of Appeal

If a PI feels the decision of ICREC/SETREC is unjustified, he/she has the right to a single appeal to the Director of the Research Office who will convene a panel with the College Secretary to decide on the appeal. ICREC/SETREC shall provide an explanation of its decision, and the PI must provide evidence to counteract that. The PI and a representative of the ICREC/SETREC shall be invited to attend the appeal meeting to discuss and answer questions on the papers and the case.

The decision of the College Secretary is final.

n. Annual Report to the College Secretary

The Committee will produce an Annual Report to be presented to the Director of the Research Office and submitted to the Provost's Board. The Annual Report should outline issues such as the work of the Committee, the names of the members of the Committee, the number of meetings and the number of applications submitted and approved by HODs and ICREC/SETREC.

o. Indemnity for Members

The College will indemnify members of ICREC/SETREC against legal liability claims made against them which arise in respect of their membership of ICREC/SETREC, provided that members have acted in good faith.

p. Decision-Making

The decision of the ICREC/SETREC is final, subject to a single appeal by a PI as set out in section m of this modus operandi. The Committee shall inform the PI of its decision, with explanations where appropriate, no more than 10 days following the meeting at which the PI's proposal is considered