STANDARD OPERATING PROCEDURE 28

Registration of Clinical Research Studies

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<table>
<thead>
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<th>Reason for change:</th>
</tr>
</thead>
<tbody>
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<td>Biennial review: Change to new format. Minor amends to text. Web links updated. Addition of requirement to keep registration data up to date.</td>
</tr>
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</tr>
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</tr>
<tr>
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</tr>
</tbody>
</table>
Registration of Clinical Research Studies

1. Purpose
This Standard Operating Procedure (SOP) describes the requirement for registering a clinical research study on a publically accessible database.

2. Background
The Declaration of Helsinki of the World Medical Association states: “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject”. It is also government policy in the UK to promote registration of clinical trials.

The International Standard Registered Clinical/soCial sTudy Number (ISRCTN) register was founded in response to calls for the registration of trials as a condition of publication in a journal, and also in response to the recognition that the results of many trials remain unpublished and, without registration, remain hidden from the scientific record. It is the main database used by UK researchers on which non-Investigational Medicinal Product (IMP) studies are registered.

The ISRCTN is a simple numeric system for the unique identification of Randomised Controlled Trials (RCTs) worldwide. The scheme was formally launched in May 2003 as ‘the first online service that provides unique numbers to RCTs in all areas of healthcare and from all countries around the world’. When the registry was started in the early 2000s, the acronym stood for International Standard Randomised Controlled Trial Number because the scope of the Registry was RCTs. Over the years the scope has been expanded and the acronym now means International Standard Registered Clinical/soCial sTudy Number. However the preferred name is simply ISRCTN and not the spelt out version.

All RCTs or studies designed to assess the efficacy of healthcare interventions (both observational and interventional) are eligible to be registered with the ISRCTN scheme. Since September 2013, registration of clinical trials in a publicly accessible database is a condition of continuing favourable ethical approval for all trials.

Registration of a clinical trial on a publically accessible database is not a legal requirement, but the trial must be registered in order for written articles to be included in journals and publications belonging to the International Committee of Medical Journal Editors (ICMJE) group.

The ICMJE does not advocate one particular registry, but its member journals will require authors to record their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organisation. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable.

Use of the ISRCTN register fulfils all the criteria for the ICMJE.

Other acceptable registries for ICMJE are listed here: http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/
Clinical Trials of Investigational Medicinal Products (CTIMPs) must be registered on the EU Clinical Trials Register (European Union Drug Regulating Authorities Clinical Trials (EudraCT) database) as a requirement of their approval by the regulatory authorities. Further details of how to obtain a EudraCT number can be found in SOP 5 ‘Regulatory Approvals and Communication’.

Alternatively, clinical research may be registered at [http://www.clinicaltrials.gov](http://www.clinicaltrials.gov) (a register of studies in the United States and around the world).

For other types of research, registration is also encouraged wherever possible. It may be possible to register a study through an NHS organisation or a register run by a medical research charity, or publish the study protocol through an open access publisher.

In general, registration is not expected for projects undertaken entirely for educational purposes below doctoral level.

3. **Procedure**

3.1 **Who?**
Any member of staff who acts in the capacity of Chief Investigator (CI) is responsible for ensuring that their study is registered in a timely fashion and is updated as required to ensure the information is up to date.

3.2 **When?**
The UK Health Research Authority (HRA) expects registration of all clinical trials before the first participant is recruited, in line with researcher and sponsor duties as set out by the World Health Organisation (WHO), current Declaration of Helsinki and in the UK Framework for Health and Social Care.

Since 30 September 2013 the HRA has identified trial registration as a specific ethical expectation within the existing duties of the sponsor, and it has been a condition of the Research Ethics Committee (REC) favourable opinion, and hence a requirement, to ensure clinical trials are registered. Failure to do so within 6 weeks of the recruitment of the first UK participant is therefore a breach of the favourable ethical opinion unless a request to defer registration has been granted by the HRA and is still valid. This action was to enable the duties of sponsors to be captured as a legal requirement from that point for all clinical trials.

The ICJME states that they will only consider a study for publication if it was registered before the enrolment of the first participant. This policy applies to all studies that started recruiting on or after 1st July 2005. Failure to do so may prevent publication in key journals, such as the BMJ, which actively implement this requirement.

3.3 **How?**
A study can be registered on the ISRCTN website via: [http://www.isrctn.com/](http://www.isrctn.com/) where full guidance is provided. It is necessary to create an account in order to log in to the system. (If the trial has been adopted onto the National Institute of Health Research (NIHR) Clinical Research Network (CRN) Portfolio of clinical trials, it is not necessary to create a registration as this will be done by the relevant CRN).
The mandatory requirement to register will apply to clinical trials which fit the definition of at least one of the first four categories listed on the Integrated Research Application System (IRAS) question 2:

- Clinical trial of an investigational medicinal product (CTIMP),
- 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.

Sponsors and investigators are not required to make a separate notification to their REC confirming the trial has been registered, but they should do so at the earliest opportunity e.g. if submitting an amendment or progress report.

A list of the required data items for an ISRCTN application can be found: [http://www.controlled-trials.com/page/definitions](http://www.controlled-trials.com/page/definitions). Guidance on the completion of the form is also available from this website. The application can be saved at any point and returned to at a later time for completion.

Please note that all study registers are publically accessible and there is a requirement to ensure the text used is in lay-persons terms so it is easily understandable.

Contact details are required but note that Sponsors and CIs may request that telephone, fax and email are not displayed in their records. Details are required for administration purposes. Use of a study resource email account is acceptable rather than personal account details.

A fee is usually required to cover the costs of assigning each number. It is a one-off payment and in return the trial record will be hosted permanently in the ISRCTN Register. The ISRCTN website has details of the current rates: [http://www.isrctn.com/page/faqs](http://www.isrctn.com/page/faqs)

However, the NIHR Clinical Research Network CRN Coordinating Centre has developed a process which enables free ISRCTN registration for all eligible new NIHR CRN Portfolio studies. For more information and to see if your trial is eligible for free registration see the NIHR CRN website: [https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/isrctn-registration.htm](https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/isrctn-registration.htm)

Once confirmation that the study has been adopted onto the Portfolio, the CRN will contact the trial manager/CI with instructions on how to complete the ISRCTN information. The CI or their delegate must then complete the registration and file the email response to confirm the registration details. Trial registration details can be subsequently accessed via: [http://www.controlled-trials.com/](http://www.controlled-trials.com/)

Ongoing maintenance of the register is required throughout the duration of the trial to ensure the information remains correct and a summary of results should be uploaded, when available, at the end of the study. More information regarding the expectations for timescales for results upload and publication can be accessed via: [http://www.who.int/ictrp/results/jointstatement/en/](http://www.who.int/ictrp/results/jointstatement/en/)

The ISRCTN website also has instructions on the practicalities of how to update ISRCTN records: [http://www.isrctn.com/page/faqs](http://www.isrctn.com/page/faqs)
List of Abbreviations

CI  Chief Investigator
CRN Clinical Research Network
CTIMP Clinical Trial of an Investigational Medicinal Product
EudraCT European Union Drug Regulating Authorities Clinical Trials
HRA Health Research Authority
ICMJE International Committee of Medical Journal Editors
IMP Investigational Medicinal Product
ISRCTN International Standard Registered Clinical/soCial sTudy Number
NIHR National Institute for Health Research
RCT Randomised Controlled Trial
REC Research Ethics Committee
SOP Standard Operating Procedure
WHO World Health Organisation