NIHR Randomised Trials Coordination

Purpose
1. Coordination activity brings key NIHR partners together to provide a level of awareness and focus for the NIHR randomised trials portfolio and planning. This work facilitates the NIHR articulating and communicating its position as the main public funder of trials in the UK and a world leader in research.

2. ‘NIHR Randomised Trials Coordination’ refers to a process whereby: NETSCC coordinates activities on behalf of NIHR and develops appropriate data and reporting resources. NETSCC will not take on the management of all trials. Commissioning and monitoring of trials remains with the awarding NIHR Programme. NETSCC also acts as a point of contact for the design, conduct, analysis and reporting for trials across the NIHR, and signpost to and collaborate with other NIHR partners including the Research Design Service, the UKCRC Registered CTU Network, and the MRC/NCHR Methodology Research Programme as appropriate.

3. Trials coordination provides:
   - The NIHR, as the main public funder of trials in the UK, with a consolidated position and improves its ability to speak in a unified, consistent manner concerning trials methodology and design, activity and the portfolio. This includes both national (researchers, policy makers, politicians) and international (other funders) audiences and forum.
   - Improved reporting of NIHR randomised trials portfolio activity and information sources. This assists NIHR Programmes in making commissioning decisions that avoid waste and duplicated activity.
   - Improved ‘pull-through’ of research questions, trial design and development activity in the translational pathway, by providing an improved awareness of the NIHR randomised trials portfolio and the staging of research.
   - Effective communication activity and helps inform other NIHR developments, through a more detailed knowledge and awareness of the current NIHR randomised trials portfolio.
   - Improved knowledge and evidence available to the research community, refines NIHR programme advice and requirements, and ultimately seeks to further improve the quality of NIHR trials and good practice through ‘developing methods in research’ and research management activities.

4. Coordination activities focus around two main areas:
   - Portfolio awareness and reporting: including the development, refinement and improvement of reporting and information across NIHR Programmes and funding streams.
   - Methods in research: including development and signposting of key NIHR documents, guidance and expectations in the design, conduct and reporting of trials.
5. The NIHR funds research studies across the methodological landscape and all research types offer a particular value. To provide a clear focus for coordination activity, one research type has been selected from within the NIHR portfolio at this stage. Randomised trials have been identified for several reasons;
   - The NIHR is the largest UK public funder of trials and therefore a leader in this field internationally.
   - Trials are recognised internationally as a ‘high profile, flag-ship gold standard’ research methodology.
   - Randomised trials are an important design type when examining interventions, and therefore of particular importance and relevance to the NIHR and NHS.
   - Randomised trials constitute the largest component of the NIHR portfolio (in terms of NIHR cost allocation and participants enrolled).

6. Wider trials activity beyond that outlined above is not within scope for pragmatic reasons. It is possible that the scope may widen to include other trial design types and/or other activities that are coordinated by NIHR centres in the future. However the key requirement would remain that the funding had been provided for the specific trial being reported.

7. The precise definition of a randomised trial used is; “An experiment in which investigators randomly allocate eligible participants into two or more groups (e.g. intervention and control) to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the intervention and control groups”.

8. In order for a randomised trial to be eligible for inclusion it must also satisfy the following additional criteria;
   - Funded by the NIHR, and/or managed by the NIHR Evaluation, Trials and Studies Coordinating Centre - NETSCC, NIHR Central Commissioning Facility – CCF (excluding the Policy Research Programme) or NIHR Trainees Coordinating Centre - TCC.
   - Registered on NIHR Portfolio Database (if eligible). Feasibility or pilot studies can be eligible for inclusion if using a randomised design.

9. Reporting is focused on current active trials only at this stage. Trials that have completed are not included.

**Benefits to the NIHR**
1. The NIHR, as the main public funder of trials in the UK, achieves a consolidated position and speaks in a unified, consistent manner concerning trials methodology and design, activity and the portfolio. This will include both national (researchers, policy makers, politicians) and international (other funders) audiences and forum.

2. NIHR Programmes are assisted in making commissioning decisions that avoid waste and duplicated activity through improved portfolio reporting and information sources.

3. The NIHR achieves improved ‘pull-through’ of research questions, trial design and development activity in the translational pathway as a result of improved awareness of the portfolio.

4. A more detailed knowledge and awareness of the current NIHR trials portfolio facilitates effective communication activity and help to inform other developments.

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1 Working definition based on version used by NIHR HTA Programme ([http://www.hta.ac.uk/atozusefulterms.shtml](http://www.hta.ac.uk/atozusefulterms.shtml))
5. ‘Developing methods in research’ activity focuses on improving the knowledge and evidence made available to the research community, refine NIHR programme advice and requirements, and ultimately seeks to further improve the quality of NIHR trials.

**Benefits to applicants and wider research community**

1. ‘NIHR randomised trials methods’ web resources provide applicants with key information on requirements, expectations, good practice and evidence in the conducting of randomised trials, thereby improving the quality of NIHR trials. Later developments may include new NIHR guidance, guideline documents, and consensus statements on key areas across the NIHR.

2. NIHR Programmes can use the increased knowledge of the NIHR randomised trials portfolio to refine advice to applicants, and better define application requirements. As a result applicants gain more clarity on requirements and remits.

3. An increased knowledge and awareness of the NIHR trials portfolio enables Clinical Trial Units and other research institutions to understand NIHR requirements and planning, and thus inform business and capacity planning.

**Activity Area One: Portfolio awareness and reporting**

1. This activity provides a data and reporting resource (using a standard data set) covering all eligible NIHR randomised trials.

2. The main data sources for this exercise are the coordinating centres management information systems. Additional sources (such as the CRN Portfolio and the UKCTG) will also be used as sources of supplementary or verification data as required.

3. Data collection is coordinated by NETSCC up to three times a year, working with the other contributing coordinating centres.

4. Routine reports and portfolio information will be available to key NIHR stakeholders to inform related activities and specific business needs.

**Activity Area Two: Methods in Research**

1. This activity provides a framework for the provision of information and resources regarding NIHR randomised trials that are relevant to all NIHR Programme activity areas.

2. A major component is a website resource providing NIHR researchers with key information on requirements, expectations, good practice and evidence in the conducting of NIHR randomised trials. This includes links to key resources (such as the Clinical Trials Toolkit, EQUATOR, SPIRIT and CONSORT), useful research papers on aspects of study design and examples of innovative or interesting trial design or methodologies.

3. Other activities will be undertaken to ensure that the NIHR’s position as the main public funder of trials in the UK is recognised and understood. This may include developing opportunities for presentations and events, and commenting on key areas of interest as they arise.

4. Later developments may include new NIHR guidance and guideline documents, and consensus statements on key areas. This latter activity will seek to include relevant contributions from across the NIHR.

*NETSCC*

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