Standard Operating Procedure (SOP)

Protocol Design

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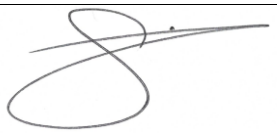
Author:	Georgia Bullock	**Title:**	Research Development and Governance Manager
Approved by:	Subhir Bedi	**Date:**	19/07/2021
Signature of Authorisor:			

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The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version.
They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Lucy H H Parker
V 2.0	Updated Logo and Trust Name – reference to SPIRIT guidelines & inclusion of randomisation/code-breaking	Fran Mautadin
V3.0	Removal of recital of ICH GCP Chapter 6. Reference to early project delivery planning to aid accurate grant costings	Debs Rolfe
V4.0	Reflecting changes in JREO to JRES and job titles and minor changes to delegations of responsibilities. Also, insertion of Associated JRES documents	Ali Alshukry / Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions	JRESDOC0001 Interventional Study Protocol Template JRESDOC0002 Non-Interventional Study Protocol Template	

Contents

1. Background

A research protocol is the legal document that outlines the procedure to answer the aims and objectives for the study. It defines every aspect of the study, including the background and rationale for the study and how the study should be conducted. It includes details of the eligible participants, all tests and procedures, any medications and dosages and timelines for the study. The protocol is an essential, version-controlled document for all clinical research studies/trials.

The protocol must be carefully designed to safeguard the health and safety of the participants, as well as to answer the specific research questions. Whilst enrolled in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of the treatment.

2. Joint Research and Enterprise Service (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

This SOP describes the development and design of a research protocol to meet the requirements of Good Clinical Practice (GCP), the current Clinical Trials Regulations and the UK Policy Framework for Health and Social Care Research.

4. Definitions

For general research-related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

For CTIMPs: the Chief Investigator (CI) is responsible for designing and developing the protocol prior to submitting it to the Sponsor (JRES) as part of the sponsorship review. It is their responsibility to ensure that the protocol and any other associated documentation complies with the relevant regulatory and ethical requirements, as well as St George's policies.

As per ICH GCP, the Sponsor takes responsibility for the initiation, management, and/or financing of a clinical trial. It is the Sponsor's responsibility to review the research proposal and assess the ethical aspects of the trial, ensuring that the proposed research respects the dignity, rights, safety and wellbeing of participants. They are also responsible for the legal aspects of the trial and must ensure that there are sufficient funds available to cover any claim for damages arising out of the conduct of the trial, eg: based on the poor science in the design of the protocol or failure of any intervention.

The CI and Sponsor are both responsible for ensuring that the research is conducted in compliance with the protocol, ICH GCP, and the applicable regulatory requirements. The protocol must be complied with at all times, unless action has to be taken for an Urgent Safety Measure (a procedure not described in the protocol that is put in place to protect study participants from an immediate hazard to their health and safety).

For all other research: the researcher is responsible for designing and developing the protocol and ensuring it complies with all relevant requirements prior to submitting for ethical review.

It is the responsibility of the JRES to ensure that the available protocol templates adhere to ICH GCP and incorporate the essence of both the SPIRIT Statement 2013 and guidance from the Health Research Authority (HRA).

6. Procedure

The JRES has produced 2 protocol templates to support the most common research studies at St George's:

1. Interventional study protocol template suitable for:
    - Clinical trial of an investigational medicinal product
    - Clinical investigation or other study of a medical device
    - Combined trial of an investigational medicinal product and an investigational medical device

- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

2. Non- Interventional study protocol template suitable for:
    - Basic Science study involving procedures with human participants
    - Study administering questionnaires/interviews for qualitative or mixed quantitative/qualitative analysis
    - Study involving qualitative methods only
    - Study limited to working with human tissue samples and/or analysis of data
    - Study limited to working with data.

The templates can be found on the JRES pages on the SGUL/SGHFT websites or can be requested directly from the JRES. The JRES can also assist with the selection of the most appropriate protocol template for an Investigator's project.

It is expected that Investigators will utilise the JRES templates for all trials/studies that are to be considered for sponsorship by St George's.

The contents and information contained in a protocol should be in accordance with ICH GCP. A protocol must also take into account the relevant laws and regulations of the countries where the study sites are located.

Throughout the JRES protocol templates, there are colour-coded instructions and notes to assist with the completion of each section. Sections may be re-arranged if necessary but they should not be deleted where they not applicable ('Not applicable' should be entered as the text in these sections).

It is recommended that wherever possible the study delivery is considered at the earliest of stages – this may impact on study costings required for grant/funding applications and will be required to facilitate accurate attribution of costs.

7. References

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/

SPIRIT:
http://www.spirit-statement.org/

Protocol Development:
http://www.ct-toolkit.ac.uk/routemap/protocol-development/

JRES Templates:
https://www.stgeorges.nhs.uk/education-and-research/research/

https://www.sgul.ac.uk/about/our-professional-services/joint-research-and-enterprise-services/clinical-research-delivery

8. Appendices

None associated with this SOP.