Document type	Keele University Health and Social Care QMS: Standard Operating Procedure				
Version No.	**1.0**	Version Date	**24-Aug-2018**	SOP index number	**HSCR-SOP49**

Study Registration

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Effective date	24-August-2018
Next review date	24-August-2020

Applicability	This Standard Operating Procedure (SOP) is applies to Health and Social Care Research (HSCR) which requires registration on a public registry.

Disclaimer

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All SOPs and associated documents must only be accessed through the dedicated SOP area of the Keele University Research Toolkit webpage to ensure the correct version is being used. The user must ensure that they are working to the current version of this document.

Version History Log

Version	Date	Reason for change	Implementation plan
1.0	24/08/2018	New SOP	This SOP will be disseminated through the HSCR newsletter (or equivalent) and must be applied to all studies which are required to register on a public database but have not yet done so. This SOP should be followed for all studies where updates to registries are required. No formal training will be provided; minimally, users of this SOP are expected to read and understand it prior to making registry applications.

Contents

Section A Scope and Applicability

A1 This Standard Operating Procedure (SOP) describes the process for the registration of clinical studies on the most common public databases ISRCTN and ClinicalTrials.gov.

A2 It also includes registration with European Clinical Trials Database (EudraCT), which is applicable to clinical trials of investigational medicinal products (CTIMPs) only.

A3 This SOP applies to any study designed to assess the efficacy of health interventions in a human population, including both observational and interventional trials. In general, registration is not expected for projects undertaken entirely for educational purposes below doctoral level.

Section B Introduction

B1 Prospective registration of clinical studies is mandatory for publication in many journals. The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, registration of clinical studies in a public registry at or before the time of first patient enrolment as a condition of consideration for publication, and plans for registration are reviewed during the REC Approval process.

B2 The purpose of clinical trial registration is to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enrol, and to help give RECs considering approval of new studies a view of similar work and data relevant to the research they are considering. Those purposes apply also to research with alternative designs, for example observational studies. For that reason, the ICMJE encourages registration of research with non-trial designs, but because the exposure or intervention in non-trial research is not dictated by the researchers, the ICMJE does not require it.

B3 For the purpose of registration, the HRA recognise any register covered by the World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP) list (http://www.who.int/ictrp/network/en/) or the International Committee of Medical Journal Editors (ICMJE) list (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/).

B4 The Declaration of Helsinki of the World Medical Association (revised 18 October 2008 at Seoul) also states that “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject."

B5 **CTIMPs only:** All Clinical Trials of Investigational Medicinal Products (CTIMPs) must also be registered with European Clinical Trials Database (EudraCT) and have obtained a registration number prior to applications to the MHRA for a Clinical Trial Authorisation (CTA) (***HSCR SOSOP01: Sponsorship, Regulatory Approvals and Green Light***)

Section C Responsibilities

C1 Summary of Responsibilities

Chief Investigator	Ensure studies are appropriately registered prior to commencing recruitment. ***For CTIMPs***, ensure a EudraCT number is received prior to submission of the Clinical Trial Application to the MHRA
Applicant (CI or delegate, e.g. Trial Manager (CTU studies), Student)	Submit applications for, and manage, study registrations.
PRS Administrator (PARI Team)	Organisation Administrator for Protocol Registration and results System (PRS) account for ClinicalTrials.gov users (Applicants)

Section D Procedure

D1 ISRCTN (International Standard Registered Clinical/soCial sTudy Number)

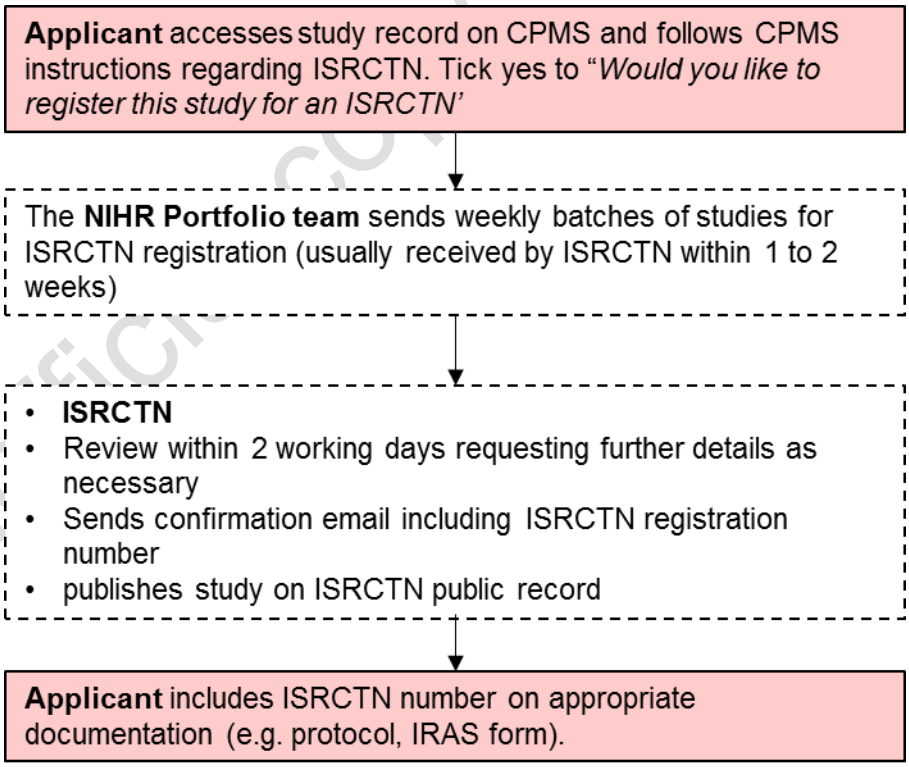
D1.1 ISRCTN is a registry and curated database containing the basic set of data items (https://www.isrctn.com/page/definitions) deemed essential to describe a study at inception.

D1.2 The ISRCTN registry accepts all observational and interventional clinical research studies designed to assess the efficacy of health interventions in a human population (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for publication.

D1.3 All clinical trials should obtain an ISRCTN **prior to the start of recruitment**. Where research is nested within a larger study, e.g. qualitative study within an RCT, there is no need for additional registration with the ISRCTN, however, a pilot and main trial must have separate ISRCN registrations.

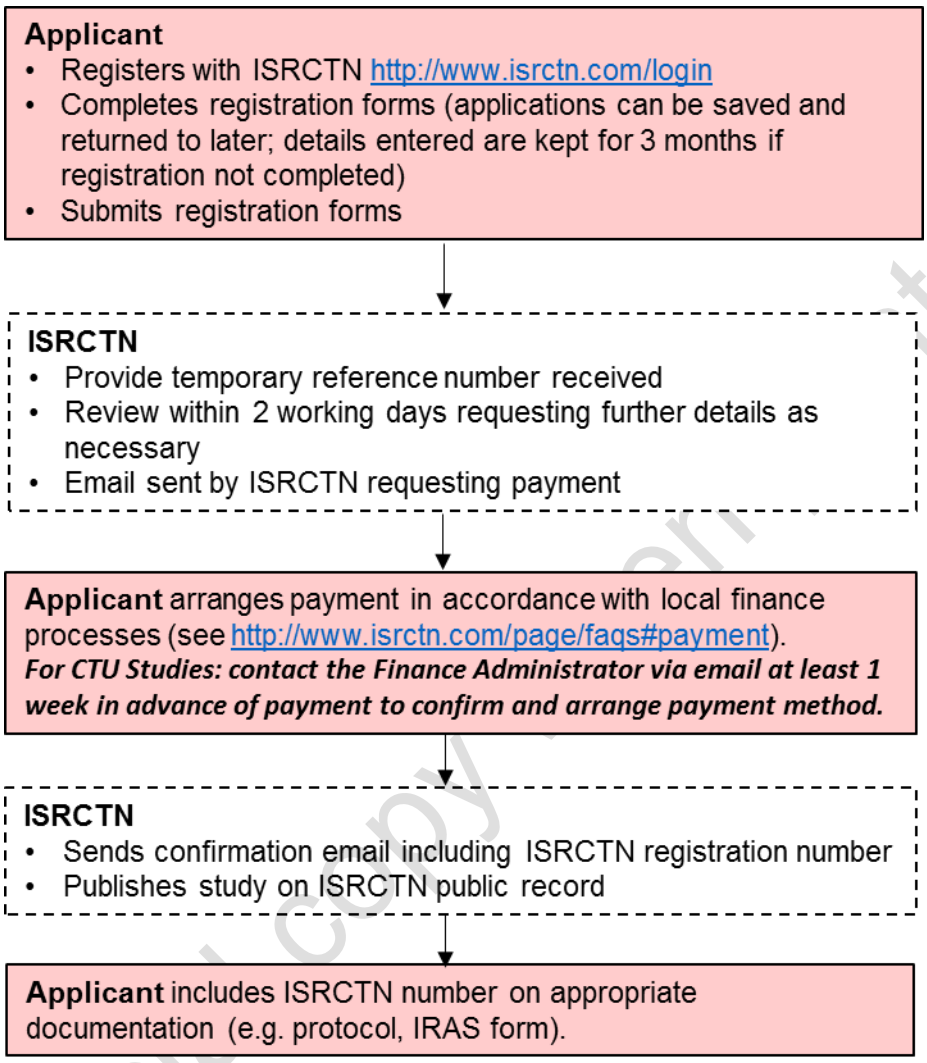
D1.4 The ISRCTN is issued after completion of the ISRCTN application form. Two methods of application are available:

D1.4.1 *Registration through the NIHR Portfolio.* There is no cost to the study team for this method; this is charged to the Department of Health (NIHR). This option is only open to studies that are eligible for the NIHR Portfolio. Application can only take place once NIHR portfolio eligibility has been confirmed and the study record is available on the NIHR Portfolio system (CPMS).



Note: In some cases, it may be preferable to pay for registration due to the time it can take to apply through the NIHR Portfolio and to ensure there is no delay to commencing recruitment (**Section D.1.4.2**).

D1.4.2 *Registration through the ISRCTN website.* The cost of registration will be charged to the study being registered, therefore it is important to agree the payment method with the appropriate Finance Administrator prior to submission of the application. (*Note:* some funders may pay ISRCTN directly through prior agreements)



D1.5 ISRCTN records should be kept up to date and reflect changes made to the study. The record should be reviewed following regulatory approval of amendments to the study (***HSCR SOP11: Study Amendments***). If information that is held in the record has changed significantly, including key dates and funder details, then the record should be updated. Updates should be managed according to ISRCTN guidance https://www.isrctn.com/page/faqs#checkingRecord.

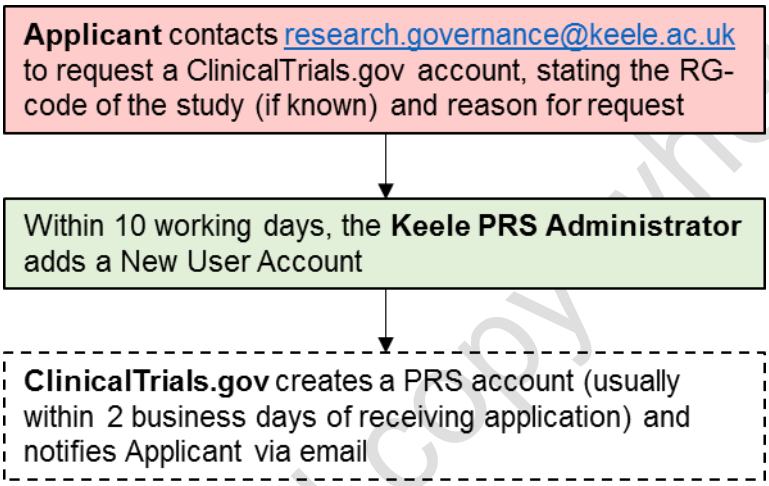
D2 ClinicalTrials.gov

D2.1 Study teams may alternatively, or additionally, wish to register a study on ClinicalTrials.gov (https://clinicaltrials.gov/ct2/home). This is a database of privately and publicly funded clinical studies conducted around the world and is provided by the U.S. National Library of Medicine.

D2.2 Keele University has a Protocol Registration and Results System (PRS) account for ClinicalTrials.gov. The organisation administrator (PRS Administrator) for this account are the members of the Project Assurance Research Integrity (PARI), who manage the account and may create logins for additional users. All investigators who are conducting studies sponsored by Keele University should only register through the organisations PRS account.

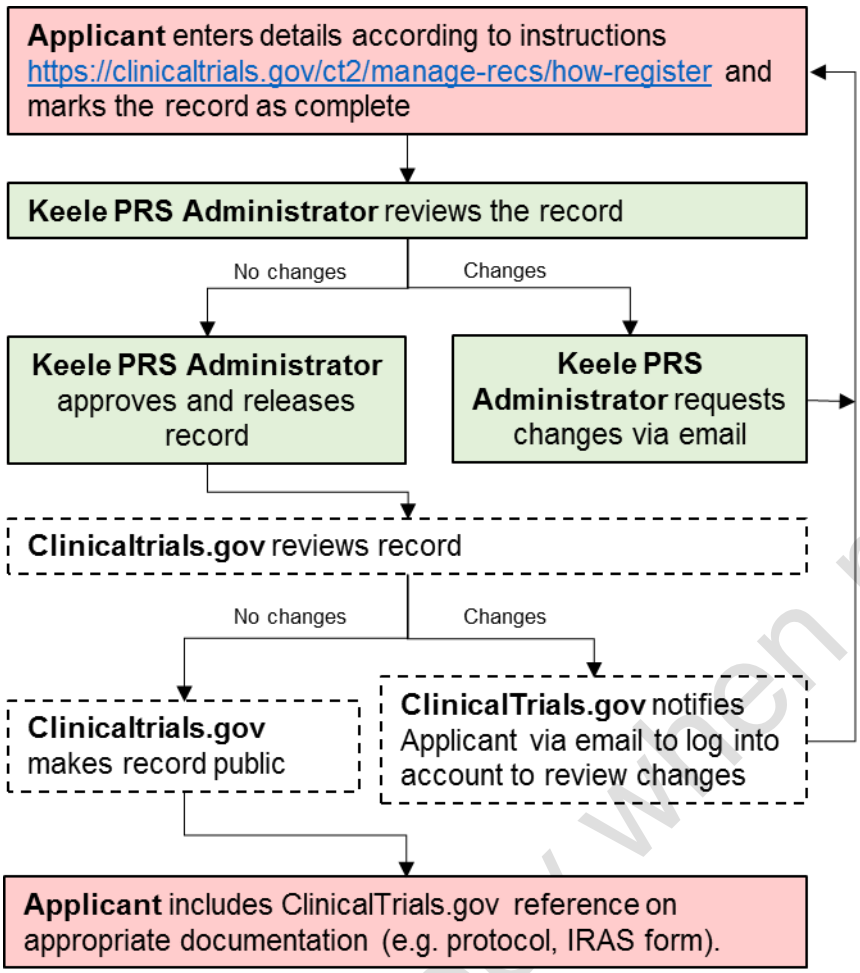
D2.3 If ClinicalTrials.gov is to be used as the only public register used for a study, registration should take place prior to the start of recruitment.

D2.4 Procedure for creating an account:



D2.5 Information on how to register a study on ClinicalTrials.gov is available on the website: https://ClinicalTrials.gov /ct2/manage-recs/how-register

D2.6 Procedure for registering a study:



D2.7 Changes or updates to the record are required to be made at least every 12 months, with reminders received if this is not completed. The record should be reviewed following regulatory approval of amendments to the study (***HSCR SOP11: Study Amendments***). Approval and release of updates are managed using the same process described in D2.6. See https://ClinicalTrials.gov /ct2/manage-recs/how-register#RequiredRegistration for further information.

D3 EudraCT (CTIMPs only)

D3.1 All Clinical trials of investigational medicinal products (CTIMPs) must register for a European Clinical Trials Database (EudraCT) number prior to application to the MHRA (***HSCR SOSOP01: Sponsorship, Regulatory Approvals and Green Light***).

D3.2 The EudraCT database (https://www.clinicaltrialsregister.eu/ctr-search/search) is a register of all CTIMPs in the European community. A CTA application cannot be submitted without a EudraCT number. It is the CI's responsibility to apply for the EudraCT number prior to submission of the CTA (this is usually delegated to a Trial Manager).

D3.3 The CI (or delegate) must register for an account on the EudraCT website (https://register.ema.europa.eu/identityiq/external/registration.jsf#/register) then log in and complete the application for a EudraCT number. A EudraCT number will be sent to the

email address provided. For further information see the https://eudract.ema.europa.eu/help/Default.htm#eudract/create_eudract_no.htm.

D4 Other registrations

D4.1 It may be possible to register a study through the participating NHS organisation or a register run by a medical research charity, or publish the protocol through an open access publisher as determined by the specific study. To comply with ICMJE requirements, an acceptable registry must include the minimum 20-item trial registration dataset at the time of registration and before enrolment of the first participant. (https://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf or http://www.who.int/ictrp/network/trds/en/).

Section E References

http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

https://ClinicalTrials.gov /ct2/home

https://www.isrctn.com/

https://www.clinicaltrialsregister.eu/ctr-search/search

https://eudract.ema.europa.eu/help/Default.htm#eudract/cta_welcome_page_ov.htm