

MRC Policy on Open Research Data from Clinical Trials and Public Health Intervention Studies (2016)

1. MRC Support for Transparency in Clinical and Public Health Research

The MRC strongly promotes the principles of research transparency and aims to make the research process and findings as open, understandable and reproducible as possible.

The MRC supports data sharing initiatives to increase the availability of study data for re-use. Sharing data from research can enhance the use of existing data, avoid duplication of research effort and stimulate new discoveries.

The MRC has a long history of supporting interventional studies involving human participants, including clinical trials at a variety of stages and studies of clinical and public health interventions. Such studies are funded through the Research Boards and other funding schemes.

2. Scope

This policy applies to the following types of study:

1. **Clinical trials and clinical intervention studies:** studies which meet the broad definition used by the [World Health Organization \(WHO\)](#)¹ for a clinical trial, which includes all studies evaluating the impact of interventions on human participants:

“any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”

Interventions may include drugs or medicines, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, changes to the care pathway, preventive care, or other treatments. Clinical trials at all stages, from Phase 1 to Phase 4, and global health trials are included in this policy.

2. **Public health intervention studies:** studies in which there is a public health intervention to promote or protect health, or prevent ill-health, in communities or populations rather than individuals.
3. **Observational studies:** studies in which the researcher assesses outcomes in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle or behaviours, or interventions that are part of routine care and not influenced by the researcher.

This policy does not apply to studies that involve human tissue only.

For studies funded through the MRC Developmental Pathway Funding Scheme (DPFS)², this policy on transparency is additional to DPFS monitoring requirements.

All of the sections below apply to the study types that are within the scope of this policy unless stated otherwise.

¹ www.who.int/topics/clinical_trials/en/

² www.mrc.ac.uk/funding/science-areas/translation/

3. Registration of Clinical and Public Health Intervention Studies

Any MRC-funded clinical trials, clinical and public health studies with a study design that is within the scope of this policy must register with the [ISRCTN³](#) Registry before the study starts and obtain a unique ISRCTN number. The MRC project/grant reference should be included in the registry entry. The MRC will cover the cost of the ISRCTN registration fee, which should be included in the application for funding.

The unique ISRCTN number must be used in all publications and provided to MRC by adding it to Researchfish® **within 12 months** of the study or trial starting. If the study or trial start date is more than 12 months after funding start, then the MRC Programme Manager should be notified.

The registry entry should include information about where summary results from the study or trial are publicly available. All relevant fields of *any* registry entry should be regularly reviewed and updated with any changes (at least annually) until the study or trial is completed and results have been made publicly available. If the study or trial is extended, then the new end date must be added to the registry entry as soon as possible.

3.1. Health Research Authority requirements for Clinical Trials and Intervention Studies

The Health Research Authority (HRA) requires clinical trials – defined as all clinical trials of medicines, devices or other clinical interventions – to be registered on a publicly accessible register as a condition of ethics approval. Failure to do so within six weeks of the recruitment of the first UK participant is a breach of this approval.

3.2. Requirements for Clinical Trials of Investigational Medicinal Products (CTIMPs) only

Clinical Trials of Investigational Medicinal Products (CTIMPs) involving sites in Europe must register their protocol and obtain a EudraCT number as part of regulatory approval from the Medicines and Healthcare Regulatory Agency (MHRA)/European Medicines Agency (EMA). Information about clinical trials registered with EudraCT can be viewed on the public EU Clinical Trials Register (EUCTR)⁴, although protocols from Phase 1 trials may be withheld if commercially sensitive.

The European Commission (EC) requires trial results to be posted onto the EUCTR within 12 months of completion. The EMA is required to publicly flag any trial that is overdue and contact the sponsor. Investigators who register a trial that is funded or sponsored by the MRC on the EUCTR must comply with EC requirements. The EUCTR entry should be regularly reviewed (at least annually) and updated whenever there are relevant changes to report.

4. Publishing the Study Protocol and Statistical Analysis

The MRC requires all funded clinical and public health intervention studies to comply with CONSORT Statement⁵ or appropriate alternative reporting guidelines and to make the study protocol, analysis plan and all relevant statistical analyses openly available. The study protocol and analysis plan must be publicly available prior to study start. The trial or study protocol (or information on where it can be found) should be

³ www.isrctn.com/

⁴ www.clinicaltrialsregister.eu/ctr-search/search

⁵ www.consort-statement.org/

added to the registry entry **within 12 months** of the trial or study start. The [SPIRIT Statement](#)⁶ (Standard Protocol Items: Recommendations for Interventional Trials) provides guidance on creating a study protocol and defines a set of items that should be included. Details of where to find the statistical analysis plan should also be provided on the ISRCTN register.

5. Publishing Study Results

Results of MRC-funded studies (whether positive or negative) must be published or made publicly available **within 24 months** of the end of the study or trial. This may include a publication in a peer reviewed journal, summary results on the clinical trials register or a public report of findings on the study website. Research results should be reported in accordance with the recommendations in the CONSORT statement or an alternative reporting guideline appropriate to the study design (reporting guidelines for all study types are available from the [EQUATOR](#) network⁷). Where a Trial Steering Committee or study advisory group has been established, results must be discussed by members before publication. Further guidance on reporting and disseminating research is provided in [MRC Good Research Practice](#)⁸.

The MRC is a co-signatory to the WHO [Joint statement on public disclosure of results from clinical trials](#) (2017), which supports the timely public disclosure of results from all clinical trials.⁹

Details of all publications or publicly available outputs associated with the study must be reported on Researchfish®.

MRC champions open access publishing, which allows readers to access published papers free of charge without paying journal subscription charges. The MRC requires all publications to be deposited within six months of publication in Europe PubMed Central. For further information on publication and reporting requirements see our guidance on Researchfish®¹⁰ and open access¹¹.

5.1. ICMJE requirements for registration and publication of clinical trials <<moved from section 3)

Members of the International Committee of Medical Journal Editors (ICMJE)¹² will consider a clinical trial for publication only if:

- it has been registered in an ICMJE-approved registry before enrolment of participants
- the manuscript includes a data-sharing statement (applicable from 1st July 2018)¹³
- a data-sharing plan has been included in the clinical trial registration (applicable from 1st January 2019).

The ICMJE broadly defines a clinical trial as a study that prospectively assigns people to a health-related intervention.

⁶ www.spirit-statement.org/

⁷ www.equator-network.org/

⁸ <https://mrc.ukri.org/research/policies-and-guidance-for-researchers/good-research-practice/>

⁹ <http://www.who.int/ictcp/results/jointstatement/en/>

¹⁰ <https://mrc.ukri.org/funding/guidance-for-mrc-award-holders/researchfish/principles-of-use/>

¹¹ <https://mrc.ukri.org/research/policies-and-guidance-for-researchers/open-access-policy/>

¹² www.icmje.org/about-icmje/faqs/clinical-trials-registration/

¹³ <http://www.bmj.com/content/357/bmj.j2372>

6. Data Sharing and Transparency: Individual Participant Data

The MRC Policy and Guidance on Sharing of Research Data applies¹⁴ to all studies: *“The MRC expects valuable data arising from MRC-funded research to be made available to the scientific community with as few restrictions as possible so as to maximize the value of the data for research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner.”*

The MRC is aware of the risks of fully open access to individual participant data, in particular the need to comply with participant consent and to avoid inadvertent or deliberate identification of participants. Therefore the MRC expects researchers to follow the guidance in [Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials](#)¹⁵ which details the good practice principles for sharing individual participant data and practical guidance on how to manage this. A data sharing policy should be developed for each clinical study and include defining the:

- data request process
- criteria and process for data release
- data use agreement.

Research involving the population health sciences, and population and patient cohorts should follow the [MRC policy on sharing of research data from population and patient studies](#)¹⁶.

The MRC expects researchers to publish summary data about the data requests made, including the number of requests fulfilled and reasons for refusal. Applications for MRC funding for clinical and public health intervention studies should include the costs of data curation, including the preparation of metadata, to support its availability for data-sharing and re-use by secondary users.

7. Secondary Use of Data

These principles on open research data also apply to secondary users of data from MRC-funded clinical and public health intervention studies. Secondary data analyses should not be registered as separate clinical trials on the ISRCTN, but it is considered good practice to make information about such studies available on a publicly accessible register. Researchers are required to include a reference or link to the original data and trial registration number with any published findings.

¹⁴ <https://mrc.ukri.org/documents/pdf/mrc-data-sharing-policy/>

¹⁵ https://www.researchgate.net/publication/284141786_Good_practice_principles_for_sharing_individual_participant_data_from_publicly_funded_clinical_trials

¹⁶ www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/

FAQs

What will happen if I do not register my clinical trial?

Failure to register a trial, to add the protocol to the registry entry, or to provide a registration number to the MRC within 12 months of the clinical trial starting may result in suspension of funding.

Journals within the International Committee of Medical Journal Editors (ICMJE) group will not consider a trial manuscript for publication if the trial has not been prospectively registered on a public register.

Will I be able to publish findings if my trial is not registered or is registered late?

If a clinical trial has not been registered in a public trials registry before the time of first participant enrolment, the ICMJE will not consider a trial manuscript for publication. Although the ICMJE does not define the timing of first patient enrolment, it is considered best practice to register the trial before the first participant is consented.

Do I have to register an experimental medicine study?

No, you do not have to register a trial that does not include human participants and/or a health-related intervention.

Do I have to register a public health intervention study?

Yes, you should register a public health intervention study if it meets the eligibility requirements for registration on the ISRCTN. You should also consider the [MRC policy on sharing of research data from population and patient studies](#) which is likely to apply to the management of data within your study.

Do I have to register a population cohort study on the ISRCTN?

The ISRCTN permits registration of observational studies in which a population behaviour, such as smoking, or an intervention is being evaluated and these studies should be registered. There is no requirement to register birth or population cohort studies that do not meet the eligibility criteria for registration on the ISRCTN.

Where should I publish my study protocol?

The MRC requires the protocol to be publicly available. You must add the study protocol, or provide details of where it is publicly available, to the ISRCTN registry within 12 months of the study start date.

Where should I publish my statistical analysis plans?

The MRC recommends that statistical analysis plans are made publicly available, generally on study or institutional website. Details of where to access the statistical analysis plan should be included in the study registration information on the ISRCTN registry.

What will happen if I do not publicly report findings from my clinical trial?

Failure to publicly report summary findings from your clinical trial within 24 months of the trial ending may result in future grant awards being suspended or restricted.