Gloucestershire Hospitals
NHS Foundation Trust

Guidelines 02: Using the non-CTIMP template protocol

GHNHSFT wishes to acknowledge University Hospitals Bristol and Western NHS Foundation Trust who gave permission to use their templates in the development of SOPS and guidelines. This template is based on the HRA standard template guidance, the HRA CTIMP Protocol Development Tool order of content and has been adapted by UHBW.

The non-CTIMPs protocol template can be used for GHNHSFT sponsored studies not subject to the relevant Medicines and Medical Devices regulations. These studies should use, along with qualitative research projects the HRA protocol templates and guidance. https://www.hra.nhs.uk/planning-and-improving-research/

The non-CTIMP template is not intended to be used for Clinical Trials of Investigational Medicinal Products (CTIMPs) or Device trials. An algorithm can be used to help you decide whether or not your study falls under the Clinical Trials Regulations: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

For further advice please contact the Research & Development team via ghn-tr.glos.rdsu@nhs.net

General Advice

Please use the accompanying protocol template, which contains section headings and standard wordings. The guidance below should be referred to when completing this. Please also read all relevant Standard Operating Procedures and Guidance, available on via this link Research at our hospitals (gloshospitals.nhs.uk)

When writing your protocol, we recommend that you follow the order of the section headings provided in the Table of Contents template. However, they can be adapted or marked as not applicable as required.

Standard protocol wording will be given in the template and must be included in the protocol – **please do not delete the standard wording.**

General advice for writing your protocol:

1. Be concise to help other readers understand your project. Consider using flow charts/tables and bullet points wherever possible.
2. Be consistent with terminology.
3. All abbreviations should be written in full when used for the first time and added to the Abbreviations List included in the protocol.
4. Please ensure protocol and accompanying documents are version controlled.

Be aware that changes to the protocol during the Sponsorship process may impact on your other study documents. When finalising your protocol ready for REC/HRA submission, please ensure that the contents of the protocol are consistent with the IRAS Form, Patient Information Sheet, Consent Form etc.

Please include other logos as appropriate e.g. Funders, collaborators, study specific logo etc. Ensure that agreement to use the logos has been obtained from the relevant organisation.

TITLE PAGE

Full/long title of study	Should make clear what the study is about and enable easy identification of relevance from literature searches
Short title/study acronym	Maximum 70 characters to comply with IRAS form. Should make clear what the study is about in plain English. Any acronyms should be explained in the full title.
Protocol version number /date	
IRAS Number	To obtain this number, register your project on IRAS via https://www.myresearchproject.org.uk/
ISRCTN/Clinicaltrials.gov number	It is a good practice requirement that all research is registered on a public research register. The R&D

	department can advise the appropriate register, if required.
Sponsor	Gloucestershire Hospitals NHS Foundation Trust
Sponsor reference number	This will be allocated by R&D at Sponsorship
Funder name and reference number (if applicable)	State name of funder and their reference
Chief Investigator	Chief Investigator Name, Job title, Employer, Employer's address, e-mail address
Sponsor Representative	Research and Development Gloucestershire Hospitals NHS Foundation Trust Leadon House, Gloucestershire Royal Hospital, Great Western Road Gloucester, GL1 3NN ghn-tr.glos.rdsu@nhs.net

PROTOCOL VERSION HISTORY

Amendment No. State whether Substantial Amendment (SA) or Non-substantial amendment (NSA)	**Version No.**	**Version Date**	**Brief summary of change(s) and reason for update.**
Initial Application		[Insert date]	

GHNHSFT as Sponsor will advise on the type of amendment upon review