Buckinghamshire Healthcare NHS
NHS Trust

Research Governance and Management Policy

Version 1.1

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Title

Version	Issue	Reason for change	Authorising body	Date
1.0		**New policy to replace Research Policy**	**Research and Innovation Committee**	
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Associated documents

BHT Ref	Title	Location/Link
BHT Pol246	**Innovation and IP Policy**	**For review with TPSG**
BHT Pol247	**SPA for Research Activity Policy**	**For review with TPSG**
BHT Pol248	**Commercial Research Policy**	**Swan Live Intranet Policies & Guidelines/Policies & Strategies/Information Governance**
BHT Pol 220	**Guidance on Information Disclosure and Sharing Decisions v5.0**	**Swan Live Intranet Policies & Guidelines/Policies & Strategies/Information Governance**
	EU General Data Protection Regulation (GDPR)	**Internet**
	European General Data Protection Regulation 2018	**Internet**
	UK Policy Framework for Research in Health and Social Care 2017	**Internet**
	The Medicines for Human Use (Clinical Trials) Regulations 2004	**Internet**
	ICH Good Clinical Practice	**Internet**
	The Mental Capacity Act 2005	**Internet**

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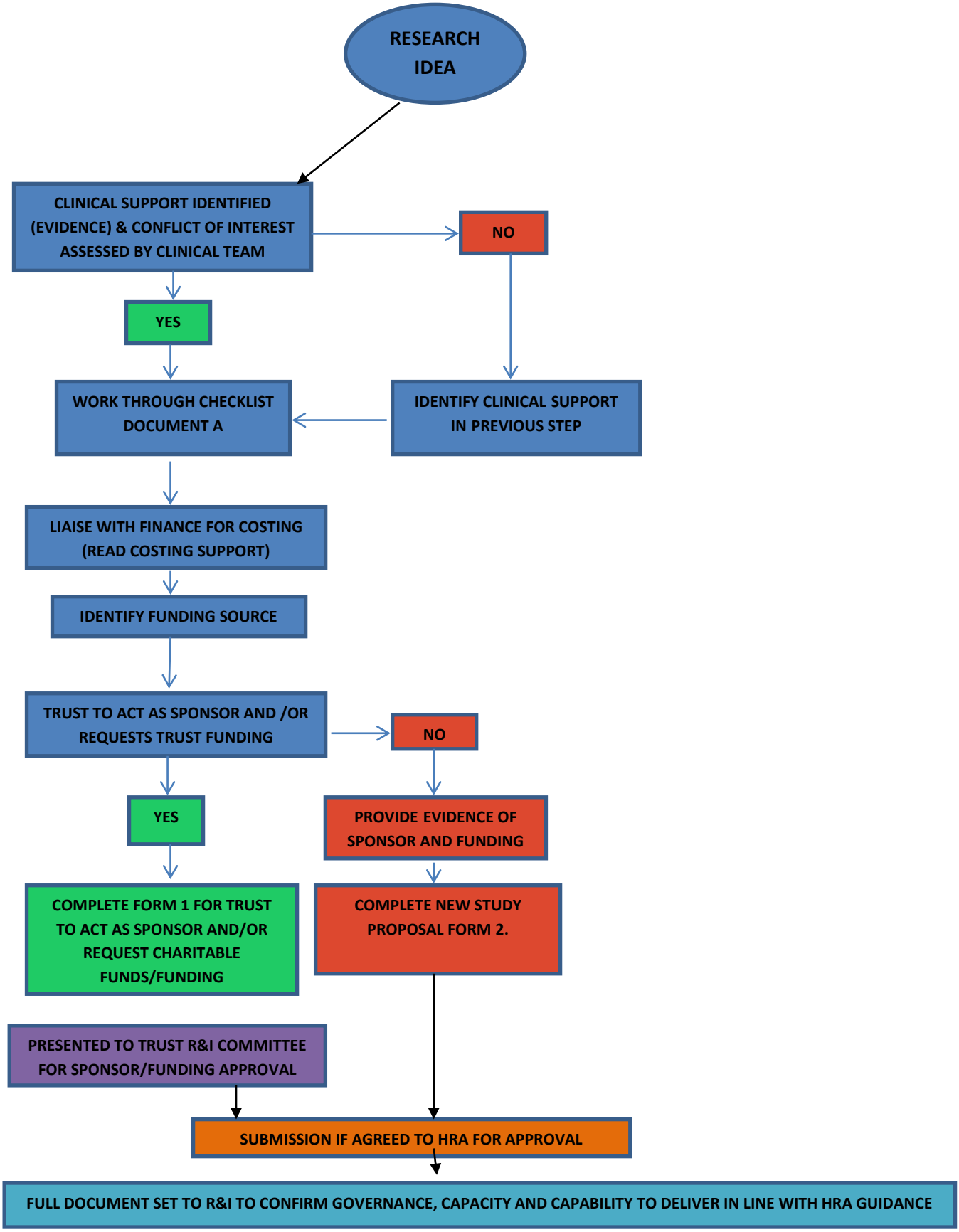
FLOW CHART (1) FOR NEW RESEARCH STUDIES (INTERNAL)



2 Introduction

Research is essential to the successful promotion and protection of health and wellbeing, and also to modern, effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants. Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision making processes, clear allocation of responsibilities and robust monitoring arrangements.

The UK Policy Framework for Research in Health and Social Care 2017 sets out a framework for the governance of research in health and social care. The standards in the Framework apply to all research that relates to the responsibilities of the Secretary of State for Health. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.

All NHS organisations must comply with the UK Policy Framework when getting involved with any research. Research Governance is now one of the core standards for healthcare requiring the health care organisations to have systems in place to ensure the principles and requirements of the framework are consistently applied. Health care organisations have to take this standard into account in discharging their duty of quality under the Health and Social Care (Community Health and Standards) Act 2008.

3. Scope & Purpose

This policy sets out the requirements for all research within Buckinghamshire Healthcare NHS Trust to ensure that research activity complies with the principles of UK Policy Framework and satisfies the. Research Governance Outcome required by the healthcare regulator, the Care Quality Commission.

The policy applies to research activity where research is defined within the Health Research Authority as:

"… the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods".

This policy covers all research activity, both commercial and non-commercial involving Buckinghamshire Healthcare NHS including:

- Research where Buckinghamshire Healthcare NHS Trust is the lead organisation.
- Research where Buckinghamshire Healthcare NHS Trust is a participating site in research.
- Research using patients, carers, volunteers and members of staff at Buckinghamshire Healthcare NHS Trust.
- Research using patient tissue, organs or data, even if obtained for clinical purposes and/or used for research purposes elsewhere, or obtained from elsewhere but used for research purposes involving Buckinghamshire Healthcare NHS Trust.

- Research taking place on Trust premises or involving Trust resources, including nonclinical and laboratory based research.
- Research being undertaken as part of an educational qualification.

The policy does not apply to audit or service evaluations. For guidance on the differentiation between research, audit and service evaluation, please refer to http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=355

4. Aim and Outcomes

The aim of this policy is to provide a framework for research that complies with good practice, yet does not unnecessarily restrict the freedom of the individual researchers to develop ideas which can improve clinical care.

5 Objectives

All research taking place in the Trust must have Trust Research & Innovation (R&I) approval prior to the commencement of any research activity. The only official notification of such approval will be a letter signed on behalf of the Trust by the Trust Head of R&I or authorised deputies (R&I Research Operations Manager and R&I Research Facilitator).

Before Trust approval a full risk assessment will be carried out through study feasibility. The assessment will be based on the principles and standards of the UK Policy Framework, with evidence required of all other regulatory approvals before the Trust R&I approval is finalised along with confirmation of capacity and capability to deliver the study. The main areas of assessment will be:

- Research Sponsorship.
- Type of study.
- Involvement of vulnerable groups.
- Involvement of Gene Therapy.
- Use of human tissue.
- Experience of Principal Investigator (PI).
- Recruitment targets.
- Appropriate funding and resources in place to deliver the study
- Conflict of interests
- Sensitivity of study issues.

Where the Trust is the Sponsor of a multi-site Clinical Trial of Investigational Medicinal Product (CTIMP) or Medical Device Investigation subject to Competent Authority Approval, a risk assessment must also be completed for each of the other sites. The external R&I Department will be asked to complete the Trust R&I feasibility form and return to the Trust R&I department, or to provide a copy of their own risk assessment (level of detail must be at least equal). Where appropriate, monitoring will be conducted by Buckinghamshire Healthcare NHS Trust at external sites.

6 Definitions

Audit:
An audit is not research and does not involve testing new or gaining further evidence on a hypothesis. Audits assess how well a pre-set standard is met. See relevant Trust policy for requirements to register and conduct an audit.

Chief Investigator (CI):
A person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site.

Employing organisation:
The organisation employing the Chief Investigator, investigators or other researchers. Employers remain liable for the work of their employees. The organisation employing the Chief Investigator normally holds the contract or grant agreement with the funder of the study. Organisations holding the contracts with funders remain responsible for the management of the funds. The organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.

Principal Investigator (PI):
The leader responsible for a team of individuals conducting a study at a site.

Research:
An attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. Research may be aimed at understanding the basis and mechanism of disease, improving the diagnosis and treatment of a disease or designing better ways of delivering healthcare.

Researchers:
Those conducting the research.

Research Sponsor:
Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in the Research Governance Framework that are relevant to the study). The sponsor will also act as data controller and will be the organisation responsible for the management and oversight of the data.

Service Evaluation:
A service evaluation assesses an existing service or established practice, whether it is worth continuing and how it can be improved. The service is not measured against a standard (which makes it distinct from audit). It is not always possible to achieve a clear separation from what is defined as research and what as service evaluation. Use the guidance from the National Research Ethics Service Website and from the lead R&I Department.

Responsible care professional:
Doctor, nurse, social worker or other practitioner formally responsible for the care of participants whilst they are taking part in a study.

Research Ethics Committee (REC):
Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority.

7 Related Trust Policies

Core Trust policies relevant to research are listed below – depending on their activity, researchers and coordinators must abide by all applicable additional clinical, administrative, managerial and operational policies:

- Incident Reporting and Management Policy
- Research Related Adverse Events Reporting Policy
- Data Protection & Confidentiality: Policy
- Trust Appearance Policy For All Staff
- Hand Hygiene Policy
- Medical Devices & Equipment Management and Training Policy
- External Agency Visits, Inspections, Accreditations and Reports Policy
- Risk Management Policy and Procedures
- Medicines Management Policy (Annexe 12)
- Clinical Audit Policy

Related Research and Innovation Policies:
- Commercial Research Policy
- Innovation and Intellectual Property Policy
- Funded Research Time through Job Planning

8 Principles

All research falling under the scope of this policy must have explicit written approval from the Buckinghamshire Healthcare NHS Trust Head of Research and Innovation (R&I) or delegated authority prior to commencing.

To obtain Buckinghamshire Healthcare NHS Trust R&I approval the research must be reviewed in accordance with the Buckinghamshire Healthcare NHS Trust R&I approval process. Exemption to this are so-called Proof-of-Concept or Method of Action projects during the developmental stage, which are done on a very small number of participants (e.g. tissue, patient data, communication with participants) in order to verify whether and how a full research project can be designed. Such projects must be presented to R&I in writing and written confirmation obtained from an R&I Senior Manager that they fall under Proof-of Concept.

Such projects do not require ethical or R&I approval, but patient consent must still be obtained for tissue/breath collection or direct contact (e.g. on the Trust's standard clinical treatment/surgery form or method study specific consent from). Within 6 months from commencing and at the end of the data collection a brief report must be submitted on the status of the project development.

All research must be conducted in accordance with:
The UK Policy Framework for Research in Health and Social Care and applicable regulations and guidance including the Medicines for Human Use (Clinical Trials) SI 2004:1031 as amended and Good Clinical Practice (GCP).
General Data Protection Act 2018
European General Data Protection Regulation 2018
Common Law Duty of Confidentiality

All breaches of GCP (for example: deviation from the protocol, adding new/omitting tests/interventions, delaying dates for visits, insufficiently trained staff working on procedures) must be recorded in the Investigator Site File. Furthermore, all serious breaches of GCP or persistent breaches of GCP (after 3 occurrences) must be expedited to Sponsor and hosting R&I Department immediately once becoming aware of the breach. A breach is defined as serious if it is likely to effect to a significant degree:

(a) The safety or physical or mental integrity of the subjects of the trial; or
(b) The scientific value of the trial".

Written "favourable opinion" from an appropriate ethics committee and R&I approval, must be obtained prior to commencing any research in Buckinghamshire Healthcare NHS Trust involving:

- Patients and users of the NHS, patient and user data and patient or user tissue. This includes all potential research participants recruited by virtue of the patient's or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions. Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.

- Access to data, organs or other bodily material of past and present NHS patients.
- Foetal material and IVF involving NHS patients.
- The recently dead in NHS premises.
- The use of, or potential access to, NHS premises or facilities.
- NHS staff – recruited as research participants by virtue of their professional role.

Following the national GAfREC (Governance Arrangements for Research Ethics Committees) changes from 01 September 2011, a risk proportionate ethical review was introduced. Research studies involving healthy volunteers on non-CTIMPs within the NHS, studies involving only anonymised patient data or patient tissue obtained previously during committees (or other HEI/Higher Education Institution ethics committees). All other projects continue to require full NRES REC review. For full details on the risk proportionate ethical review by NRES REC the latest version of the GAfREC guidance must be used, available from the NRES/National Research Ethics Service websites (http://www.nres.npsa.nhs.uk/).

For clinical trials involving an Investigational Medicinal Product, or an Advanced Therapy Medicinal Product (ATMP) or Medical Device without or outside its CE mark, Clinical Trial Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) must be obtained prior to the study commencing.

All research involving an Investigational Medicinal product undertaken within Buckinghamshire Healthcare NHS Trust, must adhere to the Trust Pharmacy Department Standard Operating Procedure for Conducting Clinical Trials Involving Medicines (Annexe 12)

All IMPs should usually be ordered, stored and dispensed by the trust pharmacy. Occasions may arise where it is more appropriate that IMPs are ordered, stored and supplied outside of the trust Pharmacy department. This must only be done following discussion and agreement with the trust pharmacy department.

In addition, all CTIMPS and Medical Device investigations must have a Data Safety Monitoring Committee and this should be independent of the actual research team.

Regarding safety reporting, where Buckinghamshire Healthcare NHS Trust is the sponsor, all SAE reports from other sites must be submitted to Buckinghamshire Healthcare NHS Trust R&I for appropriate action. Urgent Safety Measures must be notified to Sponsor and hosting R&I Office. Irrespective of the Sponsor, any incidents involving patients, their carers, visitors or staff, need to be reported under Trust's Incident Reporting policy.

All agreements relating to research studies must be signed by an authorised signatory. The authorised signatory for agreements is the Medical Director or authorised deputy/deputies. The R&I department will review all contracts as part of local governance checks to give assurance to the Medical Director before sign off.

Researchers not employed by Buckinghamshire Healthcare must obtain written approval for access to Buckinghamshire Healthcare NHS Trust patients/staff/data/facilities with a Letter of Access or Honorary Research Contract. This can be achieved through the Research Passport in the case of HEIs or through the Confirmation of Pre-engagement checks for NHS employees. Confidentiality is covered through this mechanism.

For studies where equipment is being supplied, the equipment must be checked by Buckinghamshire Healthcare NHS Trust Medical Engineering Department for safety reasons. Electrical equipment must be PAT tested according to the Trust's Medical Devices & Equipment Management and Training Policy.

9 Roles and Responsibilities

The following pages identify the roles and responsibilities for those participating in research studies

9.1 Responsibilities - All personnel on research projects

Everyone involved on a research project i.e. researchers; research nurses, research AHPs, research co-ordinators, research practitioners and students have the responsibility of being familiar with the principles of Good Clinical Practice (GCP) described in the Research Governance Framework for Health and Social Care.

All staff working on a CTIMP, ATMP or Medical Device Investigation requiring Competent Authority/MHRA approval must have completed their GCP training before they have any routine clinical care, or studies involving consented research into genetic markers usually require non- NRES ethical review. Trust R&I will accept ethical review from University ethics for staff contact or data collection/entry. It is possible for a fully trained PI to provide tailored GCP training commensurate with the roles particular staff has to fulfil on a study.

Any such tailored versions of GCP training must be approved in writing by the Sponsor.
Staff working on non-CTIMPs must have completed GCP training within a maximum of four months from the date of R&I Approval or the date of their joining of the study team. This can be either through classroom teaching or via an accepted online course.

GCP training must be updated at least every 3 years while being actively involved in research, unless the study is a CTIMP or commercially sponsored, in which case training must be updated every 2 years. Where the last GCP training took place more than 3 years ago (or 2 years for commercially sponsored studies), researchers have a maximum of 3 months to complete an update from the moment they commence their activity on a study. Where the last GCP training took place more than 4 years ago (from day the research activity will start), a full Introduction to GCP course must be completed. GCP certificates and dates of completion are checked during R&I approval for each study and during R&I monitoring.

Before agreeing to their patients or users being approached, all staff must satisfy themselves that the research has been approved by the Trust R&I Department and, where necessary, the appropriate Research Ethics Committee.

9.2 Responsibilities – Researchers.

Researchers who do not hold a substantive employment contract with Buckinghamshire Healthcare NHS Trust must obtain appropriate contractual status through the Research Passport mechanism. Researchers are responsible for ensuring that:
The research is conducted in accordance with:

- The current version of the REC and Trust approved protocol, the researcher is bound by the documents approved through ethics and should not deviate from these
- The Research Governance Framework for Health and Social Care.
- Relevant Health and Safety legislation.
- Clinical Trials Regulations (where appropriate).
- The Data Protection Act (1998); replaced by General Data Protection Regulation 25 May 2018
- The Human Tissue Act (2004).
- The Mental Capacity Act (2005).

And that:

- Care professionals are informed of a subject's participation in research (where applicable).
- The integrity and confidentiality of clinical and other records and data generated by the research is protected in accordance with current data protection legislation and the Caldicott Principles.
- Any failures in conducting the study in accordance with the above are reported as appropriate.
- All adverse events are recorded and reported in accordance with the Buckinghamshire Healthcare NHS Trust policies.
- Suspected fraud or misconduct is reported in accordance with the appropriate Trust policy document.
- Persistent breaches (3 times or more) or serious breaches of GCP will be escalated to Head of R&I, and where applicable to the Director/s of R&I and the Medical Director and may lead to sanctions such as suspension of the study, additional conditions for future studies or non-acceptance of a researcher to act as Chief/Principal Investigator or co-investigator on future studies.

9.3 Responsibilities - Chief Investigator (CI)

With the exception of student research, the Chief Investigator must be a senior individual, with appropriate experience expertise and training to either:

Undertake the design, conduct, analyses and reporting of the study to the standards set out in the Research Governance Framework or; Lead and manages others who have been delegated responsibility for some of these aspects.

For student research the student may act as the CI provided the student has a designated supervisor with appropriate experience, expertise and training.

The CI has overall responsibility for the conduct of the research and is accountable for it to their employer, and through them, to the sponsor(s) of the research. The CI is also directly accountable to the care organisation(s) where the research takes place (or through which the research team has access to participants, their organs, tissue or data). If the research is taking place at more than one site then the CI takes on personal responsibility for the design, management and reporting of the study, and co-ordinating the Principal Investigators.

A more defined list of responsibilities can be found in appendix B; researchers wishing to be a Chief Investigator (CI) should ensure they understand the role of CI before submission of study documents.

9.4 Responsibilities - Principal Investigator (PI)

The PI and the CI may be the same person. In this case the CI must assume the PI responsibilities detailed in this policy in addition to the CI responsibilities.
The PI is responsible for the conduct of the study at Buckinghamshire Healthcare NHS Trust
Researchers who are looking to be a PI should read through Appendix C for roles and responsibilities of a PI before agreeing to act as a PI.

10 Costing and funding of research

Whilst research is to be seen as part of routine care, any research activities that are outside routine clinical care should be funded. The Research & Innovation Department does not have a central budget to fund research studies, there are nominal charitable funds where applicants can bid as part of the application to the Trust R&I committee for research review who will then assess it. Funding should be sought where possible from external bodies. If an area has earned commercial income through research activity this can be reinvested into their R&I projects.

Guidance from DH on attributing the costs of health and social care R&D (AcoRD), the guidance has the following three cost categories:

- **Research costs**
  Costs of R&D that ends when the research ends and relates to activities that are being undertaken to answer the research questions. All research activities including set up, delivering study protocol activities which are not part of routine care, closedown and archiving.
- **NHS Treatment costs**
  Patient care costs which would continue after the research study had stopped (e.g. investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the R&D study stopped; patient follow up where required as part of the clinical management of a patient which is clinical not associated with the research)
- **NHS Support costs**
  The additional patient care costs associated with the research which would end once the R&D study in question had stopped, even if patient care continued to be provided.

Commercial studies
All costs over and above the standard NHS treatment costs are to be recovered from industry.

Non-commercial studies

- **Research costs**: funded by grant funders through award of a research grant, in England some costs may be met by the DH if it is a medical research charity registered through AMRC and undertaken by existing staff employed by the NHS, NIHR. The costs for AMRC studies that can be funded by existing NHS/NIHR funded staff are: local trial management and set up, data collection needed to answer research study, regulatory preparation and compliance e.g. ethics submissions and MHRA and time taken by Chief/Principal Investigators to explain studies to colleagues e.g. patient eligibility and randomisation protocol.
- **NHS Treatment Costs:** Through normal commissioning arrangements as they are non-research costs
- **NHS Support costs:** For NIHR portfolio registered studies met through the allocation the trust receives from the NIHR. If a grant has been submitted for a study this should include support costs for taking consent, identifying patients and additional investigations.

Support required from charitable funds

BHT Charitable Trust award grants to promote high quality research, not usually exceeding £20,000, to encourage pump-priming medical research projects. Research must have the potential of a clear patient benefit, be of high quality, and with an emphasis on translational and applied health services research.

- If a study is seeking funding and wishes to make a bid to a trust charitable fund, the researcher must firstly speak to finance to get a full costing.
- Once a costing has been obtained the researcher should submit it to the R&I department along with their research review form outlining of study proposal and deliverables and any study document.
- The R&I department will take the request to the R&I committee for a decision of support, feedback of amendments needed maybe provided to the researcher to enable the committee to approve the request before it goes to the Charitable Funds committee for full sign off.
- The researcher will be requested to provide the R&I committee and the charitable funds committee with a quarterly report to enable funds to be released, failure to do so will result in funding being put on hold.
- If a study is not to progress the R&I committee will review further funding.

External support for funding

Research Capability Funding (RCF)

RCF is a made available by the National Institute for Health Research (NIHR) to help research-active NHS organisations attract, develop and retain high quality research, clinical and support staff. The scheme will only fund studies which will directly generate data for NIHR grant applications..

Charitable Trust awards

Charitable Trust awards monies to medically qualified staff, not usually exceeding £25,000, to encourage pump-priming medical research projects and to support younger medical researchers seeking to establish their academic excellence, rather than existing major grant holders.

Larger Funding applications

The grants require a lot of detail not only about the research project, but about costs, intellectual property, patient and public involvement. For advice on developing your application

The links below take you directly to the latest announcements about each of the grants listed (please note this is not an exhaustive list).

Research for Patient Benefit (RfPB)

Awards up to £350,000 for a maximum of three years: http://www.ccf.nihr.ac.uk/RfPB/

Deadlines and application forms: http://www.ccf.nihr.ac.uk/RfPB/apply/

Programme Grants for Applied Research (PGfAR)

Awards up to £2 million for a programme of research over five years
http://www.ccf.nihr.ac.uk/PGfAR

Deadlines and application forms: http://www.ccf.nihr.ac.uk/PGfAR/apply/

Programme Development Grant (PDG)

Awards up to £100,000 for one year to allow you to work towards a full programme grant: http://www.ccf.nihr.ac.uk/PGfAR/PDG/

Deadlines and application forms: http://www.ccf.nihr.ac.uk/PGfAR/PDG/

11 Amendments

If any element of a study or study delivery team changes an amendment will be required. Appendix D outlines what constitutes as a substantial amendment and non-substantial amendment. Whilst a substantial amendment is going through ethical approval recruitment should cease.

If there are any changes to the delivery of a study, e.g. increased recruitment numbers or another arm or tests added to a study, the R&I departments will require a new feasibility to ensure new deliverables are manageable to enable delivery to the study.

The R&I department will issue a green light letter for the amendment to be implemented and the study to continue. Trusts now have 35 days to disagree with an amendment, if they do not raise concerns it is assumed the amendment will be implemented.

12 Set up and delivery of studies

The DH has set metrics for the delivery of research studies. Sites have to recruit 80% of their studies to the target that was agreed with the sponsor and recruit their first patient within 70 days of being accepted as a site.

Timelines

The 70 day benchmark is comprised of two parts:

40 days from site selection (when we receive our local document pack from the Sponsor) to site confirming Capacity and Capability (approving the Study).

30 days from Organisation confirming capacity and capability to recruiting 1st Participant**.**

APPROVAL PROCESS:

Date Site Invited: Date on the Sponsor email received by the site providing the Protocol in the version to be submitted for regulatory review. This allows us to hold our local Feasibility which is a Trust requirement.

Local Trust Feasibility: Teleconference is arranged (if applicable) to confirm we can deliver what is expected of us. Representation from Sponsor/Trial Office is always requested to answer any queries or concerns that might arise. Once the team are happy to proceed and all support areas are confirmed then we can move forward.

Site Selected: Date that we receive our local document pack from the Sponsor allowing us to commence our local governance checks and once this is complete confirm our local Capacity and Capability as per guidelines set by the HRA (approve the study).
This is the start of our 70 day benchmark.

Trust Approval: This is by way of confirmation email to the Sponsor representative to confirm our Capacity and Capability.

Green light: The green light is given by the Sponsor for us to begin the study.

13 Fraud and misconduct

'Research misconduct' is defined as:
The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment, and facilitating of misconduct in research by collusion in, or concealment of, such actions by others.
It also includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings or devices used in or produced by the conduct of research.
It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive.

Bribery also falls within the scope of this policy for research and innovation activity. Bribery is the act of offering someone money or something valuable in order to persuade them to do something for you. Any allegations of bribery will be escalated to the Research and Innovation Committee for action following Trust processes.

Responsibilities
The Trust's responsibilities are:

The Trust has responsibility for maintaining high ethical standards for any medical research that is undertaken either on Trust premises or by Trust employees. The Trust is also charged to monitor all research that is on-going and to investigate promptly and fairly where episodes of misconduct have been alleged. Findings of research misconduct maybe matters for consideration under the Trust's disciplinary procedures. Research misconduct is taken seriously and any member of staff raising bona fide concerns can do so confidentially, and without fear of suffering any detriment. In line with the Public Interest Disclosure Act 1998, no employee, who makes an allegation in good faith against another employee, shall suffer a detriment.

Contracts of employment for all newly appointed staff outline the need to be aware of and comply with the UK Policy for Research in Health and Social Care 2018. Access to R&I policies and procedures regarding the research will be via the Swan Live and R&I Department.

- **Responsibilities of Researchers**
  Researchers bear the day-to-day responsibility for the conduct of research. They are responsible for ensuring that any research they undertake follows the agreed protocol, for helping care professionals to ensure that participants receive appropriate care while involved in research, for protecting the integrity and confidentiality of clinical and other records and data generated by the research (including lab-based data), and for reporting any failures in these respects, adverse drug reactions and other events or suspected misconduct through the appropriate systems.

Responsibilities of the Principal Investigator
He/She accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.

Responsibilities of Universities and other organisations employing researchers
Universities and other employers of staff engaged in research are responsible for having in place systems to detect and address fraud, and other scientific or professional misconduct by their staff.

Responsibilities of Directorates and Departments:

- Departmental leads or their deputy will be responsible for the conduct of members of their own directorates or departments in conducting research.
- All new projects must have the support of their Department prior to gaining Trust R&D approval.
- The Directorate must be satisfied that all junior members of staff undertaking research are properly and adequately supervised.
- The Directorate must be satisfied that those clinicians or scientists conducting research are capable and have an appropriate level of research expertise to enable good quality research to be undertaken.
- The Directorate must be alert to the possibility of fraud within their clinical areas.
- All researchers must communicate with their supervisors, where appropriate, on a regular basis and this must be documented. Supervisors must in turn communicate regularly

with their Research Lead, and this too must be documented and reported back to the R&I Committee.

Responsibilities for Procurement

- Standing financial instructions and limits of delegation apply in full to all activities covered by this policy. Any queries on how these policies apply, or procurement of goods and services, should be referred back to the Research Department.

Responsibilities of Research Workers

- Any person undertaking research is required to record their data in a secure and durable format. Electronic data on the Trust's network is backed up to tape by the IT Dept. It is the responsibility of individual researchers to ensure that any other electronic data is backed up.
- All documentation pertaining to the research project must be kept by the Department in a secure and durable form for the period specified on their Ethics Application.
  All researchers must ensure that the projects have received Trust approval through the R&D Governance Committee, as well as Ethical approval (or Health Research Authority Approval). The granting of approval by the Ethics Committee does not mean that the Trust would necessarily approve the study to go forward. Failure to seek Trust approval is in itself tantamount to misconduct.

Responsibilities of Medical Director

The Medical Director as Executive Lead is responsible for on behalf of the board for maintaining compliance to national legislation and frameworks for the conduct of research.

Responsibilities of Head of R&I

- The Head of R&I will be the initial investigator for allegations of research misconduct, and will raise it as appropriate with the Medical Director, who can authorise an official investigation. Head of R&I and Medical Director will take the allegations of research misconduct seriously and will investigate fairly where the allegation appears justified.

- The Head of R&I will ensure that 10% of research projects are audited on a regular basis to ensure that practices are being undertaken correctly.
- The Head of R&I will ensure that a record is kept of all research being undertaken in the Trust.
- The Head of R&I will ensure that this policy is implemented by alerting researchers to it at the start of each new research project.

Authorship

- Only those workers who have had direct involvement in the work should be put forward as authors, as agreed by the Vancouver referencing guidance. .
- Investigators should disclose to the Trust and on publication any conflict of interest, such as employment, consultancies, stock ownership or options, honoraria, patents, as described by the ICMJE(recommendations (Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals)

Procedures for the reporting of concerns

- Initial contact should be made via the person's line manager or directly to Head of R&I. The Head of R&I will then take the appropriate action, according to the existing Trust policies and procedures for raising issues of concern and investigating clinical incidents.
- Allegations will be passed on to the Medical Director and other appropriate personnel depending on the nature of the allegation, grade and profession of person under investigation. The existing Trust procedures for investigation and disciplinary action8 will be followed. Where necessary, legal advice will be sought via the Trust Medico-Legal Department. Specialist and independent advice may be sought from a medico-legal investigations company that specialises in the detection of fraud.
- The Head of R&I will ensure that the appropriate funders and/or sponsors of the research project are notified at the earliest opportunity about allegations of serious research misconduct. In the case of animal research, the Home Office will be notified as soon as a concern has been raised. The Trust is also responsible for informing sponsors of the outcome of any such investigation.
- Registered Medical Practitioners who are found to have committed serious research misconduct will be reported to the General Medical Council under its Fitness to Practice Procedures. Any other healthcare professionals will be referred to their relevant bodies.

14 Protocol violations and GCP breaches

Any incidences where a protocol has not been followed or GCP has not been adhered to must be reported to the Trust R&I department and an agreed plan of action put in place.

Where a protocol violation has occurred the researcher should follow the Incident and Reporting Management Policy and report to the sponsor and follow and steps required by the sponsor keeping the Research Operations Manager informed for the resolution and action points. All GCP breaches and protocol violations are reported to the trust R&I committee.

APPENDIX A

Researcher check list for their research proposal

If you have a Study idea

- Discuss study proposal with clinical team who will have specialist knowledge to deliver study
- Understand capacity issues within team and what support would be needed to carry out the study (involve clinical team at every step)
- Is the study research? Look at: http://www.hra-decisiontools.org.uk/research/ to see if the study would be classified as research, a small number of questions about your study will tell you if the classification is research rather than service evaluation, clinical audit or surveillance
- Does the study need ethical approval?
  Refer to http://www.hra-decisiontools.org.uk/ethics/
  A small number of questions will tell you if your study needs ethical approval (it would still need to go through HRA approval though if research).

- If you need funding the Research Design Service -South Central can help you develop a full grant application from your research proposal. http://www.rds-sc.nihr.ac.uk/
- What are your timescales? From when the trust R&I department receives a full application as we are accepted as a site, the researcher is required to recruit their first patient within 70 days. Failure to do so requires the R&I department to provide explanations to DH on a quarterly basis. Studies also have to recruit as many patients as they set out so do, failure to meet those targets requires the trust R&I department to provide explanations to DH.
- How realistic is your target of patients you are proposing and how have you reached that? Engage with clinicians and the trust clinical research delivery team for advice.
- If the trust is sponsor, it will not automatically extend a study if it is not recruiting at the rate planned especially if additional funding required from trust resources. Do you have a clear recruitment strategy?
- All research has to be published as part of ethical approval - does this pose any problems? If research is not published the Chief Investigator will not be able to carry out future research in this trust as per national guidance.
- Is this a study that could be adopted onto the National Institute of Health Research? This could secure service support through the R&I department if there is capacity. R&I department can help you explore this more.
- Does everyone involved in the study have GCP training? If not the R&I department can advise on training dates

Costing

- Finance will need to sign off costings before a study is brought to the R&I team.
- If the researcher is outside of the direct clinical care team who will be identifying patients and taking consent? This needs considering for costing. Who will the trust Principal Investigator be and what time will they be expected to spend on the study?
- Who will the Chief Investigator be and what time will they be expected to spend on the study?
- What clinical team members will be needed and how much time? Make sure role in study is appropriate to individual's grade.
- Archiving-if the trust is sponsor how will archiving fees be covered?
- What non-pay items from the trust are needed that would only be incurred through the research activity? Think about every step of the study and what is needed.
- If equipment has been purchased for the study, will medical engineering cross charge any fees for safety checks and will there be maintenance costs going forward? How will they be covered if incurred during the study?
- If the study involves a drug, MHRA will require a set-up fee and annual review fee that will need to be built in.
- If an external researcher needs access to rooms, what is the charge if there is capacity? Estates and finance will need to assess
- R&I set up for non-commercial external studies is £200

- Will there be any travel expenses for patients to participate in this study? If they are being seen for follow up that is not part of clinical appointments, what will the arrangement be to cover their travel and that of a carer?
- Who will enter research information on the electronic patient notes system?
- Do you require support from pathology, radiology and pharmacy? If yes how will anything outside of routine clinical care be funded?

  The above may be built in to a grant and if the studies are NIHR portfolio studies then service support funding can be used for additional imaging and pathologies but the costs need to be clearly identified to ring fence funding.

Patients

- Have you involved patients in the design of the study? PPI is favoured in ethics applications, we do have a Trust Patient Research Ambassador who would be willing to support research design from patient perspective if needed
- Is the study schedule within the protocol realistic with patient flow? For example if there are several follow ups over a short period of time is it reasonable that patients would be able to come in for the visit in required period?
- How will you let patients know the results of the research?
- Will this research compromise dignity of the patient? How will this be minimised?

Confidentiality

- Only direct patient care teams can access patient records unless patients have consented otherwise, access has to be approved through the ethics approval process. There are important distinctions between information sharing and disclosure and whether the purpose is unrelated to healthcare.

  These are important distinctions in that the legal and ethical requirements differ in each case.

  Definitions:

  Healthcare Purposes – These include all activities that directly contribute to the diagnosis, care and treatment of an individual and the audit/assurance of the quality of the healthcare provided. They do not include research, teaching, financial audit and management activities.

- The collection of personal data should be clearly justified in the research protocol
- Please refer to the Trust Guidance on Information Disclosure and Sharing Decisions v5.0
- Anonymised data should only be used and any staff outside of the team should not see anything other than anonymised data.

- If identifiable data is required this should be clearly addressed in the ethics application, patient information sheet and consent form if appropriate. This should be in agreement with the Trust Caldicott Guardian. This should be a last resort and it is expected by the Trust R&I department that only anonymised data is used.
- If you want to discuss a study idea with a commercial company we would need to put a confidentiality agreement in place. The Trust R&I department can facilitate this.
- Please refer to the Trust Information Governance Code of Confidentiality.

Support services required

Will you require support from pathology, radiology or pharmacy?

- If yes, speak to them at the earliest point to discuss any potential issues and get guidance to ensure they are able to support the study.
- Involve the Clinical Trials Pharmacist at every point and study meetings if the study is involving a trial drug, draw up a joint action plan and timeline.
- Provide evidence within the review form that they are supporting your study (*evidence in email form is accepted)*.
- How will any additional costs be covered?

Approval process for research applications

If the study requires the trust to act as sponsor or funder
A research review form must be completed and returned to the R&I department where it will be presented to the R&I committee members for approval, you may be invited to present your study.

Appendix B

Role and Responsibilities of a Chief Investigator (CI)

The Chief Investigator is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and well-being of participants.
- The study complies with all legal and ethical requirements.
- The research is carried out to the standards in the Research Governance Framework.
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site Files (ISF) at site.
- All researchers involved in a clinical trial of IMPs are aware of their legal duties.
- Students and new researchers have adequate supervision, support and training.

- A suitable sponsor or sponsor(s) is secured and agreements are in place detailing the responsibilities of all parties involved in the research.
- R&I approval is obtained from each care organisation involved prior to commencing the study at that care organisation.
- Where the study is a multi-centre CTIMP, ATMP trial or Medical Device Investigation sponsored by Buckinghamshire Healthcare NHS Trust, this policy and the Research Related Adverse Event Reporting Policy must be followed also at all external sites.
- External Policies and SOP can only be used after having confirmed agreement with the Buckinghamshire Healthcare NHS Trust R&I Department.
- For all blinded studies, an unblinding procedure must be in place prior to the first participant dosing/intervention; non-compliance will be treated as a breach of GCP.
- The protocol is submitted for ethics review, the study does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion.
- Unless urgent safety measures are necessary1, the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust R&I department and by the sponsor(s).
- Investigators in clinical trials involving medicines have a duty to report serious adverse events immediately. In addition, the Trust's Incident reporting requirements apply for immediate reporting of serious incidents. For the definition of "serious" outside the research context, please use the guidance available in the Incident Reporting, Analysis, Investigation and Management Policy.
- For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (the Medicines and Healthcare products Regulatory Agency Urgent safety measures (within 24h), premature stopping of a study (within 7 days) must be notified to Sponsor and hosting R&I early termination of a study must be notified to Sponsor and hosting R&I within 7 days and within 15 days to REC and where applicable within 15 days to Competent Authority (MHRA)
- Substantive changes to the protocol or proposal are submitted for ethical review, for the sponsor(s) agreement and for the Trust R&I approval. With the exception of urgent safety measures these amendments are implemented only when approved.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research.
- For clinical trials involving medicines, the research follows any conditions imposed by the licensing authority. All CTIMPs (Clinical Trials of an Investigational Medicinal Product) and Medical Device Investigations must normally have a Data Safety Monitoring Committee, or similar, which is independent of the actual research team.
- CTIMPs must arrange their drug/supplement/IMP supply through Buckinghamshire Healthcare NHS Trust Pharmacy unless agreed otherwise.
- Procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage.

- Arrangements are in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising.
- Reports on the progress and outcomes of the work required by Buckinghamshire Healthcare NHS Trust R&I, the sponsor(s), funders, MHRA or others with a legitimate interest are produced on time and to an acceptable standard.
- Persistent late submission of SAE (3 times or more) and Annual Safety Reports (for CTIMPs) will be escalated to Head of R&I, and where applicable to the Associate Medical Directors of R&I and the Medical Director and may lead to a suspension of the study, additional conditions for future studies or non-acceptance of a researcher to act as Chief/Principal Investigator.
- The findings from the work are open to critical review through the accepted scientific and professional channels.
- All breaches of GCP (e.g. deviation from the protocol, adding new/omitting tests/interventions, delaying dates for visits, insufficiently trained staff working on procedures) must be recorded in the Investigator Site File. Also, for clinical trials involving medicines, to the Competent Authority (within the UK MHRA).
- Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal Products All serious breaches of GCP or persistent reaches of GCP (after 3 occurrences) must be expedited to Sponsor and hosting R&I Department.
- They accept a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.
- Where Buckinghamshire Healthcare NHS Trust is the Sponsor, SAE reports from other sites must also be submitted to Buckinghamshire Healthcare NHS Trust R&I for appropriate action.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible.
- Study documents and source data must be retained in accordance with the Buckinghamshire Healthcare NHS Trust Health Records Retention/Destruction Policy.
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.
- Where the CI delegates responsibilities to members of the research team this must be clearly documented in a delegation log or similar and kept in the Trial Master File or similar for each study. The CI remains accountable for the actions of his/her research team.

Appendix C

Roles and Responsibilities of a Principal Investigator (PI)

- The research team give priority at all times to the dignity, rights, safety and well-being of participants.
- The study complies with all legal and ethical requirements.
- The research is carried out to the standards in the Research Governance Framework.

- Each member of the local research team is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented and retained in the Investigator Site File (ISF).
- All local researchers involved in a clinical trial of IMPs are aware of their legal duties.
- Students and new researchers have adequate supervision, support and training.
- Buckinghamshire Healthcare NHS Trust R&I approval is obtained prior to commencing the study.
- The protocol is submitted for local ethics review (Site Specific Assessment), and that the study does not start without a favourable SSA opinion.
- For each participant the research study involvement must be documented into the patient medical notes/hospital records, where applicable e-records (detailed guidance available from R&I website)
- Any event falling under the definition of Trust incident must be reported according to the Buckinghamshire Healthcare NHS Trust Incident Reporting and Management Policy, using the specific forms available from wards and non-clinical areas.
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust R&I department and by the sponsor.
- Investigators in clinical trials involving medicines have a duty to report serious adverse events immediately and where applicable, also report serious incidents immediately under the Incident Reporting, Analysis, Investigation and Management Policy.
- Urgent safety measures must be notified to Sponsor and hosting R&I (notify within 24h, submit substantial amendment to REC and where applicable to Competent Authority (MHRA) within 3 days),early termination of a study must be notified to Sponsor and hosting R&I within 7 days and within 15 days to REC and where applicable within 15 days to Competent Authority (MHRA))
- Substantive changes to the protocol or proposal are submitted for ethical review, for the sponsor(s) agreement and for the Trust R&I approval. With the exception of urgent safety measures these amendments are implemented only when approved.
- When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research.
- For clinical trials involving medicines, the research follows any conditions imposed by the licensing authority.
- All CTIMPs (Clinical Trials of an Investigational Medicinal Product) and Medical Device Investigations should normally have a Data Safety Monitoring Committee which is independent of the actual research team.
- CTIMPs must arrange their drug/supplement/IMP supply through Buckinghamshire Healthcare NHS Trust Pharmacy unless agreed otherwise.
- Procedures are in place to ensure collection of high quality, accurate data and for the integrity and confidentiality of data during processing and storage.
- Arrangements are in place for the management of financial and other resources provided for the study.

- Arrangements are in place for the management of any intellectual property arising from the research.
- Reports on the progress and outcomes of the work required by the CI, Buckinghamshire Healthcare NHS Trust R&I, the sponsor(s), funders, MHRA or others with a legitimate interest are produced on time and to an acceptable standard.
- Where Buckinghamshire Healthcare NHS Trust is the Sponsor, SAE reports from other sites must also be submitted to Buckinghamshire Healthcare NHS Trust R&I for appropriate action.
- All breaches of GCP (e.g. deviation from the protocol, adding new/omitting tests/interventions, delaying dates for visits, insufficiently trained staff working on procedures) must be recorded in the Investigator Site File.
- All serious breaches of GCP must be expedited to Sponsor and hosting R&I Department within 24h. The same escalated reporting applies for or persistent breaches of GCP (i.e. 3 occurrences of the same type of event are defined as “serious”).
- The findings from the work are open to critical review through the accepted scientific and professional channels. Also, for clinical trials involving medicines, to the licensing authority.
- Also, for clinical trials involving medicines, procedures to comply with legal requirements concerning Good Clinical Practice during the trial, and Good Manufacturing Practice in manufacturing investigational medicinal products
- For clinical trials involving medicines, it is a legal requirement to follow the protocol approved by the licensing authority (the Medicines and Healthcare products Regulatory Agency).

APPENDIX D

Examples of amendment classification

Examples of substantial amendments:

- changes to the design or methodology of the study, or to background information affecting its scientific value;
- changes to the procedures undertaken by participants;
- any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
- a change of sponsor(s) or sponsor’s legal representative;
- appointment of a new chief investigator
- a change to the insurance or indemnity arrangements for the study;
- inclusion of a new trial site (not listed in the original application) in a CTIMP;
- appointment of a new principal investigator at a trial site in a CTIMP;
- temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- a change to the definition of the end of the study;
- any other significant change to the protocol or the terms of the REC application.

Examples of non-substantial amendments:

- minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
- updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial);
- changes to the chief investigator's research team
- changes to the research team at particular trial sites (other than appointment of a new principal investigator in a CTIMP);
- changes in funding arrangements;
- changes in the documentation used by the research team for recording study data;
- changes in the logistical arrangements for storing or transporting samples;
- inclusion of new sites and investigators in studies other than CTIMPs;
- extension of the study beyond the period specified in the application form.

Changes to contact details for the sponsor (or the sponsor's representative), chief investigator or other study staff are minor amendments but should be notified to the REC that approved your original application.