

Incident Procedures for University Research Ethics Committees (URECs)

This guidance applies to the following types of incidents:

- **Adverse events or serious adverse events** that occur during the course of a research study approved by the UREC.
- **Appeals** against decisions reached by the URECs
- **Breaches of ethics policy** (studies conducted without ethical approval in place or not in accordance with the approved application)
- **Complaints** about any aspect of the research ethics approval process including conduct of members of the URECs

Adverse events¹ or serious adverse events²

In the first instance the **adverse event or serious adverse event** should be raised by the principal investigator or supervisor to the Research Ethics Manager research.ethics@manchester.ac.uk by completing the [Incident Reporting Form](#).

The Research Ethics Manager will then investigate the matter in consultation with the Chair of the Ethics Oversight Committee (or another one of the UREC Chairs who is deputising on their behalf) in order to determine whether:

1. The University's Insurance Office needs to be informed
2. Other study participants needs to be informed
3. The study needs to be temporarily suspended or permanently closed

¹ Adverse events are defined as any event that has had a negative effect on the welfare of a research participant or a member of the research team. This includes (but is not limited to) distress that is not resolved at the end of an interview/focus group or other data collection method; or disclosure of information in relation to professional misconduct that then must be reported to an employer, professional body or similar organisation.

² Serious adverse events are defined as any event that has had a significant negative effect on the welfare of a research participant or a member of the research team. This includes (but is not limited to) distress that led to a formal or informal referral to urgent professional help (including the University's counselling service); or disclosure of safeguarding concerns or concerns related to current or future planned illegal activity that must then be reported to the relevant body or authority.

In the unlikely event that a medical adverse event occurs in a non-biomedical study, the [HRA definitions](#) of these terms will apply.

If researchers have been threatened or physically assaulted during their research activities, this should also be reported as an adverse or serious adverse event, depending on the resulting impact to the researcher's welfare.

4. Any changes to the study protocol, documentation or any other aspect are required before the study can continue

If an **adverse event** is deemed too serious or complex to be considered as above it may require resolution by the University's Research Compliance Committee, chaired by the Vice President for Social Responsibility. In such cases, once a decision has been reached this will be communicated first to the researcher(s) followed by relevant office holders in the Division/School/Faculty (see Appendix 2) **within 20 working days**. In both cases, the Chair of the Ethics Oversight Committee will also be informed and a copy of all correspondence should be sent to the research ethics email account for audit purposes.

Appeals against the decision of a UREC

Appeals against the decision of a UREC are to be made within **4 working weeks** of the date the formal letter confirming the decision is sent in the ERM system. Appeals made after this time will not be considered and the original decision will be upheld.

In the first instance the **appeal** should be raised informally by the principal investigator or supervisor to the Chair of the relevant UREC. Most issues should be resolved and misunderstandings clarified through this channel.

If the issue is not resolved through this channel or if deemed to be unsuitable for discussion directly with the Chair:

Appeals should be directed to the Research Ethics Manager research.complaints@manchester.ac.uk, with an adequate explanation and justification of the grounds for the appeal.

The ethics application together with the researchers' comments will be considered by another full UREC, outside of a Committee meeting. All URECs have been listed on a schedule for reviewing **appeals** and therefore the next UREC listed on the schedule will be selected to review the current case (providing that UREC is not the Committee that originally reviewed the proposal). If the case is from the Proportionate UREC, it will be reviewed by the next UREC listed on the schedule.

The decision of this UREC will be final and no further appeals will be considered. Once the final decision has been reached, this will be communicated first to the UREC that originally reviewed the proposal followed by the applicants. In both cases, the Chair of the Ethics Oversight Committee will also be informed and a copy of all correspondence should be sent to the research ethics email account for audit purposes. The process of appeal should be completed **within 20 working days**.

Breaches

The **breach** should be reported to the Research Ethics Manager with an adequate explanation of what has occurred and how it has breached ethics policy.

The Research Ethics Manager will then investigate the matter in consultation with the Chair of the Ethics Oversight Committee (or another one of the UREC Chairs who is deputising on their behalf) in order to determine whether the researcher made a genuine error or proceeded with deliberate intent. In addition, the experience of the researcher and for student projects any support (or lack thereof) provided by the supervisor will be taken into consideration. A response should be provided to the applicant **within 20 working days** with a copy also being sent to relevant office holders in the Division/School/Faculty (see Appendix 2) if deemed appropriate. In the event that the breach is also in relation to another compliance process (i.e. human tissue, information governance, devices, etc) a copy should also be sent to the relevant office holder in PS (see Appendix 1).

Where research has been conducted without the appropriate ethical approval in place or not in accordance with the approved application the Chair of the Ethics Oversight Committee (or their deputy) will determine the consequences with respect to:

1. Whether the data can be used as the basis for a submission for examination (including PhDs or dissertations).
2. Whether the data can be used for a publication.
3. Whether any examined piece of work/publication should contain a statement with respect to the lack of ethical approval.
4. Informing relevant office holders in the Division/School/Faculty of the breach and any resulting consequences or recommendations for the student, supervisor or member of staff.
5. Whether the case should be referred to the Head of Research Governance, Ethics and Integrity for consideration under research misconduct procedures.
6. Whether, in the case of UG and PGT students the School should consider referring the student for investigation under student misconduct procedures.

If a **breach** is deemed too serious or complex to be considered as above it may require resolution by the University's Research Compliance Committee, chaired by the Vice President for Social Responsibility. In such cases, once a decision has been reached this will be communicated first to the researcher(s) followed by relevant office holders in the Division/School/Faculty **within 20 working days**. In both cases, the Chair of the Ethics Oversight Committee will also be informed and a copy of all correspondence should be sent to the research ethics email account for audit purposes.

Complaints

In the first instance the **complaint** should be raised informally by the principal investigator or supervisor to the Chair of the relevant UREC. Most issues should be resolved and misunderstandings clarified through this channel.

If the issue is not resolved through this channel or if deemed to be unsuitable for discussion directly with the Chair:

Complaints should be directed to the Research Ethics Manager research.complaints@manchester.ac.uk who will investigate the matter in consultation with the Chair of the Ethics Oversight Committee and Head of Research Governance, Ethics and Integrity. A response should be provided to the Complainant **within 10 working days**.

If a **complaint** is deemed too serious or complex to be considered as above it may require resolution by the University's Research Compliance Committee, chaired by the Vice President for Social Responsibility. In such cases, once a decision has been reached this will be communicated first to the individual UREC concerned (where appropriate) followed by the applicants **within 20 working days**. In both cases, the Chair of the Ethics Oversight Committee will also be informed.

Important note

An anonymous (all identifying information removed apart from Division/School affiliation) summary of all incidents which have been reported is sent to the Research Ethics Oversight Committee and Research Compliance Committee every quarter.

Any queries relating to the UREC processes should be directed to:

Email research.ethics@manchester.ac.uk

Appendix 1

Contacts who may need to be notified of incidents	Type of Incident
April Lockyer Head of Research Governance, Ethics and Integrity research.complaints@Manchester.ac.uk	<ul style="list-style-type: none"> • Potential research misconduct • Governance/good research practice
Diane Escott HTA Compliance Officer HTAlicense.research@Manchester.ac.uk	<ul style="list-style-type: none"> • Incidents involving human tissue (all Faculties) • Adverse events (human tissue)
Mohammed Zubair Clinical Trials Manager clinicaltrials@Manchester.ac.uk	<ul style="list-style-type: none"> • Incidents involving a clinical trial (all Faculties) or medical device • Adverse events (clinical trials/medical devices)
Lynne MacRae	<ul style="list-style-type: none"> • Breaches of HRA or NHS REC approval (all Faculties)

Research Governance Practice Manager fbmhethics@manchester.ac.uk	<ul style="list-style-type: none"> Adverse events (HRA studies)
Alex Daybank Head of Data Protection Information.governance@manchester.ac.uk	<ul style="list-style-type: none"> Incidents involving data security Incidents involving personal data Data breaches

Appendix 2

Role	Name of Contact	Email
VP for Research and Innovation	Colette Fagan	Colette.Fagan@Manchester.ac.uk
VP for Social Responsibility	Nalin Thakker	N.Thakker@Manchester.ac.uk
Head of School/Head of School Operations: School of Biological Sciences	Judith Hoyland/Alison Howorth	judith.a.hoyland@manchester.ac.uk alison.howorth@manchester.ac.uk
Head of School/Head of School Operations: School of Medical Sciences	Tony Heagerty/David Pattwell	tony.heagerty@manchester.ac.uk David.Pattwell@manchester.ac.uk
Head of School/Head of School Operations: School of Health Sciences	Kay Marshall/Sharon Grant	kay.marshall@manchester.ac.uk sharon.grant@manchester.ac.uk
Head of School/Head of School Operations: School of Natural Sciences	Chris Hardacre/Sam Ryder	c.hardacre@manchester.ac.uk Samantha.Ryder@manchester.ac.uk
Head of School/Head of School Operations: School of Engineering	Alice Larkin/Sarah Mulholland	alice.larkin@manchester.ac.uk sarah.mulholland@manchester.ac.uk
Head of School/Head of School Operations: Alliance Manchester Business School	Fiona Devine/Janine Ellis	fiona.devine@manchester.ac.uk Janine.Ellis@manchester.ac.uk
Head of School/Head of School Operations: School of Arts, Languages and Cultures	Alessandro Schiesaro/Jayne Hindle	alessandro.schiesaro@manchester.ac.uk jayne.hindle@manchester.ac.uk
Head of School/Head of School Operations: School of	Martin Evans/Kay Hodgson	martin.g.evans@manchester.ac.uk Kay.Hodgson@manchester.ac.uk

Environment, Education and Development		
Head of School/Head of School Operations: School of Social Sciences	Brian Heaphy/Alison Wilson	Brian.Heaphy@manchester.ac.uk Alison.Wilson@manchester.ac.uk
Director of Research and Business Engagement	Andrew Walsh	Andrew.Walsh@Manchester.ac.uk
Designated Individual HTA Research Licence	Andrew Povey	andy.povey@manchester.ac.uk
Designated Individual HTA Anatomy Licence	Ingrid Gouldsbrough	niggy.gouldsbrough@manchester.ac.uk
Director of HR	Karen Heaton	Karen.Heaton@Manchester.ac.uk
FBMH (School of Medical Sciences)	Lisa Roach	Lisa.J.Roach@manchester.ac.uk
FBMH (School of Biological Sciences)	Stephen Johnston	Stephen.Johnston@manchester.ac.uk
FBMH (School of Health Sciences)	Greg Pass	Greg.Pass@manchester.ac.uk
FBMH (Faculty Offices)	Fiona Coll	Fiona.Coll@manchester.ac.uk
FSE	Phillip Ashcroft	Phillip.Ashcroft@Manchester.ac.uk
Student Conduct and Discipline Manager	Matthew Valentine	Matthew.Valentine@Manchester.ac.uk
University Lawyer	Iram Kiani	Iram.Kiani@Manchester.ac.uk
Head of Office	Jacqueline Henshaw	Jacqueline.Henshaw@Manchester.ac.uk
Executive Assistant	Roz Dutton	Roz.Dutton@Manchester.ac.uk
Director of Communications and Marketing	Sally Sykes	sally.sykes@manchester.ac.uk
Head of Compliance and Risk	David Barker	David.Barker@Manchester.ac.uk
Data Protection	Alex Daybank	Alex.Daybank@manchester.ac.uk

<u>External Site</u>	<u>Name of Contact</u>	<u>Role</u>	<u>Email</u>
----------------------	------------------------	-------------	--------------

Manchester University NHS Foundation Trust (MFT)	Lynne Webster	Head of Research Office	Lynne.Webster@mft.nhs.uk
The Christie NHS Foundation Trust (Christie)	Wes Dale	Managing Director of Research, Innovation and Education	wes.dale@christie.nhs.uk
Greater Manchester Mental Health NHS Foundation Trust (GMMH)	Sarah Leo	Head of Research & Innovation	researchoffice@gmmh.nhs.uk
Salford Royal NHS Foundation Trust (SRFT) & Pennine Acute Hospitals NHS Trust (Pennine Acute)	Katie Doyle	R&I Manager	Katie.doyle@srft.nhs.uk