UREC SOP-003 COMMITTEE ARRANGEMENTS (SYSTEMS) FOR RESEARCH ETHICS REVIEW

Must be read and used in conjunction with the [UREC SOP-003 'Criteria and Classifications Table'](#)

BACKGROUND

National and international standards for research dictate a consistency in approach for ethics review across institutions whilst maintaining flexibility for those institutions and the disciplines within them, and respecting professional, legal and ethical standards of best practice.

Following the [UKRIO/ARMA guidance](#) it is important to define the various 'tiered' approaches to review (also known as 'arrangements, or systems for review'), an institution has, beyond that of the full Committee review.

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1. SCOPE AND PURPOSE

This Standard Operating Procedure (SOP) covers research and knowledge exchange (KE) activity carried out by the University's colleagues and students and those whom they work with, to carry out their research and KE activity. The purpose is to illustrate the different 'arrangements for review' at the University and how these should be used by the reviewers, and in which circumstances.

In addition, the SOP outlines the mechanism for upward referral or **escalation** should it transpire that a review by a full Committee is required despite the allowances made for arrangements of review which are devolved from the full Committee.

This SOP also covers **standards** for ethical review required by the various systems which should have the same rigour of review as by a full Committee. The various systems allow for **proportionality** rather than variance in the principles and parameters of review.

This SOP outlines and signposts the mechanisms to operate the various arrangements of review in **Appendix One**.

2. PROCESS FOR EMPLOYING AN ARRANGEMENT FOR REVIEW:

The important issues to specify in forms of review which are devolved from the full Research and Knowledge Exchange Ethics Committee (REC) are:

| • | **what criteria are used to permit applications to use alternative routes** |
| • | **what the review arrangements (systems) are for those alternative routes** |

A combination of classifications can apply at the same time, and therefore the criteria and arrangement for review will follow that of the highest classification numerically.

3. CRITERIA (CLASSIFICATIONS) AND SUBMISSIONS OF APPLICATIONS FOR RESEARCH ETHICS REVIEW

The [Criteria and Classifications table](#) illustrates the **first submission** of a research ethics review application route. In general, where an application is **re-submitted** as a *Response to Conditions* it should receive the same arrangement type review as the initial (first) review.

However, if the earlier review colleagues agreed that *Response to Conditions* can be considered by *Chair's Action* or *Secretary's Action*, then that should occur and a sensible approach should be taken, for example a Class 4 or Class 3 application may be more complex, and it would be better for *Responses* to be considered by a wider group, unless the single person Chair or Secretary is highly experienced in ethics review. There is also a route for Escalation below in Section 4.

There is also a mechanism for **expediting an application (timewise)** whilst maintaining the same rigour of review, however that is exceptional and therefore sits separate from the 'alternative arrangements' described above. A process for how an application can be expedited (fast tracked) is available via [UREC-SOP-005 Expedited Review](#).

4. PROCESS FOR UPWARD REFERAL (ESCALATION):

Although there is a system in place which allows for a rigorous review devolved from the full Committee or to UREC, it may be considered necessary for a number of reasons to escalate this review upward.

Escalation can occur from CREC to UREC if the research is perceived as CLASS 4 or CLASS 3 Health Research Authority/Sponsorship.

Escalation can also occur to a full Committee (of the CREC itself), if the review requires a wider group of colleagues to participate than the one accounted for in any devolved arrangements (such as sub-panel, chair's action etc.). This can be for any CLASS of research.

Where a review has not yet occurred, if the receiving Committee consider it should be escalated, this needs to occur *prior* to an initial review via the designated system, in order to **avoid a dual review.** If that is the case, Committee Representatives should

follow the process for escalation within the **[UREC-SOP-001 Security Sensitive Research and Knowledge Exchange](#)**.

Where a ***Response to Conditions*** or ***Request for More Information*** has raised issues which are considered reasons for escalation, for CLASS 4, the Committee Representative should escalate upwardly at the first opportunity.

Where it is not clear or the query is directly from the applicant, they can seek the view of UREC Chair or Secretary, including where the compliance teams wish to escalate.

Where an applicant does not agree with Conditions or Final Outcome (i.e. Favourable Opinion not Received) of an ethics review person/body, they must follow the ***[Appeals Process](#)***.

5. STANDARDS OF REVIEW:

All arrangements for ethics review at the University, should follow the standards and principles within the *[Research Ethics Policy](#)*, *[Research Ethics Governance Framework](#)* as a whole, and the [associated *Guidance*](#).

5.1. COMMITTEE TERMS OF REFERENCE:

Both UREC and CREC Terms of Reference follows the highest standards of ethics review recommended, by including REC members who are appropriately trained, and formed from a **range of disciplines** and **expertise** and incorporating principles of **independence.**

5.1.1. CONFLICTS OF INTEREST, INDEPENDENCE AND FREEDOM FROM BIAS

All arrangements for review must follow the principle of independence, fairness, transparency and declarations and avoidance of conflicts of interest.

- **Full Committee Review and Sub Panels:**

Independence and freedom from bias is ensured through the inclusion of reviewers from outside the College for CREC's full Committee reviews. Reviewers external to the University are included on the UREC. Where a Sub Panel occurs, the inclusion of at least one reviewer from outside the applicant's **School** helps with ensuring **independence.**

- **Chair's Action or other reviews involving less than 3 colleagues:**

Conflicts of Interest must be noted (via the VRE notes) and declared and an alternative nominee/s appointed for the specific research ethics proposal/s for all arrangements of ethics review.

- **Supervisor**

If a supervisor is listed as a co-Investigator on their student's application, rather than correctly as a 'Supervisor/PI' they will not be able to review or sign-off their own application.

5.2. MAINTAING THE STANDARDS AND MANAGING RISK IN ALL ARRANGEMENTS FOR RESEARCH ETHICS REVIEW:

It is recognised that taught student work is not necessarily the lowest risk, however a **proportionate** system of review (via Sub Panel) is available in order to allow flexibility of review for large numbers of proposals for ethics review.

Sub Panels can limit the expertise, breadth and impartiality of reviewers due to the small number of colleagues included in review, and therefore create an element of risk, when moving away from the standard full Committee composition recommended.

However, by creating proportionality of the level of ethical implications via the classifications criteria, and the opportunity to clearly upwardly refer proposals to full Committee review, the risk is managed.

All reviewers (members and/or ad hoc reviewers) must undertake the *Introduction to Research and KE Ethics Module* as a minimum.

Where Human Tissue work is being proposed, reviewers should refer to the University's Human Tissue Authority SOPs such as Consent, Managing Participant Complaints, Import/Export, Material Transfer Agreements.

All Human Tissue Authority related research ethics reviews must include either the HTA Designated Individual (HTA DI) or Persons Designate. In cases of transfer of materials, the Head of School permission will also be needed by the researcher for the REC to note.

5.2.2. Rigour of Review by:

- **Chair's Action or less than 3 colleagues**
- **Sub Panel**
- **Supervisor Sign off**

These devolved reviews will **not** be less rigorous nor the standards lower, only that certain proposals may be reviewed more quickly or more flexibly than other

applications that require full committee scrutiny, as the above forms of review are more agile.

5.2.3. Where a single reviewer is involved such as **Chair's Action** or **Supervisor** Sign Off, the reviewer must be confident in recognising, articulating and mitigating for ethical implications. The minimum standard recommended, in line with external benchmarks for ethics review is for all Supervisors to undertake the Introduction to Research Ethics module, a Research Ethics Workshop or similar training and refreshers, to familiarise themselves with University's research ethics principles and guidance.

6.   ADAPTABLE AND SENSITIVE REVIEW:

Arrangements for review which are phased applications can enable process-based reviews, with proposals (the same application) returning for review at different stages of a project.

Generally, it is more convenient for an applicant and reviewers to have a single application, but in some cases that would not be the preferred case, including for example where project design is iterative and not easily specified in proposals for review, or where the particulars around aims and/or methods is not yet known for future portions of research.

The CREC Chair and UREC can advise if more advice is needed.

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- **Please see the Criteria and Classifications Table document.**