Registration of Clinical Trials
For Publication

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<tr>
<th>Version</th>
<th>1.3</th>
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<td>Effective date:</td>
<td>25 November 2013</td>
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<tr>
<td>Author:</td>
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<td>CTU approval:</td>
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<tr>
<th>Revision Chronology:</th>
<th>Effective Date</th>
<th>Reason for change</th>
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<tr>
<td>Version 1.3</td>
<td>25 November 2013</td>
<td>Addition of HRA requirement to register all trials as a condition of favourable ethical opinion.</td>
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<tr>
<td>Version 1.2</td>
<td>23 April 2012</td>
<td>Website links updated. Trial detail requirements for registration updated.</td>
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<tr>
<td>Version 1.1</td>
<td>21 April 2010</td>
<td>Addition of information on free ISRCTN registration for eligible NIHR CRN Portfolio trials.</td>
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<tr>
<td>SOP 5 v1.0</td>
<td>March 2006</td>
<td>SOP 5 v1.0 split into two separate documents; MHRA Authorisation remains as SOP 5. Registration of a trial for publication is now SOP 28.</td>
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Registration of Clinical Trials for Publication

1. Purpose
This Standard Operating Procedure (SOP) describes the procedures for registering a clinical trial on the International Standard Randomised Controlled Trial Number (ISRCTN) register.

2. Background
The Declaration of Helsinki of the World Medical Association states: “19. 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 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’.

All RCTs or studies designed to assess the efficacy of healthcare interventions are eligible to be registered with the ISRCTN scheme.

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

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 ICJME.

3. Procedure
3.1. Who?
Any member of Warwick Medical School (WMS) who acts in the capacity of Chief Investigator (CI) is responsible for ensuring that an ISRCTN is obtained.

3.2. When?
A trial can be included on the ISRCTN register at any stage during its development but from 30 September 2013 registration of clinical trials in a publicly accessible database will be a condition of a favourable ethical opinion from an NHS REC. Failure to register will therefore be a serious breach of good research practice. All trials must be registered before the first participant is recruited.
The ICJME states that they will only consider a trial for publication if it was registered before the enrolment of the first participant. This policy applies to all trials that started recruiting on or after 1st July 2005.

3.3. How?
A trial can be registered online via: http://www.controlled-trials.com/isrctn/submission/ where full guidance is provided.

The mandatory requirement to register will apply to clinical trials which are defined as the first four categories 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 main 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 is given below. Please note that all four sections of the application must be completed in one session. It is not possible to save one section and return to it later.

1. Applicant details
2. Trial details
   - Protocol/serial number
   - ClinicalTrials.gov identifier (if available)
   - Public title
   - Scientific title
   - Acronym (if available)
   - Study hypothesis
   - Ethics approval
   - Study design
   - Countries of recruitment
   - Participants - inclusion criteria
   - Participants - exclusion criteria
   - Patient information material
   - Target number of participants
   - Anticipated start date (dd/mm/yyyy)
   - Anticipated end date (dd/mm/yyyy)
   - Disease, condition or study domain
   - Interventions
   - Primary outcome measure(s)
   - Secondary outcome measure(s)
• Trial website (if available)
• Publications (if applicable)
• Sources of funding

3. Sponsor details

4. Contact details
(Note: Sponsors and CIs may request that telephone, fax and email are not displayed in their records, but are asked to provide these for administration purposes if at all possible).

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.

However, the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Coordinating Centre has developed a process which enables automatic, 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:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/isrctn_index/index

Once confirmation that no fee is required or payment has been received, the ISRCTN editorial office will inform the applicant and the CI of the ISRCTN that has been assigned to the trial and the record will be included in the ISRCTN register:
http://www.controlled-trials.com/isrctn/

List of Abbreviations
CI Chief Investigator
CRN Clinical Research Network
CTIMP Clinical Trial of an Investigational Medicinal Product
ICMJE International Committee of Medical Journal Editors
IRAS Integrated Research Application System
ISRCTN International Standard Randomised Controlled Trial Number
NIHR National Institute for Health Research
RCT Randomised Controlled Trial
REC Research Ethics Committee
SOP Standard Operating Procedure
WMS Warwick Medical School