BU RDS SOP 004 V1

Title: Review of Study Protocol and Associated Documents	
Effective Date: 19/11/2019	Review Date: 19/11/2021
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Approver: University Research Ethics Committee	

1. Scope

The purpose of this Standard Operating Procedure (SOP) is to outline the requirements and processes expected from researchers conducting clinical research, with regard to their study documents, before applying for their external study approvals.

2. Responsibilities

The *Chief Investigator*[1] *(CI)* or the *Researcher* is responsible for seeking the review of their study protocol and associated documents by the *Clinical Governance Advisor*, whose role is to advise and modify content, on behalf of the Sponsor*, in accordance with best practice, Good Clinical Practice (GCP) guidelines and appropriate legislation.

*In the case of research carried out by the institution's staff or students, Bournemouth University is best placed to be the research Sponsor – this complies the UK Policy Framework for Health and Social Care Research. The Sponsor takes on the responsibility for the initiation, management and financing (or arranging the financing) of a research project.

3. Procedure

3.1 The CI/Researcher should forward the study protocol, Participant Information Sheet (PIS) and Informed Consent Form (ICF) to the Clinical Governance Advisor in order to review the content and to minimise the feedback received from the Health Research Authority (HRA)[2] and NHS Research Ethics Committee (REC) following their reviews of the study and associated documentation.

3.2 The CI/Researcher may wish to forward these documents once request for sponsorship has been granted, or beforehand, but should request sponsorship for their study in all cases, and prior to submission of the IRAS (Integrated Research Application System) form.

[1] The Chief Investigator (CI) is the overall lead researcher for a research product, however in the case of student research or postgraduate research (where the postgraduate researcher has no appropriate clinical background), the CI is expected to be the lead supervisor.
[2] Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

3.3 The Clinical Governance Advisor will ensure that the PIS meets the expectations of the BU Research Ethics Code of Practice, in consulting the template PIS document and the HRA guidance on General Data Protection Regulations (GDPR) and 2018 Data Protection Act compliance.

3.4 The Clinical Governance Advisor will also ensure that the Informed Consent Form meets the expectations of GCP and is an ethically sound document in ensuring fully informed consent is obtained from the research participants.

3.5 The study protocol will likewise be reviewed in order to ensure that it complies with GCP and references the correct legislation and frameworks, whilst also ensuring that procedures such as archiving, safety reporting, and obtaining informed consent are set out adequately, and in accordance with RDS SOPs.

3.6 Once the study documents have been reviewed and are fully compliant, they should then be filed by the researcher, with the assistance of the Clinical Governance Advisor, within the applicable I:Drive folders and in the Trial Master File (TMF), and uploaded to the checklist on IRAS, ready for submission with the completed application.

3.7 The study protocol and associated documents should be reviewed by the researcher and their team on an ongoing basis, and any changes submitted as an amendment, in accordance with BU RDS SOP 002. Superseded versions of the documents should be filed within the applicable I:Drive folders and in the Trial Master File (TMF).

4. Abbreviations and definitions

GCP	Good Clinical Practice
GDPR	General Data Protection Regulations
HRA	Health Research Authority
ICF	Informed Consent Form
IRAS	Integrated Research Application System
PIS	Participant Information Sheet
REC	Research Ethics Committee
TMF	Trial Master File

5. Related documentation and references

BU RDS SOP 002 - Amendments

Integrated Research Application System – www.myresearchproject.org.uk

UK Policy Framework for Health and Social Care Research. (2017). Health Research Authority