 Leeds Institute of Clinical Trials Research	Title	<b>Clinical Trials Transparency</b>			ID	<b>PO16</b>
	Scope	Applicable to all CTRU Staff				
	Version	<b>1.0</b>	Date	<b>13 March 2020</b>		

**CLINICAL TRIALS RESEARCH UNIT  
UNIVERSITY OF LEEDS**

**Clinical Trials Transparency  
PO16**

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Signature (available on paper copy): \_\_\_\_\_

Date: 13/03/2020

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## 1. Introduction

Leeds Institute of Clinical Trials Research (LICTR) is a research department of the University of Leeds. LICTR conducts non-commercial clinical trials and associated applied health research and teaching.

We believe that transparency in clinical trials is fundamental to improve the efficiency and accountability of clinical trials conduct and in meeting the expectations of research participants, regulators and the scientific community. Transparency means registering trials, reporting and publishing trial results, making data from trials available for further research purposes and making information available at the end of trials for trial participants.

## 2. Policy Scope and Governance

This Policy describes the CTRU expectations for all staff and research collaborators in meeting clinical trials transparency requirements and the mechanisms to ensure transparency requirements are met.

This Policy applies to all clinical trials which are conducted by the CTRU. This includes any clinical trial where the CTRU has responsibility for the design and analysis of the clinical trial irrespective of data and trial management involvement.

This Policy supplements the ***University of Leeds Publication Policy which is available on the University of Leeds Staff Portal.***

Compliance with this Policy is monitored by the CTRU Senior Management Team.

## 3. Registering Trials

### 3.1 All Clinical Trials

All clinical trials that started on or after 1<sup>st</sup> July 2005 are registered in ISRCTN\*. Registration is completed during trial set up, prior to opening to recruitment.


\* Some trials are also registered on ClinicalTrials.gov. This applies where the clinical trial receives support from a pharmaceutical company operating in the USA or where registration in this Registry will raise the international profile of the clinical trial.

### 3.2 Clinical Trials of Investigational Medicinal Products (CTIMPs)

CTIMPs regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments) are registered on the European Clinical Trials Database (EudraCT) prior to applying for clinical trials authorisation.

### 3.3 Maintaining Registry Information

Registry information is regularly maintained by the CTRU trial team.

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## 4. Reporting Trials

### 4.1 Definition of End of Trial (All Clinical Trials)

The end of the trial is defined in all CTRU clinical trials as 'the date of the last participant's last data item'.

### 4.2 Definition of Reporting and Reporting Policy

For **All Clinical Trials**: Reporting means:

- Reporting the published results of all analysis onto the relevant trial registry(ies) (see Section 5.1 for definition of Published Results).

In addition, **for CTIMPs**: Reporting means:

- Uploading trial results onto the EudraCT database within 12 months of the End of Trial date.
- Primary and Secondary Results for all CTIMPs that ended on or after 21<sup>st</sup> July 2014 until June 2019 were reported onto the EudraCT database within twelve months of the End of Trial unless results were embargoed as a result of journal publishing requirements. From July 2019 reporting is undertaken within 12 months of the End of Trial date.

## 5. Publishing Trial Protocols and Results

Some funders and journals have specific policies regarding protocol and trials results publishing. The funder and / or journal policy is followed in these cases.

### 5.1 Definition of Publishing

Publishing means, within 24 months of the Grant Completion / End Date:

- Publishing the clinical trial results in a scholarly journal.

Some funders have specific policies regarding timeframes for publishing and in these cases the date for publishing will be the earliest date occurring as defined either by this Policy or the funder policy.


### 5.2 Quality Control of Trial Results

Clinical trial results are quality assured by the CTRU.

### 5.3 Authorship Policy for Scholarly Journals

Credit for the main trial results will be given to all those who have collaborated in the trial through authorship and contributorship. Authorship for scholarly journals will be in line with the International Committee of Medical Journal Editors Guidelines and requirements of the scholarly journal, these state that authorship credit should be based only on substantial contribution to: conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; final approval of the version to be published.

The Chief Investigator, Scientific Lead and relevant CTRU staff are named as authors in any scholarly journal publication.

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Individual research site Principal Investigators are not permitted to publish data concerning their participants which is directly relevant to the questions posed in the trial unless prior permission has been provided by the Independent Trial Steering Committee.

We do not publish personally identifiable information about any of our research participants when reporting the results of our clinical trials.

#### 5.4 Open Access to Publications in Scholarly Journals

The **University of Leeds Publication Policy** (reflecting REF requirements) is followed. All newly accepted research outputs (from 1<sup>st</sup> April 2016) which are not in a 'gold' open access journal, are recorded in Symplectic and full text copies deposited in a repository (e.g. White Rose Repository) allowing either green access as a minimum or registry with an embargo, within three months of journal acceptance.

In addition to the REF, funders have different requirements regarding publication and access for research outputs. The specific requirements of the trial funder(s) and contract holders are followed.

#### 5.5 Acknowledgements in Scholarly Journals

Funders and contracting parties have different requirements regarding acknowledgements. The specific requirements of the trial funder(s) and contract holders are followed as well as those of the Institute infrastructure awards.

## 6. Providing Results to Trial Participants

For all trials that were ongoing or have started since 1<sup>st</sup> April 2015 information about when and how results will be made available from the clinical trial through the trial sites are provided to participants at the beginning and / or the end of trial participation, where they want to be notified.

## 7. Accessing Research Data for Further Purposes


CTRU operates a controlled access approach to accessing research data; data are made available for valid research projects and access granted following a standard review process. This means that individuals requesting data are required to complete an application form detailing the nature of the proposal and the data items being requested.

From January 2019 a statement describing the CTRU policy for accessing research data is included at the point of registering the clinical trial.

### 7.1 Guiding Principles for Data Access

The following guiding principles are applied in the review of all data requests:

- The value of the proposal will be considered in terms of the strategic priorities of the CTRU, Chief Investigator and Sponsor, the scientific value of the proposed project, and the resources necessary and available to satisfy any data release request.
- We encourage a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets.
- The timing and nature of any data release must not adversely interfere with the integrity of the trial or research project objectives, including any associated secondary and exploratory research

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objectives detailed in the ethically approved original research protocol. On an individual trial or research project basis, a reasonable period of exclusivity will be agreed with the trial or research project team.

- Any data release must be lawful, in line with participants' rights and must not compromise patient confidentiality. Where the purposes of the project can be achieved by using anonymised or aggregate data this will always be used. We will release individual patient data only in a form adjusted so that recipients of the data cannot identify individual participants by any reasonably likely means. We will also only share data when there is a binding agreement in place stating that data recipients will not attempt to re-identify any individual participants.
- Any data release must be in line with any contractual obligations to which the CTRU is subject.
- The research must be carried out by a bone fide researcher with the necessary skills and resources to conduct the research project.
- The research project must have clear objectives and use appropriate research methods.
- The research must be carried out on behalf of a reputable organisation that can demonstrate appropriate IT security standards to ensure the data is protected and to minimise the risk of unauthorised disclosure.

## 7.2 Reviewing, Approving or Rejecting Access Requests

Whilst a clinical trial is ongoing (prior to publication of the results), all requests for access to anonymised or aggregate research data for other research purposes (i.e. additional to those described in the ethically approved protocol) are reviewed by an independent committee (e.g. Trial Steering Committee). The Committee is responsible for governing use of the data to protect the integrity of the research and to respect agreed periods of exclusivity for the research team.

Requests to access and use anonymised individual participant data or aggregate data for further purposes once the clinical trial or research project has closed (after publication of the trial results) are considered by a Clinical Trial Data Access Committee.