Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Research Governance Audit**		
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	Name and Position	Signature	Date
Author:	Mrs Louise Dunlop Head of Research Governance	----------	----------
Reviewed by:	Professor James McElnay, Chair Research Governance and Integrity Committee	----------	----------
Approved by:	Mr Scott Rutherford Director, Research and Enterprise	----------	----------

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* For all University sponsored research recorded as risk category level 4, including IMP studies
# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Draft v 2.0
Draft v 2.0	09/09/11	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	22/08/2012	Periodic Review	Final v 3.0
Final v 3.0	06/03/2013	Revised to include audit of studies involving relevant material as defined by the Human Tissue Act	Final v 4.0
Final v 4.0	23/10/2014	Periodic Review	Final v 5.0
Final v 5.0	19/01/2017	Periodic Review	Final v 6.0

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. Introduction

As legal sponsor of research studies being conducted under the Research Governance Framework for Health and Social Care (DHSSPS, December 2006) and/or as co-sponsor of projects undertaken under the UK Clinical Trials (Medicines for Human Use) Regulations 2004, Queen's University, Belfast, is responsible for auditing research practice and ensuring that it complies with the aforementioned guidance and legislation.

It should be noted that the Sponsor's audit, is independent of and separate from routine monitoring or quality control functions that must also be undertaken. The purpose of an internal Sponsor's audit will be to ensure the safety of participants and staff, ensure compliance with the regulatory requirements, protocol, SOPs and GCP. An internal audit programme will also prepare researchers for external audit processes.

Category A and B studies will be randomly selected for audit from the University's Sponsorship and Ethics Database. Studies involving the use of human tissue will be randomly selected for audit from the University's Tissue Register. Existing holdings will also be subject to audit. All Category C studies, as defined by the University's Research Governance Framework, will be subject to audit annually. Other studies will be audited in accordance with the funder's requirements. In addition, the Research Governance Team and/or Director of Research and Enterprise reserve the right to undertake a targeted audit, if they have suspicion of non-compliance to legislation, or when monitoring reports provide information of concern.

Where a study is co-sponsored with a Health and Social Care Trust it may be appropriate to undertake a joint audit. If any non-compliances are identified for which the Health and Social Care Trust have responsibility, the audit report will be shared with that Trust for their action.

3. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

4. Responsibilities

4.1 Research Governance Team

The Research Governance Team will conduct an internal audit of research studies sponsored by the University. The Head of Research Governance will provide oversight for the internal audit process. A Lead Auditor will be appointed from within the Research Governance Team. The Lead Auditor will be expected to assume the following responsibilities:

- Identify an annual programme of research projects to be audited;
- Direct that an annual aggregate report of audit findings be compiled for the Research Governance Steering Group or the Human Tissue Steering Group as appropriate;

- Escalate critical non-conformances as appropriate;
- Manage any potential misconduct in research matters;
- Audit the research projects collecting evidence of current research practice and adherence to legislation, guidance and standards;
- Compile a report for the Chief Investigator, identifying areas of non-conformance, good practice and other observations;
- To update the Research Governance Site Audit Matrix;
- Ensure that the process and associated documentation is kept confidential, unless concerns are raised relating to misconduct in research, as defined by the University Regulation for an Allegation and Investigation of Misconduct in Research;
- Ensure appropriate follow-up in the event of non-compliances being identified;
- Provide a summary for the Research Governance Department on the main aspects of the audit and any unresolved issues.

The Research Governance Team should be independent of the research and qualified by training and experience to conduct audits properly. For Category C studies these qualifications should be documented (ICH GCP 5.19.2) and will be available in the training records of each member of the Research Governance Team.

4.2 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.

5. Procedure

5.1 Preparation for Audit

On an annual basis, the Research Governance Team will prepare a list of studies to be audited. 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 of their intention to audit their study. A mutually convenient date will be arranged and the CI 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 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. The trial master file, all source documents, Case Report Forms, laboratory notebooks, training records and other study documentation must be available.

5.2 Audit Processes

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 Trial Master 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.

5.3 Audit Findings

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 how well regulatory requirements have been met;
- 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.

5.4 Audit Outcome

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 trial, in accordance with SOP QUB-ADRE-019 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 the Pro-Vice-Chancellor for Research and Postgraduates 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.

5.5 Audit Close-out

Once all recommendations have been addressed and assurances gained the CI will be written to. 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 Steering Group or Human Tissue Steering Group for their consideration and action, if required.

6. References:

DHSS&PS, Research Governance Framework for Health and Social Care, December 2006 (last accessed 19 January 2017).
http://www.research.hscni.net/sites/default/files/research_governance_framework_0.pdf

International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) (last accessed19 January 2017).
http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html
Imperial College London, Clinical Research Office Audit SOP. 31 May 2007 (last accessed October 2014, no longer publically available)
http://www3.imperial.ac.uk/pls/portallive/docs/1/16925697.PDF

7. Appendices

Appendix 1 Template Audit Tool/Report Category B and C Studies
Appendix 2 Template Audit Tool/Report Human Tissue Studies

Audit Report: Template Category B and C Studies

Research Ref No(s): QUB: REC:	**Research Title:**	
EudraCT No: N/A	**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 DHSS&PS Research Governance Framework, December 2006, the Medicines for Human Use (Clinical Trials) Regulations 2004, and subsequent amendments 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 (MHRA and/or ORECNI) 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.

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.

Minor

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

2. Audit Findings

A	Protocol and Associated documents	Yes	No	N/A	Comments
	Has a TMF been prepared for the study?				
	Is the final approved version of the protocol in the TMF (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 MHRA 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**				
	Is there a record of a favourable opinion from a 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 and/or MHRA (copied to RPO)?				
	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?				
	Has EudraCT number been received?				
	Has there been CTA approval from the relevant Competent Authority (e.g. MHRA)				
	Is there a record of MHRA approval of any amendments?				
	Is any relevant human material being collected?				
C	**Data Collection and Storage**				
	Are laboratory notebooks available and appropriate?				
	Are paper records being stored in a locked filing cabinet?				
	Are electronic files on a password protected computer?				
D	**Researchers**				
	Are signed training records available for each Investigator?				
	Is there evidence of Good Clinical Practice Training for all researchers?				
	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?				
	Is there a signed training log in place?				
	Is there a current and effective study delegation log?				
E	**Adverse Events**				
	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 MHRA				
	Has an annual safety report been sent to ORECNI and/or MHRA (copied to sponsor(s))?				
F	**PARTICIPANTS**				
	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?				
G	**STUDY COMPLETION**				
	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, Funders and MHRA (or other competent authority), 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?				
H	**FUNDING**				
	Has the Research Support 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 RSO, 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?				

I	**Laboratory Review**									
	Samples Reviewed									
		Bloods*			**Urines***					**Other Info**

*Headings amended as appropriate

ADDITIONAL COMMENTS
For example: **Study documentation** **FINDING:** **Serious Adverse Event** **FINDING:** **Annual Progress Reports** **FINDING:** **Training Records** **FINDING:**

3. Conclusion

4. Signatures

Auditor: **Chief Investigator:**

Date: **Date:**

5. Corrective Actions Completed

Yes ☐ **No** ☐ **Not required** ☐

Name: **Date:**

Audit Report: Template Human Tissue

Research Ref No(s): QUB: REC:	**Research Title:**	
EudraCT No: N/A	**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 requirements of the Human Tissue Act 2004 and Queen's University Belfast Standard Operating Procedures for Human Tissue.

This report documents the findings and observations made during the audit of "Generation of genetic signature of severe RSV disease – a step towards maximizing efficiency of synagis prescription (07/NIR02/115)". Audit shortfalls 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.

1.2 Grading Audit Shortfalls (as defined by the HTA)

Critical shortfall

- 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 shortfall

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 shortfall

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

2. Audit Findings

	Protocol and Associated documents	**Yes**	**No**	**N/A**	**Comments**
1	Has all the study documentation been collated for the study?				
2	Is the final approved version of the protocol available (with version number and date)?				
3	Have the research protocol and/or associated documents been amended in any way since ethical approval?				
3a	If yes, have the amendments been approved by the same ethics committee?				
	Approvals				
4	Is there a record of a favourable opinion from a School Ethics Committee?				
5	Is there a record of a favourable opinion from ORECNI/other REC?				
6	If the ethics committee specified any amendments to the protocol (restrictions or conditions), have these been carried out?				
	Research Team	**Yes**	**No**	**N/A**	**Comments**
7	Is there evidence of Human Tissue Act Training for all researchers?				
8	Have the researchers received Health and Safety training/guidance?				
9	Are Protocols/Guidelines or Standard Operating Procedures available for the research?				
10	Are these SOPs fit for purpose and in line with the University's HTA SOPs?				
	Adverse Events	**Yes**	**No**	**N/A**	**Comments**
11	Have there been any accidents/incidents/adverse events since the research commenced?				
12	Is there a record of these accidents/incidents/adverse events?				
13	If yes, have the following been notified? University Trust Funding Body Person Designated Designated Individual				
	Participants	**Yes**	**No**	**N/A**	**Comments**
14	Is there a full record of all research participants (clients, staff or healthy				

	volunteers)?				
15	Is there a full record of all research participants written informed consent and/or where appropriate written carer consent/assent?				
16	Are all signed consent forms on headed paper with the correct version number?				
17	Are the consent forms stored securely?				
18	Have any complaints been received from the participants regarding the research?				
19	Do all recruits fall within the inclusion criteria?				
	Human Tissue Samples	**Yes**	**No**	**N/A**	**Comments**
20	Are the human tissue samples logged on the QOL Human Tissue Register?				
21	Are the human tissue samples stored in appropriate conditions?				
22	Are the human tissue samples labelled appropriately?				
23	Are records maintained of sample storage, use and disposal?				
24	Are Material Transfer Agreements and/or Authority to Import forms in place?				
25	Does the CI intend to retain the tissue samples for future research?				
26	Has consent for use of the samples in future research been sought?				
	Data Collection and Storage	**Yes**	**No**	**N/A**	**Comments**
27	Are laboratory notebooks available and appropriate?				
28	Are paper records being stored in a locked filing cabinet?				
29	Are electronic files on a password protected computer?				
30	Is there an electronic backup system?				
	Study Completion	**Yes**	**No**	**N/A**	**Comments**
31	Were recruitment targets met?				
32	Have the human tissue samples been retained?				
33	Have the Ethics Committee, Sponsors and Funders (or other competent authority), as appropriate, been informed of the study completion?				
34	Have arrangements been made for appropriate archiving?				

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:** **Sample labelling** **FINDING:** **Training Records** **FINDING:**

3. Conclusion

4. Signatures

Auditor 1: **Auditor 2:**

Date: **Date:**

5. Corrective Actions Completed

Yes ☐ **No** ☐ **Not required** ☐

Name: **Date:**