NHS Grampian

1495 UNIVERSITY OF ABERDEEN

SOP-QA-3 V5

Title: Protocol guidance for high risk trials and CTIMPs	
Effective Date: 6-1-22	Review Date: 6-1-25
Author: Clinical Research Operational Group	QA Approval: Richard Cowie, QA Manager
Approver: Prof Maggie Cruickshank, R&D Director	Approver: Prof Siladitya Bhattacharya, Head of School

Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse and correction of associated documents	2-10-15
2	Reformatted and clarification of version numbering at 3.2 Inclusion of laboratory if laboratory analysis is included in protocol 3.4	1-4-17
3	Clarification of version date at 3.3	26-1-18
4	Change of author, clarification of signatures required in protocol at 3.4 Reference to protocol being publically available at 3.9	5-11-18
5	Clarification of using HRA template for CTIMPs only at 3.1 Clarification of version control for drafts at 3.2 Reference to IRAS and IRSCTN numbers at 3.3 Clarification of CTIMP at 3.4 Reference to publically available database at 3.9	6-1-22

1. Scope

1.1 This SOP applies to all research and Sponsor staff participating in, or supporting high risk trials, Clinical Trials of Investigational Medicinal Product (CTIMPs) and Medical Device Clinical Investigations (MDCIs) sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

1.2 Interventional and non-interventional research projects must have a protocol prepared which is compliant with the principles of Good Clinical Practice (GCP).

2. Responsibilities

Chief Investigator (CI)	Designing and writing the protocol compliant with the principles of GCP and relevant regulations, appropriate to the research.
Sponsor	Ensure any amendments to the protocol are managed correctly.
Research Monitors	Monitoring researchers against the current protocol.

3. Procedure

CTIMPs, MDCIs and high risk research protocols

3.1 The CI, or delegate, must use the Health Research Authority (HRA) Protocol Template (for CTIMPs), available from the HRA website, unless previously discussed and agreed with the Sponsor.

3.2 All protocols shall be version controlled; eg 'Draft 1',' Draft 2' 'Draft 3'etc before being finalised and then recorded as 'V1', 'V2', 'V3' etc. Versions shall **never** be 0.1, 1.1, 1.2, 1.3 etc.

3.3 All pages shall be numbered and include the EudraCT number (if appropriate), version number, version date and the study title (or acronym). IRAS and ISRCTN numbers can also be included when available.

3.4 The Approval Page shall be signed and dated by the Sponsor representative, CI, the individual responsible for statistical review and any other appropriate trial staff **prior** to distribution. If a trial is a CTIMP, the Clinical Trial Pharmacist must also sign the protocol (please note that the HRA template does not include the Clinical trial Pharmacist and this should be added when required). If laboratory analysis is included in the protocol, the CI must ensure the appropriate laboratory representative (eg Laboratory Manager) has been involved prior to finalising the protocol. By signing the protocol the individuals concerned are making a formal agreement to adhere to it at all times.

3.5 Where appropriate, the protocol may refer to information listed in other documents eg the Summary of Product Characteristics (SPC), Investigator Brochure (IB), Trial Steering Committee (TSC) or Data Monitoring Committee (DMC) remit and membership.

3.6 If separate site specific information relating to the protocol is required (eg local handling procedures, storage etc) this shall be provided as an appendix to the protocol.

3.7 All planned amendments to the protocol must be submitted in the first instance to the Research Governance Team.

3.8 All fully approved amended protocols are subject to the same processes listed above.

3.9 In the interests of transparency, University of Aberdeen and NHS-Grampian require that protocols are registered on a publicly accessible database (*https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/*). This shall create an early scientific record of methodology, help with publication and potentially reduce duplication of some research effort.

4. Abbreviations and definitions

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
DMC	Data Monitoring Committee
EudraCT	European Union Drug Regulating Authorities Clinical Trials
GCP	Good Clinical Practice
HRA	Health Research Authority
IB	Investigator Brochure
MDCI	Medical Device Clinical Investigation
SPC (or SmPC)	Summary of Product Characteristics
TSC	Trial Steering Committee

5. Related documentation and references

National Research Ethics Service/Health Research Authority website.