St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)
Publicly Accessible Databases

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Signature of Authorisor			

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They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	New SOP	Lucy H H Parker
V2.0	Trust logo and Trust name updated. AllTrials campaign & amended to include ALL clinical trials to be registered on a public database.	Debs Rolfe

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1. Background

In September 2004, the International Committee of Medical Journal Editors (ICMJE) published an editorial aimed at promoting registration of all clinical trials on a publicly accessible database. It laid out their requirement that member journals would only consider a trial for publication if it had been registered on a publicly accessible database before the enrolment of the first patient.

This requirement applied to randomised, controlled trials that started recruiting on or after July 1, 2005. Any current and on-going trials that were not registered at inception would only be considered for publication if they were registered before September 13, 2005.

In July 2015 both St George's University of London and St George's University Hospitals NHS Foundation Trust agreed to support the 'AllTrials Campaign'. The AllTrials campaign calls for all past and present clinical trials to be registered and their results reported. St George's have stated that all trials active in or after 2013 of which St George's is named as Sponsor will require registration records to be completed, updated regularly and for result summaries to be uploaded.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

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

3. Scope

This SOP outlines the process of obtaining an account for a publicly accessible database and registering a study where it is proposed that SGUL or SGHT act as Sponsor.

4. Definitions

4.1 Clinical Trial

The ICMJE, in June 2007 adopted the WHO's definition of a clinical trial as

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"Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

The ICMJE defines health-related interventions to "include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes).

Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration."

St George's JREO recommends Investigators to err on the side of registration for trials where it is not clear whether a study should be registered or not. The author(s) of an unregistered trial will have to convince the editor of their reasons for not registering trials

4.2 Recommended Registry

The ICMJE editorial sets out 5 criteria for an acceptable trial registry. These were defined as:

1. The registry must be accessible to the public at no charge.
2. It must be open to all prospective registrants
3. Managed by a not-for-profit organisation.
4. There must be a mechanism to ensure the validity of the registration data
5. The registry should be electronically searchable.

Currently, the following registries meet the criteria and are recommended by the JREO:

- www.clinicaltrials.gov (This is a free registry)
- www.ISRCTN.org
- https://eudract.ema.europa.eu/ (new registrations after June 20, 2011)

Therefore, this SOP will describe how to create a study record onto the Clinicaltrials.gov database. The responsibility for deciding which registry to use and to create the record, lies with the Chief Investigator.

4.3. Minimum Data Set

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A meeting of the WHO registration advisory group identified a minimal registration data set of 20 items, which the ICMJE has adopted as its requirement for a minimum data set (see appendix one for the full list)

In order for a trial to be considered for publication, all 20 fields in the WHO minimal data set must be completed. A data set will be deemed inadequate if it is missing fields

The JREO have included within their research protocol templates a 'Study Synopsis' with fields that correspond to the information required for the minimum dataset which may assist the Chief Investigators.

4.4 clinicaltrials.gov

Clinicaltrials.gov is a free, publicly accessible database. It will accept any trial that meets the ICMJE definition of a clinical trial, regardless of where the trial is to take place.

4.4.1 Administrator

The Joint Research and Enterprise Office (JREO) is St George's designated Administrator for registering trials on clinicaltrials.gov.

As Administrator, the JREO will create a user account for the Investigator upon request, giving them access to register trials on the system and release records for public view once they have been completed.

Please note:

- The study must be registered under the Sponsor's account. If the Sponsor is St George's, the JREO can assist with the registration of trials on clinicaltrials.gov
- If the Sponsor is another organisation, the Investigator will need to liaise with them in order to register the study.

4.4.2 Investigators – Users

Once a user account has been created, the Investigator will be able to enter information about clinical trials online at register.clinicaltrials.gov

Information must be correct and easily understood by members of the public. Importantly, the Investigator is required to update each clinical trial record **every 6 months**.

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5. Responsibilities

This SOP is to be followed by the JREO governance section and the Chief Investigator (CI) of the proposed study.

It is the responsibility of the Head of Research Governance (HRG) of the JREO to ensure that this SOP is updated by the review date or as necessary.

It is the responsibility of the CI to ensure that they register their study on an acceptable database before the first participant is enrolled into the study.
An exception to this is made where a study has been active since 2013 and is not yet registered. Retrospective registration is required to be completed by the CI.

6. Procedure – Direct Instructions to the Investigator

These procedures are simplified based on the information provided by clinicaltrials.gov. For specific information and guidance, please use the help guide once you are in clinicaltrials.gov.

6.1 Ask the JREO to Create a User Account

- To obtain a user account, you need to email the Joint Research Enterprise Office requesting access - please contact your assigned Research Governance Officer
- The JREO will create your account. It will log your:

Login Name: [Surname] [Initial]
Full User Name: [First name] [Surname]
Password: you will need to change this when you first access the site
Email address: your standard St Georges email address (notifications from clinicaltrials. gov will be sent to this account)

- Your log in details will be sent to you automatically via email.

6.2 Log In/Out

- Go to register.clinicaltrials.gov and
- Complete the three fields on the Login screen (as provided to you in the automatic email notification after your account was created):

Organisation: organisation login name
Username: user login name (It will be your Surname followed by the first letter of your first

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name.
Password: (case-sensitive)

- To log out, select [Logout] from the Main Menu screen.

6.3 Create a Record

- A record may be created at a single session or created and saved for completion later. To create a record during a single session:
- Follow [Create] from the Main Menu screen.
- Enter a Unique Protocol ID and Brief Title for your record on the Create New Protocol Record screen.
- Follow [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
- After following [Continue] on the final data entry screen (Links), use [OK] on the Study Completed screen.
- To create a record and save for completion later, use [Quit] to stop data entry after step b (above), or any other successive screen. Then use [Save Protocol Record] to keep your data. The record will be saved for later.

6.4 Data Entry Tips

- Brief Summary: Use language that is easily understood by a lay person.
- Paragraph Separation: Leave a blank line between paragraphs (press enter twice).
- Create Lists: Keep each item on a separate line (press return after entering text for each line); bullet items by starting each line with two spaces, a hyphen, and a space before entering the text; and press return after text for each item.
- Follow the link on any data entry field name to obtain a description of the field.
- Progress in creating the trial record is recorded as follows:

Description	Record Status
User is creating (or modifying) the record	In Progress
User has finished - record is ready for review	Completed
Administrator has reviewed record and has made any	Approved

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necessary changes	
Administrator has released the record to clinicaltrials.gov	Released

It is important that once you are ready for the record to be made live on the system that you change the status to "completed". This field is in relation to the record that you are creating, not the actual study status. If you leave it as in progress, the record cannot be released by the JREO.

6.5 Submit a Record to the JREO - 'Administrator'

- Follow [Modify] from the Main Menu.
- Follow [Edit] next to the record you wish to submit.

Look for any error messages on the Edit Protocol Record screen:

ERROR messages indicate serious problems that need to be addressed.

ALERT messages indicate problems that need to be addressed.

NOTE messages indicate potential problems that should be reviewed and corrected as needed.

- After data entry for a record has been completed, enter any comments about the record for the JREO (as the 'Administrator') and follow [Complete] in the Record Status area of the screen. We will then be notified that the record is complete.
- We will review, approve and release the record to clinicaltrials.gov. If there are any errors, we will email you to correct the error. We will not release the record for public viewing until these changes have been made.
- Clinicaltrials.gov administrators will review the record 'released' by the JREO administrator and will either return the record with comments for action by the CI or confirm record will be available for public viewing within 2-3 days. The email confirming public viewing will also contain your record reference number. The record will need to be added to your protocol and the JREO RGO will need to update the ReDA database.
- If the Clinicaltrials.gov administrators return the record with comments the CI will need to log back into the system to address the comments and adjust the record and resubmit to the JREO Administrator for review.

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6.6.Modify Record

- Use [Modify] on the Main Menu.
- Use [Edit] next to the record to be modified on the Select Protocol Record - Edit screen.
- Use on the corresponding [Edit] for that field.
- Use [OK] to save the changes and return to Edit Protocol Record.
- Update Verification Date.

6.7 View Record

- Use [View] on the Main Menu.
- Use [View] next to record to be displayed on the Select Protocol Record - View screen.
- View Protocol Record is read-only.

6.8 Preview Record as it Appears on clinicaltrials.gov

- Follow [Modify] on the Main Menu.
- Follow [Edit] next to the record to be previewed.
- Follow [Preview] to see the record displayed similar to how it appears on clinicaltrials.gov.
- Follow [Continue] to return to the Edit Protocol Record screen.

6.9 Delete your Record

- Follow [Modify] on the Main Menu.
- Follow [Edit] next to the record to be deleted.
- Follow [Delete].
- Follow [OK] on the Delete Protocol screen or use [Cancel] to return to the Edit Protocol Record screen without deleting the record.

A deleted record can be recovered via the [Undelete] option on the Main Menu.

6.10 Change Your Password

- Use [Change password] on the Main Menu.
- Enter:

  Old password

  New password

  New password again for verification

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- Follow [Change Password] to save the new password.

Please contact the JREO if you forget your either your username, password and we can reset your account for you.

7. References

International Committee of Medical Journal Editors (ICMJE) WWW.ICMJE.ORG/ WHO www.who.int/en/

8. Appendix

8.1 WHO/ICMJE Minimum Data set

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Appendix 8.1. WHO/ICMJE Minimal Registration Data Set*

Item	Comment
1. Unique trial number	The unique trial number will be established be the primary registering entity (the registry).
2. Trial registration date	The date of registration will be established by the primary registering entity.
3. Secondary IDs	May be assigned by sponsors or other interested parties (there may be none).
4. Funding source(s)	Name of the organization(s) that provided funding for the study.
5. Primary sponsor	The main entity responsible for performing the research.
6. Secondary sponsor(s)	The secondary entities, if any, responsible for performing the research.
7. Responsible contact person	Public contact person for the trial, for patients interested in participating.
8. Research contact person	Person to contact for scientific inquiries about the trial.
9. Title of the study	Brief title chosen by the research group (can be omitted if the researchers wish).
10. Official scientific title of the study	This title must include the name of the intervention, the condition being studied, and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure).
11. Research ethics review	Has the study at the time of registration received appropriate ethics committee approval (yes/no)? (It is assumed that all registered trials will be approved by an ethics board before commencing.)
12. Condition	The medical condition being studied (e.g., asthma, myocardial infarction, depression).
13. Intervention(s)	A description of the study and comparison/control intervention(s) (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified.
14. Key inclusion and exclusion criteria	Key patient characteristics that determine eligibility for participation in the study.
15. Study type	Database should provide drop-down lists for selection. This would include choices for randomized vs. non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment, (e.g., parallel, crossover, factorial).
16. Anticipated trial start date	Estimated enrollment date of the first participant.

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17. Target sample size	The total number of subjects the investigators plan to enroll before closing the trial to new participants.
18. Recruitment status	Is this information available (yes/no) (If yes, link to information).
19. Primary outcome	The primary outcome that the study was designed to evaluate Description should include the time at which the outcome is measured (e.g., blood pressure at 12 months)
20. Key secondary outcomes	The secondary outcomes specified in the protocol. Description should include time of measurement (e.g., creatinine clearance at 6 months).

*The data fields were specified at a meeting convened by the WHO in April 2004; the explanatory comments are largely from the ICMJE.

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