

## UREC SOP-003 CRITERIA AND CLASSIFICATIONS FOR REVIEW TABLE

Must be read and used in conjunction with the [UREC SOP-003 Committee Arrangements \(systems\) for Research Ethics Review](#)

### INTRODUCTION

This Criteria and Classification Table provides the criteria for classification designation as currently deployed in the University's Research Ethics Review and Management System (VRE System: Research Governance and Ethics Module).

The final column of this Table also shows the corresponding route or arrangement for Review (including, self-assessment or supervisor sign off).

The Criteria and Classification Table includes some of the main questions in the *Research Ethics Self-Assessment Form (Part A Form)* but does not include the full list of questions in Part A Form (there are a few further filter questions). The Table also provides mainly headings of the various sections in the full *Research Ethics Review Application Form (Part B Form)*. To see the full question set for both Forms as appearing in the current VRE System, please see the [research ethics website](#) for a document copy titled '**Blank Research Ethics Self-Assessment and Research Ethics Review Forms (PDF)**'.

A second table 'Appendix One,' is at the end of this document. It aims to provide an explanation of what each 'arrangement for review' constitutes and the practical manner in which it is carried out.

Most University research ethics reviews are carried out at College Research and Knowledge Exchange Ethics Committee (CREC) level Sub-Panel for class 2 and class 3 research. There are some exceptions where class 3 research involves University Sponsorship, where it will be reviewed via the University Research and Knowledge Exchange Ethics Committee (UREC) and Research and Knowledge Exchange Office (RKEO). All class 4 applications are reviewed at the UREC level with input from RKEO and other professional teams.

## CRITERIA AND CLASSIFICATIONS TABLE:

CLASSIFICATION	CRITERIA	ARRANGEMENT (SYSTEM) FOR REVIEW
<b>CLASS 1 (Low or No Risk of Harm)</b>	<p><b>ALL the below (criteria) must apply:</b></p> <ul style="list-style-type: none"> <li>- No participants (human or animal: living or deceased)</li> <li>- No issues of personal safety</li> <li>- No collection, analysis, and/or re-use of any directly or indirectly identifiable or traceable personal data as defined by data protection legislation? In the UK or European Economic Area? YES/NO; Outside UK or EEA? YES/NO</li> <li>- No Security Sensitive Research and KE</li> <li>- No Human Tissue</li> <li>- <b>*COMING SOON:</b> No significant risk due to politically sensitive research</li> <li>- <b>*COMING SOON:</b> No Research travel or research fieldwork where a Foreign and Commonwealth Development Office Travel Advisory is in place</li> <li>- <b>*COMING SOON:</b> No Animals non-living tissue or materials</li> </ul>	<p><b>CLASS 1 (Student):</b> Supervisor sign off</p> <p><b>CLASS 1 (Colleague):</b> *VRE System sign off</p> <p>* currently requires 'progression' by a VRE Committee Representative for the status (and audit) record to update and for the applicant to receive a VRE email notification to state the application has been received and lodged for future audit and monitoring.</p>

	<ul style="list-style-type: none"> <li>- <b>*COMING SOON:</b> No potential ethical implications or risk of harm to the environment or significant natural habitats</li> <li>- <b>*COMING SOON:</b> No work with or potential harm to historically and culturally significant sites or objects?</li> </ul> <p><b>OR the below applies:</b></p> <p>Includes ‘participants’, but ‘no’ to <u>all</u> Questions in Section 6 (Risk of Harm), including the above.</p>	
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CLASSIFICATION	CRITERIA	ARRANGEMENT (SYSTEM) FOR REVIEW
<b>CLASS 2 (potential risk of harm)</b>	<p><b>At least ONE (or more) of the below applies:</b></p> <ul style="list-style-type: none"> <li>- ‘Yes’ to any Question in Section 6 (Risk of Harm)</li> </ul> <p><b>AND/OR</b></p> <ul style="list-style-type: none"> <li>- ‘Yes’ to any Question in Section 7 (participants)</li> </ul> <p><b>AND/OR</b></p> <ul style="list-style-type: none"> <li>- ‘No’ to any Question in Section 8 (information to participants)</li> </ul>	<p><b>CLASS 2 (Student):</b> Sub-Panel</p> <p><b>CLASS 2 (Colleague):</b> Sub-Panel</p>

CLASSIFICATION	CRITERIA	ARRANGEMENT (SYSTEM) FOR REVIEW
<b>CLASS 3: PART A Form (Self-Assessment Form) only</b>	<b>BOTH apply:</b> <ul style="list-style-type: none"> <li>- ‘Yes’ to Question 2.1. ‘<i>External funding or collaborators/co-investigators?</i>’</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>- Any Class 1 criteria</li> </ul>	<i>CLASS 3 (students and colleagues)</i> Sub-Panel

CLASSIFICATION	CRITERIA	ARRANGEMENT (SYSTEM) FOR REVIEW
<b>CLASS 3: PART A and PART B (FULL ETHICS REVIEW FORM)</b>	<b>BOTH apply:</b> <ul style="list-style-type: none"> <li>- ‘Yes’ to Question 2.3.1. Require external ethics review or external governance, legal, regulatory permissions?</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>- Any Class 2 or Class 4 criteria</li> </ul>	<i>CLASS 3 (students and colleagues)</i> Sub-Panel

CLASSIFICATION	CRITERIA	ARRANGEMENT (SYSTEM) FOR REVIEW
<b>CLASS 4 (potential significant risk of harm)</b>	<p><b>At least ONE (or more) of the below applies:</b></p> <ul style="list-style-type: none"> <li>- 'Yes' to Question 6.11. Security Sensitive Research</li> </ul> <p>AND/OR</p> <ul style="list-style-type: none"> <li>- <b>*COMING SOON:</b> 'Yes' to Politically sensitive research which may cause higher risk of harms</li> </ul> <p>AND/OR</p> <ul style="list-style-type: none"> <li>- <b>*COMING SOON:</b> 'Yes' to Research which proposes travel or research fieldwork to a location where an FCDO travel advisory is in place, or, where the purpose of the travel/fieldwork or the characteristics of those involved in the travel/fieldwork may present a significant risk of foreseeable harm.</li> </ul>	<p><b>CLASS 3 (students and colleagues)</b></p> <p>University Research and Knowledge Exchange Ethics Committee (UREC) Sub-Panel</p>

## NOTES FOR RESEARCH ETHICS COMMITTEES/REVIEWERS, AND RESEARCHERS:

**\*COMING SOON:** The VRE Research Ethics Review System will introduce these new questions in the Research Ethics Self-Assessment and Research Ethics Review Application Form as appropriate. At the time of publication of this table (July 2025) this VRE System development is still taking place.

However, in the meantime, if the research ethics proposal includes reference to including any of these items your proposal will be handled under the relevant arrangements for this type of view, regardless of VRE system restrictions. This is in order to manage the ethical harms which may arise by allowing a proportionate review to occur, and mitigations to be required or recommended by a REC or other ethics reviewer at the University.

Further, work is ongoing to ensure where research has external requirements or governance requirements, such as compliance, these will be captured in VRE System developments going forward. For now, if this is indicated in your research ethics proposal, then you will need to liaise with the CREC Chair **and** Research and Knowledge Exchange Office (RKEO) for advice:

- Ministry of Defence (MoD)
- His Majesty's Prisons and Probation Services (HMPPS)
- Prisons in another jurisdiction
- Mental Capacity Act
- Controlled Drugs and Substances
- Human Tissue transfers of materials inc. data
- Living animals or their tissue (or deceased animal tissue, where the tissue was gained when the animal was alive, from another institution)
- UK Health Security Agency
- Schools and/or research with minors (Safeguarding)

**Appendix One (operation of review arrangements) Table:**

<b>SYSTEM TYPE</b>	<b>FUNCTION</b>	<b>AUDIT RECORD</b>	<b>MEDIUM</b>
<b>Supervisor's sign off</b>	Supervisor confirms in VRE as not requiring further ethics review.	Yes (VRE System)	VRE System
<b>VRE System sign off</b>	Requires 'progression' by a REC Representative for the status (and audit) record to update and for the applicant to receive a VRE email notification.	Yes (VRE System)	VRE System
<b>Full Committee review</b>	Forty percent of ex-officio and nominated/elected members, counting for conflict of interest (with ad-hoc reviewers upon request from UREC).	<b>YES</b> (VRE and Minutes)	Online real-time <b>or</b> in person real-time <b>or</b> VRE E-meeting (online, non-real time)
<b>Sub Panel review</b>	Three ex-officio and nominated/elected members, including the Chair, counting for conflict of interest (with ad-hoc reviewers upon request from UREC).	<b>YES</b> (VRE)	Online real-time <b>or</b> in person real-time <b>or</b> E-meeting (online, non-real time)
<b>Ethical quality soundness review</b>	By CREC (or UREC if appropriate) for <b><i>Class 3 proposals which require or have received external ethics review.</i></b>  Via same mechanism as <b>Sub-Panel's</b> (see above).	<b>YES</b> (VRE)	Online real-time <b>or</b> in person real-time <b>or</b> E-meeting (online, non-real time).

SYSTEM TYPE	FUNCTION	AUDIT RECORD	MEDIUM
<b>Noting external ethics review</b>	Via same mechanism as <b>Sub-Panel's</b> (see above).	<b>YES</b> (VRE)	Online real-time <b>or</b> in person real-time <b>or</b> E-meeting (online, non-real time)
<b>Chair's action</b>	CREC/UREC Chair or their Deputy (or named Acting Deputy Chair).  In the absence of Chair or Deputy the CREC/UREC Secretary can request an Acting Chair from the ex-officio or nominated/elected members of any REC.	<b>YES</b> (VRE)	VRE Reviewer's function <b>or</b> VRE Notes function <b>or</b> VRE E-meeting comment and recommendation (online, non-real-time)
<b>Compliance And Governance checks and authorisations</b>	Variety of colleagues: HoS, Line Manager, Lab Staff, HTA Designated Individual/Person Designate, SHW Team, Estates Team, Procurement Team, RKEO, Finance Team, senior management (example only, University Executive Board).	VRE <i>and</i> IRAS (HRA/NHS REC) <i>or other external portal for authorisations</i>	VRE attachments compliance work-flow  <b>And</b>  VRE Notes function.

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**Prepared by:** Huzma Kelly, Research Ethics and Integrity Officer: 25 April 2023

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- Please see the [UREC SOP-003 Committee Arrangements for Research Ethics Review](#).