Standard Operating Procedure

Title:	**Research Governance Audit**		
SOP Reference Number:	QUB-RGEI-015	Version Number:	FINAL v 1.0
Revision Date	21 September 2021	Review Date	21 September 2024

	Name and Position	Signature	Date
Author:	Research Governance, Ethics and Integrity Team	----------	----------
Reviewed and Approved by:	Chair Research Governance, Ethics and Integrity Committee	----------	----------

This is a controlled document.
When using this document please ensure that the version is the most up to date by checking the Research Governance, Ethics and Integrity Website

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) describes the procedures for the audit of research projects to ensure compliance with research governance arrangements and Good Clinical Practice (GCP). It will outline what should be audited, how the audit(s) will be conducted, their frequency, the form, and content of the audit report.

This SOP is relevant for any research being undertaken under the auspices of the University.

2. Responsibilities

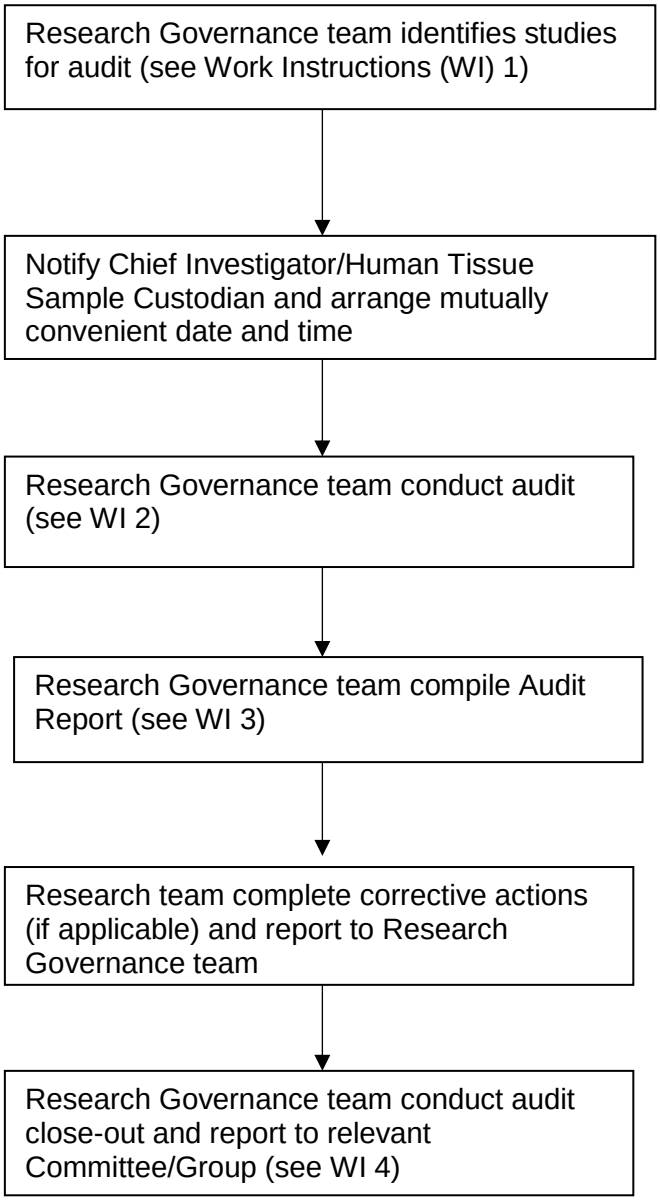
2.1 Research Governance Team

The Research Governance Team will conduct an internal audit of research studies sponsored by the University. The Research Governance Team will implement an audit schedule to ensure that studies are conducted and managed safely and effectively and in compliance with relevant SOPs, study protocols and regulations. Further details on how this will be conducted is found in the Working Instructions (WI).

2.2 Chief Investigator

It is the responsibility of the Chief Investigator (CI) to fully co-operate with the audit procedure, make available any documentation requested and implement any corrective actions within the designated time period.

3. Procedure



4. References:

UK Policy Framework for Health and Social Care, 2018 (last accessed 30 March 2021). https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) (last accessed 30 March 2021). https://www.ich.org/page/ich-guidelines

5. Appendices

Work Instructions 1 – Identification of Studies for Audit
Work Instructions 2 – Conduct of Audit
Work Instructions 3 – Compilation of Audit Report
Work Instructions 4 – Audit Close-Out

Appendix 1 Template Audit Tool/Report Category B and C Studies and Human Tissue

Work Instructions 1 – Identification of Studies for Audit

On an annual basis, the Research Governance Team will prepare a list of studies to be audited. A risk based approach will be employed in selecting studies for audit. Priority will be given to studies deemed to be of high risk; due to the nature of the study population, the study intervention, the complexity of the study, the level of funding received for the study, the experience of the research team; or those which involve the use of human tissue. Funder Terms and Conditions may also mandate a specific audit schedule, and this will be taken into consideration. Lower risk studies may be assessed using a desk-based audit process. In the case of co-sponsored studies, the audit process will be governed by the Memorandum of Understanding (MoU) for Research Governance (2011).

One month prior to the audit being undertaken the Research Governance Team will inform the CI/Sample Custodian of their intention to audit their study. A mutually convenient date will be arranged and the CI/Sample Custodian will be advised of the documentation required and the people/groups to be audited. The Centre Director, Head of School, Centre Manager and School Manager as appropriate will also be informed of the intention to audit.

The CI will be provided with a copy of the audit tool for their information (see Appendix 1).

The CI/Sample Custodian must be available to answer any queries that may arise during the audit. In addition, other investigators must also be available to clarify any points.

A room in which to conduct the audit must be provided by the CI/Sample Custodian. The research study file, all source documents, Case Report Forms, laboratory notebooks, training records and other study documentation must be available. If the audit is to be desk-based, then the CI/Sample Custodian will be advised what documentation should be provided for review. Care should be taken to preserve participant confidentiality when providing this information.

Work Instructions 2 – Conduct of Audit

The audit team will use the most appropriate methodology to assess compliance with research governance arrangements. This may include a combination of the following:

- Reviewing documentation;
- Assessing and comparing documentation;
- Checking that the research study file contains the up-to-date and relevant documents;
- Ensuring that research participants have given their informed consent;
- Interviewing any member of the research team;
- Determining compliance with the University's SOPs for research governance;
- Inspection of laboratory or other facilities relevant to the study.

Work Instructions 3 – Compilation of Audit Report

The audit team will compile a report detailing their findings, within four weeks of completing the audit. A template for the audit reports is attached as Appendices 1 and 2.

The audit report will include:

- A list of identified non-conformities with GCP, the Human Tissue Act 2004 and research governance, presented as a table;
- An assessment of protocol and legislative compliance;
- Where appropriate, a list of corrective actions to be taken to ensure compliance;
- In the event of critical and/or moderate findings, a date for re-audit.

The audit report will be distributed to the CI, Centre Director, Head of School, Centre Manager and School Manager as appropriate. The Trust Research Office will also be provided with the audit report as appropriate. For studies involving the use of human tissue, the Designated Individual will be provided with a copy of the audit report.

In the event that the audit has identified serious and/or persistent noncompliance on the part of an investigator/institution, the University will terminate the investigator's/ institution's participation in the study, in accordance with SOP QUB-RGEI-011 and inform the MHRA and main REC as required by law.

Where corrective actions are identified these will be discussed with the CI and a time-scale agreed within which actions must be addressed and the Research Governance Team notified. A follow-up visit may be scheduled to provide assurances that recommendations have been implemented.

In the event that corrective action(s) is/are not completed in time for the re-audit, Centre Director, Head of School or Dean of Research and Pro-Vice-Chancellor for the Faculty will be notified as appropriate. He, She, or their nominee, may deem it necessary to suspend recruitment until all actions are addressed or notify the researcher's line manager.

Work Instructions 4 – Audit Close-Out

Completion of Corrective Actions will be documented on the Audit Report. An indication will be given if a routine re-audit will be undertaken and an approximate timescale for this.

An aggregated report of audit activity and findings will be brought to the attention of the Research Governance, Ethics and Integrity Committee or Human Tissue Steering Group for their consideration and action, if required.

Audit Report: Template Category B and C Studies and Human Tissue

Research Ref No(s): QUB: REC:	**Research Title:**	
Chief Investigator:	**Other Investigators:**	
Lead Sponsor:	**Other Sponsor:**	**Funding Body:**
Start Date:	**End Date:**	
Audit Personnel:	**Site Personnel:**	**Audit Date:**

1. Introduction

The purpose of this audit was to establish if the research study was compliant with the UK Framework for Health and Social Care Research (2017), the requirements of the Human Tissue Act 2004 (where the study involves human tissue) and Queen's University, Belfast Standard Operating Procedures for Research Governance.

This report documents the findings and observations made during the audit of "{*insert title}*". The findings have been categorised according to their seriousness and the actions required have been specified. Where there have been Critical or Major findings the actions must be addressed within 4 weeks from the date of this report. For minor matters, these must be addressed within 3 months.

1.1 Grading Audit Findings

Critical

- Where there is evidence that the safety, well-being or confidentiality of research participant has been (or has the significant potential to be) jeopardised.
- Where approval for the study has not been sought from the appropriate regulatory body and the study has commenced.
- Where the procedures being undertaken differ from those outlined the study protocol and these have not received the approval from the appropriate regulatory body.
- Where participants have either not been consented, or have given their consent without the full information being provided to them.
- Where inadequate indemnity is in place for study participants.

Critical (as defined by the HTA)

- Where there is evidence that there is a significant risk to human safety and/or dignity or a breach of the HT Act or associated Directions or
- Where there is a combination of several major shortfalls, none of which is critical on its own, but which in combination could constitute a critical shortfall.

Major

This is where the integrity of an aspect of the study has been compromised and includes:

- The CI's failure to comply with the requirements of the regulatory body.
- The principles of Good Clinical Practice have not been adhered to, e.g. providing the research participant with the information sheet, or a copy of their consent form.
- Where the University's SOPs have not been closely adhered to.

Major (as defined by the HTA)

A non-critical shortfall that:

- Poses a risk to human safety and/or dignity, or
- Indicates a failure to satisfactorily carry out procedures, or
- Indicates a breach of the HTA Code of Practices, the HT Act or other statutory guidelines
- Has the potential to become a critical shortfall
- Where the University's SOPs for human tissue have not been closely adhered to
- Where there is a combination of several minor shortfalls, none of which is critical on its own, but which in combination could constitute a major shortfall.

Minor

Findings that do not compromise the study's integrity but require attention to improve the overall quality of the study.

Minor (as defined by the HTA)

A shortfall which indicates a departure from expected standards but cannot be categorised as a critical or major shortfall.

2. Audit Findings

A	Protocol and Associated documents	Yes	No	N/A	Comments
	Has a Research File (RF) been prepared for the study?				
	Is the final approved version of the protocol in the RF (with version number and date)?				
	Is the final version of the protocol signed by the CI?				
	Have the research protocol and/or associated documents been amended in any way since ethics approval?				
	If yes, have the amendments been approved by the same ethics committee?				
	If yes, has the funding body been informed of these amendments?				
	If yes, have the sponsor(s) been informed of these amendments?				
	Does the protocol clearly define: Inclusion and Exclusion Criteria? Monitoring Policy? Publishing Policy? Risk Threshold?				
B	**Approvals**	**Yes**	**No**	**N/A**	**Comments**
	Is there a record of a favourable opinion from a Faculty/School Ethics Committee?				
	Is there a record of a favourable opinion from ORECNI/other REC?				
	If the ethics committee specified any amendments to the protocol (restrictions or conditions), have these been carried out?				
	Has an annual report been sent to ORECNI (copied to Research Governance)?				
	Is there a record of a favourable ethical opinion for any amendments?				
	Is there confirmation of sponsorship from the sponsoring organisation(s)?				
	Is the appropriate start certificate(s) in place?				
	Is there evidence of indemnity for the research?				
	Is any relevant human material being collected?				
C	**Research Team**	**Yes**	**No**	**N/A**	**Comments**
	Are signed training records available for each Investigator?				

	Is there evidence of Human Tissue Act Training for all researchers?				
	Have the researchers received Health and Safety training/guidance?				
	If research involves clients that 'have a direct bearing on the quality of care' does the researcher hold a Trust employment contract, or Trust honorary contract?				
	Are Protocols/Guidelines or Standard Operating Procedures available for the research?				
	Have these been signed off by the CI?				
	Are these SOPs fit for purpose and in line with the University's SOPs?				
	Are the SOPs fit for purpose and in line with the University's HTA SOPs?				
	Is there a signed training log in place?				
	Is there a current and effective study delegation log?				
D	**Adverse Events**	**Yes**	**No**	**N/A**	**Comments**
	Have there been any accidents/incidents/adverse events since the research commenced?				
	Is there a record of these accidents/incidents/adverse events?				
	If yes, have the following been notified? University Trust Funding Body Person Designated Designated Individual				
	Are these outlined in the Annual Progress Report to the REC (copied to Research Governance)?				
E	**Participants**	**Yes**	**No**	**N/A**	**Comments**
	Is there a full record of all research participants (clients, staff or healthy volunteers)?				
	Is there a full record of all research participants written informed consent and/or where appropriate written carer consent/assent?				
	Are all signed consent forms on headed paper with the correct version number?				
	Are the consent forms stored securely?				
	Have any complaints been received from the participants regarding the research?				

	Do all recruits fall within the inclusion criteria?				
F	**Human Tissue Samples**	**Yes**	**No**	**N/A**	**Comments**
	Are the human tissue samples logged on the QOL Human Tissue Register?				
	Are the human tissue samples stored in appropriate conditions?				
	Are the human tissue samples labelled appropriately?				
	Are records maintained or sample storage, use and disposal?				
	Are Material Transfer Agreements and/or Authority to Import forms in place?				
	Does the CI intend to retain the tissue samples for future research?				
	Has consent for use of the samples in future research been sought?				
G	**Data Collection and Storage**	**Yes**	**No**	**N/A**	**Comments**
	Are laboratory notebooks available and appropriate?				
	Are paper records being stored in a locked filing cabinet?				
	Are electronic files on a password protected computer?				
	Is there an electronic backup system?				
H	**Study Completion**	**Yes**	**No**	**N/A**	**Comments**
	Were recruitment targets met?				
	Has effort been made to disseminate the research findings to the research participants?				
	Has effort been made (or is planned) to publish research findings in professional and where appropriate in peer reviewed journals?				
	Have all queries raised through monitoring or audit been resolved?				
	Have the Ethics Committee, Sponsors, and Funders, as appropriate, been informed of the study completion?				
	Has a final report been submitted to the Data Monitoring Committee and/or other relevant Committee(s)?				
	Have arrangements been made for appropriate archiving?				
I	**Funding**	**Yes**	**No**	**N/A**	**Comments**
	Has the Research Contracts Office approved all agreements/contracts with external funders?				
	Is the Chief Investigator taking responsibility to ensure the project is				

	conducted according to strict financial probity?				
	Are there agreements covering IPR with any 3rd party researchers/organisations?				
	Have these been approved through the appropriate channels (eg Research Cotnracts, a Trust Finance Dept or by the original Research Management System?				
	Is the research recorded on the Insurance database?				
	Are all contracts signed off appropriately and in a timely manner?				

Human Tissue Sample Review (random selection)

Sample ID	Sample Type	Logged on QOL Tissue Register	Consent Available	Labelling Appropriate	Storage Appropriate	Comments

ADDITIONAL COMMENTS

For example:

Study documentation

FINDING:

Serious Adverse Event

FINDING:

Annual Progress Reports

FINDING:

Sample Labelling

	FINDING
Training Records	**FINDING:**

3. Conclusion

4. Signatures

Auditor: **Chief Investigator:**

Date: **Date:**

5. Corrective Actions Completed

Yes ☐ **No** ☐ **Not required** ☐

Name: **Date:**