Research Sponsorship Policy & Procedure

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1		Initial draft		
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Definitions

C.I.	Chief Investigator
CPMS	Central Portfolio Management System
CRF'S	Case Report Forms
DMEC	Data Management and Ethics Committee
GCP	Good clinical practice - A set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.
HB	Health Board
HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
JSRC	Joint Scientific Review Committee
LPMS	Local Portfolio Management System
MTA	Material Transfer Agreement
OID	Organisation Information Document
Portfolio	Health and Care Research Wales Portfolio is a register of high quality health and social care research studies active in Wales. Registering on the portfolio gives you access to NHS support for study delivery like research nursing. Each UK country manages its own research portfolio and researchers need to register their study in the country where they plan to conduct the research. Commercial and non-commercial research studies can be registered on the portfolio. Each study has to meet specific criteria to be eligible for the research portfolio in all UK countries.
QA	Quality Assurance
QMS	Quality Management System
R&D	Research and Development
RA	Risk Assessment
RDCS	Research Design and Conduct Service
REC	Research Ethics Committee
RGF	Research Governance Framework
SB UHB	Swansea Bay University Health Board
SLA	Service Level agreements
SOP	Standard Operating Procedure
Sponsor	The individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor.
STU	Swansea Trials Unit
TM	Trial Manager
TMG	Trial Management Group

1. Purpose

The purpose of this Policy & Procedure is to define the conditions by which the Health Board will accept Sponsorship responsibility for an interventional trial or other research under the UK Policy Framework for Health and Social Care and the subsequent delegation of duties in performing the Sponsorship role including defining the quality system in place for managing sponsorship oversight.

The SOP shall be applicable to all research, which requires the Health Board to act as Sponsor or Co-Sponsor.

2. Background

All research studies require a Research Sponsor. The UK Policy Framework for Health and Social Care Research 2017 defines a Research Sponsor as:

–'the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor.

3. Roles and Responsibilities

Swansea Bay UHB R&D Department has responsibility to ensure that this policy & procedure remains fit for purpose.

4. Sponsorship principles

The Health Board will Sponsor or Co-Sponsor with Swansea University all studies initiated by Health Board employees where no collaborative partner is in place. If there is an academic or commercial collaborative Partner, early discussion with the R&D department will be required to establish appropriateness of the Sponsor role. It is intended that (where deemed necessary) all externally funded ***interventional studies*** will be co-sponsored in line with the Co-Sponsorship Framework and Joint Working Protocol agreed between Swansea University & the Health Board. It is intended that the Commercial partner should sponsor all commercial collaborative studies, unless agreed otherwise following an appropriate level of risk assessment.

It is the expectation that research undertaken for ***educational purposes*** will be sponsored by the relevant Academic Institution unless (following discussion with the R&D Department) it is deemed more appropriate by both institutions for the Health Board (HB) to assume the Sponsorship role due to the nature of the study and the ability of the Academic Institution as awarding body to effectively oversee the research, due for example for those Swansea Bay UHB staff enrolled on distant learning courses.

4.1 Procedure of Sponsor review

For all interventional and non-interventional trial ideas, the R&D department will refer the Chief Investigator to the South West Wales Research Design and Conduct Service (RDCS), based in Swansea Trials Unit as appropriate. Following an initial discussion with the RDCS, if agreed there is a research question to answer, the study will proceed to ***protocol development*** (utilising HB approved protocol templates) & ***peer review*** by the Joint Scientific Review Committee if no external peer review has already been undertaken. The Chief Investigator (C .I.) will be asked to complete a ***risk assessment*** (RA) of the project risk with the combined clinical risk and sponsor risk score determining the level of monitoring and oversight required for the study. The Health Board utilises Swansea Trials Unit (STU) suite of Standard Operating Procedures. Project risk assessments will be undertaken in accordance with STU SOP STU-CT007 – Standard Operating Procedure on Risk Assessment and associated documents. If the study has been adopted by STU, co-ordination of the RA process will be delegated to STU. If the study is not adopted by STU, co-ordination will be undertaken by the Health Board QA Officer and overseen by the HB Sponsor Representatives.

According to the risk score, the Sponsor or Co-Sponsor partners may convene a ***Trial Management Group (TMG)*** proportionate to the study type. A member of R&D will be a member of the TMG to ensure correct processes are followed and the protocol adequately describes sponsor quality procedures for reporting within the study. With input from R&D, each TMG, with responsibilities usually delegated to the CI or to a Trial Manager (TM), will be responsible for overseeing and ensuring submission of relevant regulatory and R&D approval submissions and convening an appropriately constituted ***Data Management and Ethics Committee (DMEC)*** or equivalent, if required commensurate to the complexity of the study.

4.2 Agreements

In commitment to good governance of research, whenever the Health Board is asked to Sponsor research a Conditions of Co/Sponsorship agreement must be signed by the Investigator. Co-sponsorship will be governed by an overarching Framework agreement and Joint Working Protocol signed by the Health Board and Swansea University. Study level collaborative agreements may also be used, as deemed necessary according to risk.

This will ensure clear assignment of delegated duties in order for the trial to be conducted in accordance with appropriate standards, for example GCP standards where deemed necessary according to study type (Appendix A) and for the Investigator to be fully aware and sign up to their responsibilities that will ensure effective compliance to the governing Regulations, including responsibilities under the Data Protection Act 2018, incorporating the General Data Protection Regulations 2018.

Service Level agreements (SLA) and Material Transfer Agreements (MTA) may also be required according to specific study requirements, as identified during the Sponsor review.

4.3 Local Delegation

As Co/Sponsor of a research study, the Health Board may invoke the power within the Clinical Trial Regulations and the UK Policy Framework to delegate any or all of its Sponsorship duties to named personnel or any other corporate body. This delegation will not affect the overall responsibility of the Health Board as Co/Sponsor of the trial but recognises the resource capacity of the Health Board in performing all of its Sponsorship duties. Notably, the HB will seek to delegate responsibility for study management to an appropriately costed Clinical Trials Unit, such as Swansea Trials Unit (STU).

4.4 Liability & Indemnity

All research requires provision to be made for insurance or indemnity to cover the liability of the Investigator & Co/Sponsor. As a potential Sponsor of a research study and as a NHS organisation, this requirement will be met through provision within Welsh Risk Pool arrangements (Technical note 12) whereby all research registered and approved by the Health Board and the HRA Permissions Service will be indemnified for negligent harm and through appropriate contractual terms with any third party supplier of any drug, device or equipment.

The WRP Technical Note outlines the conditions which must be in place in order for NHS Indemnity to apply and details situations where NHS indemnity would not apply or where there would be an expectation that University trials insurance would apply, recognising the integrated responsibilities of interventional and non-interventional academic research.

4.5 Quality System

Systems for managing research within the Health Board are described within the R&D Operational Framework. Co-sponsored interventional studies are governed by the Co-sponsorship Framework agreement with Swansea University supported by a Joint Working Protocol under an overarching Memorandum of Understanding.

HB R&D representatives will provide assurances to the Joint Study Review Committee (JSRC) as the HB and University Sponsorship Oversight Committee on the progress of each Sponsored study including reports from the R&D QA Officer on GCP compliance.

SOPS

The Health Board has adopted the use Swansea Trials Unit suite of SOPs and associated documents, with the addition of some local SOPs to cover local research management issues.

4.6 Data Management

Data collection and management processes for all Co/Sponsored studies will be discussed at an early stage of study development to ensure they are robust and suitable for the study type and volume of data collected, this will ensure the risks associated with inaccurate collection and misrepresentation of data is mitigated.

A central study database should be established for all HB Sponsored research studies, where deemed appropriate. This central study database contains all collected data from consent forms, Case Report Forms (CRFs), questionnaires, interview notes etc. that will be used for analysis in your study. Either the appointed study trial manager, the Chief Investigator (CI), or delegated individual will co-ordinate the collection of study data from within the Health Board and from other sites if the study is multicentre. The central study database should be kept within a robust data management system suitable for the study type and volume of data collected. This central study database will be used for verification of recruitment data throughout the study and should be kept live and as up to date as possible at all times. Suitability of an appropriate data management system will be discussed at study development.

The Portfolio status and monthly recruitment upload route for a study are all determined at study set up. Portfolio eligibility is reviewed against set criteria by the Portfolio team within Health and Care Research Wales when a study is submitted via IRAS. Confirmation of status will be issued by the portfolio team via email to the CI after they have completed their assessment. The default data upload route for all studies at present is set to upload recruitment via the Local Portfolio Management System (LPMS) of each site taking part in the study. For Co/Sponsored portfolio studies that are only open within the Health Board (single centre), we would request the upload route for these studies be set to 'Manual Upload' i.e. direct to the Central Portfolio Management System (CPMS), to eliminate the need to verify our own data. This will be decided upon with the support of the Portfolio team within Health and Care Research Wales.

All studies regardless of Portfolio status need to ensure that monthly recruitment data is uploaded to the relevant system within five working days of the end of each month. Recruitment data will either be entered onto a sites' LPMS that feeds through for verification in CPMS by Sponsor/CI/ delegated individual, or some studies will need to upload direct to CPMS, in which case the verification process will not take place. For all Co/Sponsored studies with recruitment upload routes set to LPMS, verification of data in CPMS should be completed using the central study database.

4.7 Management of Human Samples

Co/Sponsored studies involving human samples are subject to ongoing internal review by the HTA Governance Officer in relation to donor consent, study approval status and planned future sample storage. Oversight is maintained throughout initial study submission and subsequent amendments which may impact on compliance of the HB with HTA license standards, best practice and human tissue legislation.

A joint quality management system (QMS) with Swansea University is in place to guide research teams of Co/Sponsored studies in compliance with the human tissue legislation and Human Tissue Authority (HTA) research licensing standards for HTA license 12651. The QMS is applicable to Co/Sponsored studies notably where there is an intention at study outset to retain

relevant material under the joint research HTA license following study completion. Consideration is given to existing sample governance processes and quality management arrangements within HB or partner laboratories, remaining in line with the legislation, to ensure that application of the QMS remains flexible. Documentation and guidance within the HTA QMS is applied as appropriate to guide researchers in best practice of Co/Sponsored studies which use human samples that fall outside of the remit of the human tissue legislation.

Co/Sponsored studies using surplus, previously collected or archived diagnostic samples and the addition of sub-studies which fall entirely under the scope of an existing approval are considered within the Co/Sponsor governance team on a case by case basis in line with HRA guidance.

Breaches of the HT Act that occur within a Co/Sponsored study are handled in accordance with the joint QMS HTA Adverse Event SOP. Summaries of such events will be provided to the Designated Individual, HB HTA Assurance Committee and to the HTA as part of the compliance report.

Where a risk to patient care related to sample collection and use is identified within a Co/Sponsored study but which does not constitute a breach of the HT Act, the HTA Governance Officer, R&D QA officer and Sponsor representatives will liaise with the research team to determine the root cause and appropriate corrective and preventative actions and will be reported in line with normal HB incident reporting processes.

Where human samples are compromised during a Co/Sponsored study where no breach of legislation has occurred and no patient risk is identified, the incident is reported and managed using the normal HB incident reporting system.

Where human samples are transferred to or from another organization, transfer agreements documenting the responsibilities of sample providers and recipients are signed by the R&D Department for outgoing or incoming human samples. Agreements may be standalone Material Transfer Agreements, Organisation Information Document, Service Level Agreement or model agreement.

5. Responsibilities

The Health Board will execute its responsibility as Research Sponsor through the R&D department. The R&D department will report to the Joint Study Review Committee as the HB and University Sponsor Oversight Committee, the JSRC will provide assurances to the HB R&D Committee.

References

MHRA – Good Clinical Practice Guide

UK Policy Framework for Health and Social Care Research 2017

The Clinical Trial Regulations 2004

International Conference in Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; ICH Harmonised Tripartite Guideline; Guideline for Good Clinical Practice E6(R1)

Related Documents

- *STU-SOP-TM-011* Identifying and Assessing Deviations, Breaches and Urgent Safety Measures
- STU-AD-FRM Deviations, Breaches & USMs Log
- STU-AD-FRM-029 Breach Reporting Form
- STU-AD-FRM-030 USM Notification Form

- STU-SOP-TM-001 Safety Reporting in CTIMPS
- STU-AD-FRM-007 eSUSAR Registration Form
- STU-AD-TMP-008 Adverse Event Log
- STU-AD-FRM-008 SAE Report
- STU-AD-FRM-009 Pregnancy Form
- STU-AD-GDN-003 Guidance on Reporting SUSARs via eSUSAR website D-GDN-

Appendix A

CONDITIONS AND PRINCIPLES, WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on Articles 2 to 5 of the GCP Directive

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.

2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.

3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.

5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.

7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

Conditions based on Article 3 of the Directive

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.