NIHR policy on prospective trial registration and timely disclosure of Clinical Trial results

1. Introduction

1.1. The purpose of this document is to present NIHR's draft policy on prospective trial registration and disclosure of Clinical Trial results.

1.2. This draft policy has been released for feedback from stakeholders. Any comments should be sent to AddingValueInResearch@nihr.ac.uk by **21st September 2018**.

1.3. Prospective study registration and timely disclosure of results are important for ethical, moral, accountability, research integrity and waste reduction perspectives. As a public funder of research involving patients and the public these are particularly important perspectives. Clarifying our expectations and improving practice in prospective registration and timely disclosure of results will help raise the probability of impact of NIHR funded research and thereby support the NIHR's mission to improve the health and wealth of the nation through research.

1.4. This policy was developed under the NIHR Adding Value in Research framework in response to NIHR signing the WHO Joint statement on public disclosure of results from clinical trials.

2. Scope

2.1. All Clinical Trials in receipt of Research Costs from NIHR.

3. All clinical trials within scope must be registered before the first participant receives an intervention

3.1. All NIHR-funded primary research projects are required to register onto the International Standard Randomised Controlled Trial Number Register (ISRCTN). In some cases other recognised registries may be appropriate for the primary registry; for example if the NIHR funded study is part of an international trial registered elsewhere. Registration advice is provided in the documentation supplied by NIHR programmes as part of the application, contracting and start-up processes.

3.2. Registration must occur before the first participant receives an intervention as part of the Clinical Trial.

4. Registries should be updated during the study and key outcomes and trial protocol are to be made publicly available within 12 months of study completion

4.1. Registry information should be updated regularly as appropriate with any amendments to recruitment data and key outcomes.

4.2. Trial protocols must be made publicly available within 12 months of study completion in all cases and before the first participant receives an intervention, in most cases.

4.3. Summary Results should be quality assured and validated by the research team however NIHR acknowledge this may mean the results have not been Peer Reviewed and therefore should not be used to inform practice.

5. Trial findings should be published in a peer reviewed journal within 24 months from study completion

5.1. Publication of trial findings in a Peer Reviewed open access journal is also an expectation. NIHR acknowledge publication in a Peer Reviewed journal is not within the complete control of the research team and so set an indicative timeframe of 24 months from Primary Study Completion.

5.2. Trial findings should be disseminated directly to participants and others involved in the research.

6. Past publication and registration practice should be taken into account when reviewing applications for funding for new clinical trials.

6.1. When submitting an application to NIHR programmes for funding for a new Clinical Trial, the applicant must disclose past publication and trial registration history for the recent relevant publications and research grants held referenced in the application (section three '*Research Background*', of stage two of the Standard Application Form).

6.2. Applicants may alternatively comment on why prospective registration and/or publication was not possible.

7. Monitoring and reporting on compliance

7.1. Clinical Trial registry records should be updated as necessary to include final enrolment numbers achieved, and the date of Primary Study Completion (defined as the last data collection time point for the last subject for the Primary Outcome measure).

7.2. All relevant trial registry information must be reported via agreed progress reporting schedules.

7.3. When in place, NIHR will make summary reports on compliance available in the public domain.

8. Individual Participant Data (IPD)

8.1 NIHR supports re-use IPD as outlined in the applicant's contract for research which requires the full reporting of findings and outputs from research. However, NIHR recognises this remains a challenging issue and will continue to engage with partners in developing standards for sharing of IPD from Clinical Trials.

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Definitions

Clinical Trials - A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Individual Participant Data (IPD) is raw data from individual participants of the clinical trial.

Peer Review - An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and represents good value for money.

Primary Outcome - Primary Outcome is the data or results, as specified in the trial protocol, from which the main aim of the clinical trial can be assessed.

Registration means completing the registration process and obtaining a unique trial registration number. All NIHR-funded primary research projects are required to register onto the International Standard Randomised Controlled Trial Number Register (ISRCTN). In some cases other recognised registries may be appropriate for the primary registry.

Research Costs are defined by "Attributing the costs of health and social care Research and Development (AcoRD) policy framework". Research costs are the costs of the research and development itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions.

Study Start Date - Date of Health Research Authority (HRA) Approval for study as per HRA Approval Letter.

Primary Study Completion - Date of the last visit of the last subject for collection of data on the Primary Outcome (WHO definition)

Summary Results - Summary results include information on the primary and any secondary outcomes measured and statistical analysis.