University of Exeter

CLINICAL TRIALS TRANSPARENCY POLICY

1.0 Introduction

1.1 The University of Exeter seeks to promote the highest standards of scientific, scholarly and professional integrity and to give due consideration to the ethical, social and environmental issues arising from its activities. We support researchers to work within the Code of Good Practice in Research.[1]

1.2 The University recognises the ethical imperative to publish results and also that poor allocation of resources or sub-optimal regulatory and public health recommendations may occur when decisions are based on only a subset of completed clinical trials.[2]

1.3 Since July 2014, the European Commission has required all trials on the EU Clinical Trials Register to report results within 12 months of completion and the FDA Amendments Act 2007 requires results of certain trials registered on clinicaltrials.gov to report results, again within 12 months of completion. The UK policy framework for health and social care includes principles on information about research and accessible findings which all health and social care research in the UK are expected to meet[3], although this policy particularly applies to clinical trials as defined in 2.4 below.

2.0 Scope and Definitions

2.1 The term University refers to University of Exeter as well as any subsidiary majority-owned by the University of Exeter.

2.2 This Policy applies to all researchers affiliated with the University of Exeter who are conducting clinical trials within the definition in 2.4 below. This will be taken to mean any of the following:

a. full and part time staff employed by the University, or engaged by or directors of subsidiary companies of the University;

b. anyone affiliated to the University by way of an honorary contract (including but not limited to honorary academics, emeritus academics, visiting academics and visiting researchers);

c. research students registered at the University; and

d. external members of the University's clinical trial research teams (e.g. members of Trial Steering Committees, Data Monitoring Committees and patient/public co-applicants)

2.3 This Policy applies whenever a member of the University carries out activities relating to a clinical trial as defined in 2.4 below.

2.4 For the purposes of this policy, the definition of clinical trials includes (regardless of funding source):

a. A Clinical Trial of an Investigational Medicinal Product (CTIMP), including Phase 1 trials in healthy volunteers

b. A Clinical Investigation or other study of a Medical Device

c. A combined trial of an Investigational Medicinal Product and a Medical Device

d. A Clinical Trial to study a novel intervention or randomised Clinical Trial to compare interventions in clinical practice

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[1] University of Exeter Code of Good Practice in the Conduct of Research
http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/

[2] WHO Joint Statement on the public disclosure of results from clinical trials
https://www.who.int/ictrp/results/jointstatement/en/

[3] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

3.0 Policy statement

The University of Exeter expects that any clinical trial led by University of Exeter researchers or affiliated with the University of Exeter will:

3.1 Be registered in a publically accessible registry before recruitment of participants begins and ensure that the registration is maintained as the trial progresses (e.g. final enrolment, completion or trial termination).

3.2 Report at least summary results via the registry or suitable repository within a maximum of 12 months of completion, and have updated the registration appropriately. The trial protocol will be made publically available (including amended versions) before results are reported. The University of Exeter promotes the use of recognised reporting guidelines such as CONSORT and SPIRIT.

3.3 Have published results in an appropriate journal or repository within an indicative timescale of 24 months of completion. The University of Exeter supports the UKRI position that publicly funded research is a public good that should be made openly available to the public when legally, commercially and ethically appropriate[4].

4.0 Mechanisms

4.1 Trial Registration

The University of Exeter holds an institutional registration for the ClinicalTrials.gov registry and the Research Ethics and Governance team will facilitate its use, for example by setting up individual user accounts on request and approving registry entries. At present there is no cost for registration on ClincialTrials.gov. Other registries include ISCRTN and EudraCT. Costs for registration should be included at grant application stage and the Principal Investigator[5] (PI) is responsible for identifying appropriate trial registration mechanism and ensuring that the registration is completed before the first participant is recruited. Exeter Clinical Trials Unit and Clinical Research Facility staff can also facilitate and advise.

It should be noted that some publishers require trial registration as condition of publication, and the PI is expected to plan ahead for the publication and dissemination stage.

The protocol, including amended versions, should be made publically available via a suitable repository or open access route before trial results are published.

4.2 Reporting Results

All publications related to the trial should include the trial registration number. Plans for dissemination and reporting of results should be developed during the set-up phase of the trial. Researchers are expected to report results in accordance with recognised reporting guidelines as relevant to the research (see, for example, https://www.equator-network.org/).

It is also expected that researchers will also make results available to participants in an easily understandable and appropriate format, in line with information sheets given to participants during the trial and relevant data protection regulations.

4.3 Monitoring compliance

PIs are responsible for ensuring that the requirements for registering and reporting their trials are met and that relevant SOPs are followed. PIs will be asked to account for any completed trials where results have not been reported.

Where the University of Exeter is acting as sponsor for the trial, the registration and publication of results will be monitored by the Research Ethics and Governance team. PIs will be asked to provide progress reports as part of the trial monitoring process and the

[4] University of Exeter Open Research and Data Management Policy
http://www.exeter.ac.uk/media/universityofexeter/research/openaccess/OA_RDM_Policy_Final.pdf

[5] Defined as the main applicant, lead researcher and responsible for the preparation, conduct and administration of a grant. The term 'Chief Investigator' may also be used.

conditions of sponsorship will also include a requirement to provide copies of reported results and other outputs in a timely manner.

5 Review of Policy

The Clinical Trials Transparency Policy will be reviewed every two years and compliance will be monitored by the Open Research Operational Group and the Research and Impact Executive Group.

6 Linked policies

6.1 The University has a number of related ordinances, policies and procedures already in place, which should be considered in conjunction with this Policy. These include:

a. Open Research and Data Management Policy;

b. Exeter Clinical Trials Unit standard operating procedures (as relevant to the trial);

c. Good Practice in the Conduct of Research (incorporating Guidance on the reporting and investigation of misconduct in research);

d. Public interest disclosure policy; and

e. University of Exeter sponsorship requirements.

f. Ethics Policy

6.2 A number of external policies and procedures may also need to be considered in conjunction with this policy. These include:

a. UK Policy Framework for Health and Social Care Research;

b. Clinical trial funder terms and conditions;

c. Clinical trial sponsor requirements (where the sponsor is not the University of Exeter);

d. Other Clinical Trial Unit standard operating procedures.

6.3 The University treats equality of opportunity seriously and has a dignity and respect framework that is applicable to staff in order to promote and ensure equality of opportunity. Implementation of this procedure must be clear and transparent and not subject to any unfair discriminatory practices.

V2.0 August 2019

G Seymour

Reviewed by RIEG, 27th June 2019