Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-35 **Version: 1.0**

Title: **Complaints procedure for human tissue studies**

Purpose: To provide a standardised procedure for dealing with complaints received against studies using human tissues.

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Approved By:	Clark Crawford	Date: 17.10.16

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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

Under the ISTM HTA Licence No.12349 we are required to have a procedure in place for dealing with complaints received in relation to research projects using human tissue. This SOP sets out the process which should be followed if a complaint is received by a member of staff relating to a research project involving human tissue.

It is our policy to follow the procedures outlined in the University Hospital of North Staffordshire document "*RM02: Policy and Procedures for Handling Complaints".* Those handling a complaint should also make themselves aware of the Parliamentary and Health Service Ombudsman's *Policy on Good Complaint Handling* (see below for link).

2. Underlying Principles:

When handling a complaint, members of staff should be aware of the following guiding principles. (Adapted from *RM02: Policy and Procedures for Handling Complaints*)

- Complaints should be viewed as an opportunity to improve quality of experience for research participants and therefore should be responded to positively.
- All staff must be aware of a participant's right to comment on the standard of care they receive during their participation in a research project.
- Participants should be assured that lodging a complaint should not affect their care as part of the research project they are involved in. They should also be aware of their right to withdraw from the project at any time.
- All participants should be able to lodge a complaint regardless of their age, race, gender, nationality, religion, sexuality, level of mental or physical ability.
- Staff should treat all participants politely and with respect at all times
- All complaints should be taken seriously regardless of the staff members view of the complaint
- Response to complaints must address the substance of the complaint with the aim of satisfying the participant
- Both the participant and the research team who are being complained against should feel that any investigation has been handled impartially.

3. Procedure:

3.1 All complaints received by staff or students working as part of a human tissue research project must be treated seriously and must be recorded and responded to promptly. Complainants must be treated courteously and respect given to their concerns.

3.2 Verbal complaints should be annotated onto Part 1 of the *HTA-35: Complaints Form*. It may not always be possible to complete all sections of the form (e.g. a complaint received by phone call will prevent a signature being garnered from the complainant), but this should be completed as far as is practical. This should be immediately passed onto the Designated Individual (DI) to investigate, unless the DI is the subject of the complaint. In these circumstances the complaint should be passed to the License holder (Professor David Amigoni)

3.3 When discussing a complaint, staff should attempt to understand the event that has triggered the complaint, when this event occurred, who was involved and what the complainants desired resolution to the complaint would be. These details should be included in the form.

3.4 If the staff member is able to take any steps to resolve the complaint at this point and this action should be noted on the form. If this is not possible, then the staff member should politely inform the complainant that they will pass on their complaint to the DI immediately and that they will be in contact to discuss the complaint in more detail as soon as possible.

3.5 Written complaints should be passed directly to the Designated Individual (Prof Nick Forsyth; n.r.forsyth@keele.ac.uk) to investigate and respond to. If a written complaint is received regarding the Designated Individual, this should instead be passed to the License holder (Professor David Amigoni).

3.6 Upon receipt of a written or verbal complaint, the DI should, as far as possible, alert the Chief Investigator of the study immediately that a complaint has been received and is being investigated. The DI should also establish contact with the complainant to discuss

the incident in no more than one week. A copy of the complaint record should also be passed to the Head of Research and Clinical Governance (Dr Clark Crawford; c.crawford@keele.ac.uk) to ensure that central university are alerted to the complaint and can offer support as needed. If the DI is not available to contact the complainant within this timeframe, then the complaint should be passed to the Head of Research and Clinical Governance to instigate an investigation.

3.7 The DI should discuss the nature of the complaint confidentially with the complainant as soon as reasonably possible either by face-to-face meeting or via phone, depending on the preferences of the complainant. The notes of this discussion should be recorded on Part 2 of the HTA-35: Complaints form. The DI should attempt to understand the incident which has led to the complaint, as well as to understand the complainant's concerns and desired outcomes.

3.8 If the complainant is a third-party acting on behalf of the research study participant, then the DI should also, where possible, discuss the complainant directly with the participant to ensure that the complaint is made with their knowledge and consent.

3.9 If an appropriate resolution can be found at this time (e.g. an apology) then this should be offered, and this should be indicated on the report form. The CI should be informed of the outcome of the complaint. As far as is practical the complainant, CI and DI should sign off the report form to indicate resolution of the complaint.

3.10 If a resolution cannot be immediately offered, an investigation should be conducted. The investigation should be held discreetly with all conversations treated as confidential. The members of the research team involved in the incident as well as the CI should be interviewed. Notes of the interview should be recorded and signed off by both the DI and the interviewee. Records of these meetings as well as the report forms should be held in a secure location only accessible to the DI. If the complaint is about the DI this function will be performed by the Head of Clinical and Research Governance.

3.11 Once the investigation has been completed, the DI or the will decide upon the

action to be taken and contact both the complainant and the CI of the study to discuss the outcome of their investigation. If the complaint has been successfully resolved, then the actions will be put into practice. If the complainant remains unsatisfied, the complaint should be referred to both the License Holder to review decisions made, and amend if necessary. If the complaint is about the DI this function will be performed by the Head of Clinical and Research Governance.

References:

University Hospitals of North Midlands Trust complaints policy

Parliamentary and Health Service Ombudman's policy on good complaint handling
http://www.ombudsman.org.uk/improving-public-service/ombudsmansprinciples/principles-of-good-complaint-handling-full