

RECRUITMENT OF HUMAN PARTICIPANTS

1. Purpose

This policy sets out our position on all research involving recruitment of human participants (including interventional and observational studies) as referred to in Section 3.2. of the [UK Policy Framework for Health and Social Care Research](#).

2. Scope

This policy applies to all research involving human participants including observational studies and interventional trials such as behavioural, prevention, screening, diagnostic and treatment trials; and includes such studies funded or endorsed by all our funding committees and Scientific Executive Board, as well as any studies associated with one of our Accelerator Awards.

Trials sponsored by our Centre for Drug Development (CDD) are covered separately in CDD's suite of policies. From here on in, clinical trials, behavioural intervention trials and clinical studies will collectively be referred to as research projects throughout this policy, with specific requirements for interventional clinical trials outlined in the appropriate sections.

This policy forms part of our [Grant Conditions](#) and sets out the requirements for our grantholders before, during and after their research projects supported by us.

3. Key points

3.1. Pre-research project requirements

3.1.1. Approvals

Grantholders and host institutions must have the relevant regulatory and ethical approvals and appropriate governance mechanisms in place before participants can be recruited. We reserve the right to view approvals documentation.

Approvals are not required when you submit your grant application but you must obtain these if your funding application is successful.

3.1.2. Declaration of interests

Grantholders and host institutions should adhere to Section 10 of our grant conditions and must avoid any conflicts of interest in relation to the project and notify us if any arises.

Applicants may be required to complete a Disclosure of Potential Competing Interests form at application stage as outlined in the application scheme guidelines.

3.1.3. Sponsorship and insurance

All research projects must have a sponsor/co-sponsors who can accept the required responsibilities and accountabilities. If a sponsor(s) is not established in the UK or in a European Union (EU)/European Economic Area (EEA) country, grantholders must appoint a legal representative based in the UK or an EEA country for the purposes of the research project. In addition, UK sponsors of research projects in the EU/EEA must now have legal representation in the EU.

Any changes in sponsorship during the course of the research project must be communicated to us in writing as soon as possible.

The sponsor is responsible for ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

3.1.4. Registration

The HRA (Health Research Authority) requires clinical trials to be registered on a publicly accessible register as a condition of ethics approval. For clinical trials of investigational medicinal products (CTIMPs), trial registration will also become a

legal requirement under new UK clinical trial regulations, coming into force 28 April 2026. See here for further [guidance](#).

Grantholders must register any funded or endorsed project on a recognised trials registry such as the [ISRCTN](#) registry or the [ClinicalTrials.gov](#) registry before the first participant is recruited or within 90 days of approval (whichever is earlier).

Details included in the registry must be kept up-to-date throughout the lifetime of the project. Clinical trial registry records should be updated as necessary to include:

- final enrolment numbers achieved
- date of primary study completion (defined as the last data collection timepoint for the last subject for the primary outcome measure)

If projects are terminated, their status should be updated to note the date of termination, and to report the numbers enrolled up to the date of termination.

CTIMPs involving sites in a European Union country must be registered on the Clinical Trials Information System (CTIS) and obtain a European Union Clinical Trial (EU CT) number as part of regulatory approval from the relevant competent authority(ies). All research projects must follow the applicable regulatory requirements in all countries where the study is running.

Grantholders must notify us of the registration number before the first patient has been recruited and where relevant, no later than the time of the subsequent scientific milestone report. For awards not subject to scientific milestone reports, the relevant grants management team should be notified. We reserve the right to suspend awards that have not been appropriately registered but have recruited patients until the trial has been registered.

3.1.5. Our trials database

Grantholders and research personnel conducting research projects will assist our Patient Involvement team by doing the following:

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1. Include the URL for our clinical trial database (cruk.org/trials) on the patient information sheet. (Including our logo is also strongly encouraged).
2. Provide us with the study protocol and patient information sheet to support the development of an accurate lay summary of the trial.
3. Assist us to draft a lay summary of the trial and or study as well as the findings when results are available for inclusion on our online clinical trials database, and subsequently provide regular updates to the information as requested so that the database can be kept reasonably up to date.

3.2. Research project requirements

3.2.1. Conduct of research projects

All research projects must be conducted in accordance with the UK Policy Framework for Health and Social Care Research, and any relevant frameworks of local ethics committees, General Data Protection Regulation (GDPR) guidelines, recognised good practice guidelines, and any applicable regulatory requirements.

Please find guidance from the HRA and [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) on the updates that come into effect in April 2026.

3.2.2. Chief investigator expectations

All research projects must be led by a chief investigator, who is responsible for the overall conduct of the research project. A chief investigator's responsibilities are set out in more detail in the UK Policy Framework for Health and Social Care Research.

The chief investigator may be an academic, clinician or healthcare professional in a UK university, medical school, hospital, clinical trials unit or research institution. Any change to the chief investigator must be agreed with us.

Grantholders are strongly encouraged to use any research project we support to facilitate the training and development of any junior investigators on the research project team.

3.2.3. Broad consent for re-use of datasets and sample collections

For all research projects, you must clearly indicate in the consent clauses that samples and data collected in the study can be shared with organisations in and outside of the UK, including commercial organisations to support other health-related research in the future. Further guidance can be found in our [template for consent wording](#).

Get in contact with your committee team for further information.

3.2.4. Making the protocol public

For all research projects, we expect a sufficiently detailed summary of the research project protocol, written in plain language, to be made publicly available prior to the start of recruitment. Any changes to the protocol must be approved and updated on the registry as soon as possible.

Details of where and how the trial summary may be accessed must be provided on the trial website, if one exists.

3.2.5. Governance

For early phase interventional trials, observational studies and other research projects

Governance arrangements must be agreed with us at the application stage. For all trials, a trial management group should be established to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

In addition, Trial Steering and Independent Data Monitoring Committees should be established if required.

For late phase clinical trials

Trial Steering Committee (TSC)

In addition to a trial management group, a Trial Steering Committee (TSC) should be set up. The membership should include an independent chair, a statistician, a clinician(s) and any others with expertise relevant to the project, with at least one individual who is able to contribute a patient and/or wider public perspective and any additional relevant observers. Please note that independent members (i.e. these individuals should not be partly or fully employed by the host institution, listed on the grant application, or an author on the main trial publication) must make up a minimum of two thirds of the TSC membership. In some cases, an Umbrella Trial Steering Committee (UTSC) may be appropriate (e.g. for a group of trials within the same disease area), and in this case grantholders must ensure the UTSC has the required expertise.

Responsibilities of the TSC/UTSC should be set out in a Terms of Reference or Charter, and should include:

- approving the trial protocol and any significant modifications
- supervising the progress and conduct of the study
- where applicable, consider recommendations from the Independent Data Monitoring Committee

We reserve the right to attend TSC/UTSC meetings as an observer.

Copies of all TSC/UTSC minutes should be included in scientific milestone reports or where these are not required, minutes should be sent to the grants management team for your committee.

Independent Data Monitoring Committee (IDMC)

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The research project sponsor should determine whether an Independent Data Monitoring Committee (IDMC) is required. Members of the IDMC should be independent of the study team and the TSC.

Responsibilities of the IDMC should be set out in a Terms of Reference or Charter, and may include:

- reviewing the conduct of the trial, and the safety and efficacy data
- advising whether the trial should continue, be modified or closed.

Copies of all open IDMC minutes should be included in SMRs or submitted to the relevant committee team.

For research projects with an international sponsor

There may be differing oversight of committee arrangements, and these should be clearly presented to us in the relevant application form. As a minimum, we expect either a UK Trial Management Group to be established which should include UK patient and public involvement (PPI) representatives, or UK involvement in an international TMG (including UK PPI representatives) with relevant minutes included in scientific milestone reports or submitted to the grants management team for your committee. In addition, if an IDMC or TSC is in place then the relevant minutes should also be included in scientific milestone reports or submitted to the grants management team for your committee.

3.2.6. Monitoring by us

All supported research projects must be reviewed via independent peer review as per our funding committee review processes. Where required, grantholders must provide adequately completed milestone reports as requested by us and in line with timelines set by the relevant panel or committee.

We reserve the right to withdraw funding or endorsement if deemed appropriate following independent peer review. We will work with the grantholder to develop an

effective plan to withdraw support in the most appropriate way, without detrimental impact to participants receiving treatment through the trial. If we deem it appropriate to withdraw funding or endorsement, we will inform the NIHR Clinical Research Network about this change if appropriate.

Where awards are not completed in the expected timeframe, grantholders must follow the relevant funding committee process for any costed or non-costed amendments or extension. We will carry out ongoing monitoring to ensure research projects are registered and reported in line with the expectations outlined within this document.

3.2.7. Expectations of patient and public involvement

We are committed to ensuring high quality PPI and engagement plays a critical role in all supported trials. Grantholders must incorporate meaningful PPI throughout their study.

We expect PPI to be meaningful, not tokenistic, at every stage, including in the defining and developing of any research questions and study rationale where possible. In addition, PPI should be included in, but not limited to, the following activities:

- planning and design of the study
- ongoing input into the governance, management and the monitoring of the study (including having an active role in trial management groups and/or steering committees)
- developing and maintaining patient facing materials
- contributing to dissemination plans

Appropriate payments for PPI participants should be considered throughout the award. See our guidance on [budgeting for patient and public involvement activities](#).

Grantholders should ensure that the quality of PPI is continuously considered and evaluated for the duration of the trial to ensure ongoing relevant and maximum impact. Grantholders should provide training and support to PPI representatives as required to ensure high quality input. We encourage all grantholders to consider how PPI can best represent diverse perspectives to identify, reduce and remove any potential barriers to participation that may be faced by any potentially underserved groups within the trial population in question.

For further information, please refer to our webpage on [patient and public involvement in research](#).

3.2.8. Including people from under-served groups

We are committed to equality, diversity and inclusion. Furthermore, it is essential that any intervention is safe and effective for the whole population.

We expect grantholders for all research projects supported after March 2022 to do the following:

- Endeavour to recruit a diverse group of participants that represent the population needing healthcare intervention.
- Take steps to remove any potential barriers to people from under-served groups participating in research.

We expect grantholders to review their research project target population, intervention and research questions to identify what 'under-served' means for their project.

We expect grantholders to have developed recruitment strategies that aim to reach and engage any relevant under-served groups, and to be able to justify any inclusion and exclusion criteria that have been defined. Where appropriate equality, diversity and inclusion considerations should be accounted for in the statistical analysis plan.

Our expectations are consistent with the expectations of the [HRA and MHRA](#).

3.2.9. Collection of NHS numbers

The NHS number (or equivalent) should be recorded for all patients or participants entering clinical trials supported by us.

The collection of NHS numbers is strongly encouraged in other research projects involving healthy volunteers and any other study we support where long-term follow-up is likely. The purpose of this is to enable linkage between routine and clinical data sets.

3.2.10. Trials supported by commercial entities

Where a research project is supported in any way by a commercial entity, grantholders should additionally adhere to Section 11 of our Grant Conditions.

3.3. Post-research project requirements

3.3.1. Reporting of results

Summary of results

Grantholders are required to make summary results (whether positive or negative) of their research project funded or endorsed by us publicly available, within 12 months of the end of the research project. For CTIMPs, publishing a summary of results within 12 months of the end of the trial will become a legal requirement under new UK clinical trial regulations. For more information, see the guidance on changes to the clinical trial regulations. The results must be posted on the same registry as the research project was listed.

A summary of results should also be offered to the participants (or their representative) This will become a legal requirement for CTIMPs under new regulations in April 2026.

For further guidance and considerations on sharing results with participants, please read this information created by a [cross-funder UK working group](#).

Publishing findings

When submitting findings for publication grantholders must take the following actions:

- Include the trial registry ID.
- Acknowledge our support.
- Ensure publications are aligned with our [policy on open access](#).

For further information on expectations for publication, please refer to Section 13 of our Grant Conditions.

3.3.2. Making datasets and sample collections accessible for further research

At the time of publication of the primary analysis, grantholders are required to make their datasets available to other legitimate access requests for secondary research where appropriate. They must ensure discoverability of the research project dataset (for example through a suitable clinical trials data sharing repository) and have processes in place to manage data access requests and to achieve secure transfer of data where requests are granted. Data must be managed in accordance with our [Data Sharing and Management policy](#).

All sample collection associated with our awards should be made discoverable via the UKCRC Tissue Directory and Coordination Centre within a year of the collection commencing – this includes both samples banked for future use and samples collected with planned analysis (including detail on current status of accessibility – closed, open, restricted).

Grantholders are required to make their sample collections available to legitimate secondary research requests as early as possible and throughout the lifetime of Recruitment of Human Participants Policy – April 2026

the study, provided this does not conflict with the study's intended purpose. In cases where there is a well-justified reason to delay, we would normally expect samples to be made available no later than three years after the study closure date or the last visit of the final participant, from prospectively collected samples. Retaining samples beyond this three-year period without providing access for secondary research must be supported by a clear justification.

We expect an independent member (independent to the trial/study team) to be on the re-use request access committee.

4. Support and advice

For any queries about this policy please contact policies@cancer.org.uk.

5. Related documents

For more information, please see the following documents and webpages:

- [UK Policy Framework for Health and Social Care Research.](#)
- [Grant Conditions](#)
- [ISRCTN registry](#)
- [ClinicalTrials.gov](#)
- [HRA guidance on changes to the clinical trials regulations](#)
- [MHRA clinical trials hub](#)
- [Guidance on consent for future reuse](#)
- [Budgeting for patient and public involvement activities.](#)
- [Patient and public involvement in research](#)
- [Guidance for inclusion and diversity plans](#)
- [Addressing barriers to sharing results with trial participants](#)
- [Policy on Open Access](#)
- [Data Sharing and Management Policy](#)

Policy sponsor	Executive Director of Research & Innovation
Policy owner	Governance and Finance team

Executive Board or Council approval required?	Scientific Executive Board
Date of last review	April 2026
Next review due	April 2028
Superseded documents	1

8 Summary of Changes

Key changes to the policy should be recorded below:

Version	Date	Author	Approved by	Summary of Changes
2	April 2026	Kirsty Naylor	Scientific Executive Board	<ul style="list-style-type: none"> • Policy name updated • Updated or additional links to external sites (1, 3.1.4, 3.3.3, 3.2.7, 3.2.8, 3.3.1) • Additional information included to clarify scope of the policy (2) • Updated wording to references incoming HRA requirements (3.1.4, 3.3.1) • Inclusion of new section (3.2.3) • Updated wording around compliance to our policy on open access (3.3.1) • Addition of sample collections and associated

				requirements for re-use (3.3.2)
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