Research Governance Standard Operating Procedure 11 – Reviewing consenting processes, consent forms and participant information

Document details		
Version	V1.0 26/02/2026	
Effective from	26/02/2026	
Review date	26/02/2028	
Owner	Research Governance Team (research-governance@bristol.ac.uk)	
Originally Prepared by	Matt Hewson, Research Quality Officer (matt.hewson@bristol.ac.uk)	
Reviewed by	Adam Taylor, Head of Research Governance, adam.taylor@bristol.ac.uk	
Approved by	Adam Taylor, Head of Research Governance, adam.taylor@bristol.ac.uk	DocuSigned by: A6FCBDDBFE914CD...
Superseded documents	N/A	

Document history						
Version	Review date	Reviewer	Section(s) Amended	Updated version	Approver	Effective date

Table of Contents

1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found on the Research Governance webpages.

2. Background

Informed consent is the cornerstone of ethical research involving human participants, their tissue and their data. In addition to the moral obligations placed upon researchers to seek informed and appropriate consent, there are legislative, regulatory and other requirements to do so: for instance, **The Medicines for Human Use (Clinical Trials) Regulations 2004**, the **Human Tissue Act 2004**, the **UK Policy Framework for Health and Social Care Research**, and **Good Clinical Practice** (in its various guises).

In rough outline, the involvement of a participant in a study requires three things:

- That the participant, or someone who is an appropriate person to make assessments about what the participants' decision would likely be were they able to make a decision, has been given information about the study.
- That this person has freely agreed to the participant's involvement in the study, or assessed that they would freely agree to be involved were they able to do so.
- That the above has been documented.

The specifics of ensuring this is actually achieved in research can involve considerable complexity, as described below. The **member of the RGT** reviewing the consent form, participant information and those parts of the protocol concerned with consenting, should ensure that these conditions will be met by the intended documentation and forms.

This SOP generally refers to 'the person responsible for the participant's involvement' rather than 'the participant' in connection with the consenting process. For studies involving adults with capacity, the person responsible for the participant's involvement is just the participant themselves. However in two specific cases, participants are not responsible for their own involvement in the research, and another party is responsible.

- *Adults lacking capacity to consent*.
    - CTIMPs: **The Medicines For Human Use (Clinical Trials) Regulations 2004** specifies that where adults lack capacity in the sense of **The Mental Capacity Act 2005** consent can only be given by their 'legal representative' (though where the participant lacking mental capacity is able to "form an opinion and [assess] the information", this must also be considered).
    - Non-CTIMPs: The **Mental Capacity Act 2005** specifies that for non-CTIMPs some representative (typically a family member) should be consulted on whether the participant would wish to be involved. These regulations do not require that where the participant lacking mental capacity can form an opinion, this must be considered. However they do state that where the participant "indicates (in any way) that [they wish] to be withdrawn from the project [they] must be withdrawn without delay" and it is best practice to seek assent from the person lacking capacity wherever possible.
- *Children*.
    - CTIMPs: **The Medicines For Human Use (Clinical Trials) Regulations 2004** specify that for participants under 16, consent can only be given by someone

with 'parental responsibility' in the sense of the **Children Act 1989** in England and Wales, or where this is not possible, a legal representative. Where the minor is able to "form an opinion and [assess] the information" though, their own opinion must be considered – this is typically referred to as 'assent'.

- Non-CTIMPs: The study protocol should specify whether the CTIMP approach, with a clear cut-off at 16, will be adopted **OR** that the investigator seeking consent will assess, on a case-by-case basis, whether a participant under 16 (and often above a lower, stated age) is competent to understand the study and to make their own decision regarding consent. As above, where parental consent is sought, participant 'assent' should also be considered.

This SOP describes how **members of the RGT** reviewing studies prior to Sponsorship should assess the consenting processes described in the protocol, and associated consent forms and participant information, to ensure their compliance with the above requirements. Parenthetically, therefore, it describes how researchers should design their consent-taking processes prior to review by **members of the RGT**.

3. Scope

This SOP applies to the consenting processes, informed consent forms and participant information reviewed by **members of the RGT** prior to study Sponsorship by the University. It does not provide exhaustive information, and where necessary the **reviewing team member** should consult the **Head of Research Governance**, and the external documentation linked at the bottom of this SOP.

In certain narrow sets of circumstances, participant tissue or data may be used without consent; for instance, human tissue studies that acquire surplus samples which are used under a consent exemption, or data studies that use participant data without consent under the auspices of the CAG. Definitionally, this SOP does not apply to these situations.

This SOP should be used in conjunction with **RG SOP 6 – Sponsoring a study**.

4. Responsibilities

This SOP is for use by the **RHTMs** and **RGOs** when reviewing study materials prior to Sponsorship, and for answering queries from researchers concerning consent.

5. Procedure

The **member of the RGT** reviewing the documentation should assess whether it satisfies the below requirements, as appropriate to the precise nature of the study.

5.1 Participant information - content

HRA guidance specifies that the person responsible for the participant's involvement "be informed, in broad terms, of the nature and purpose of the research and the material risks, benefits and reasonable alternatives", and moreover, for CTIMPs, "have been informed of the nature, significance, implications and risks of the trial".

The information provided should usually include the following (some of which are from the HRA Participant Information Quality Standards, which must be separately reviewed by the study team and incorporated into the documentation):

- The research project

    - The nature and purpose of the research
    - Why the individual has been approached
    - The name of the research project
    - The IRAS/REC number of the project
    - That the trial involves research
    - Who is conducting the research
        - Investigators
        - Sponsors
        - Funders
    - Contact details for:
        - Someone who can provide more information and discuss this with the person responsible for the participant's involvement.
        - Complaints or concerns
        - A contact point available throughout the study
        - One of the above must be able to refer enquirers to the Data Protection Officer
    - The research treatments, and the probability of assignment to each treatment (where applicable)
    - The procedures involved in the research, including all invasive procedures
    - The number of participants involved
    - Aspects of the trial that are experimental or outside normal practice
- The role of the participant in the research
    - The reason the participant has been approached
    - Their right to refuse or withdraw at any time, and how to do this
    - What will happen to the participant
        - The treatments, interventions, and investigations the participant may undergo, the appointments they are expected to attend, the questionnaires they are expected to complete or discussions they are expected to participate in.
        - The duration of their involvement
        - Any possible risks or benefits
        - Alternative treatments that are available
    - What will happen to the participant's data
        - What data of the participant's will be accessed, and by whom.
        - The ways identifiable data will be made confidential, using the HRA's UK GDPR 'transparency wording'.
        - Whether and how data (typically, though not always, anonymised data) will be stored, published and/or shared with other researchers.
    - What will happen to the participant's tissue (where applicable)
        - How its collection, storage and disposal will work, including whether consent will be sought for the samples to be retained for further research at the end of (or during) the study.
        - Where DNA analysis is intended, whether the analysis will be genetic or non-genetic, and whether any non-human micro-organisms in the human tissue sample will be analysed.
    - Any compensation for their time, remuneration for expenses or associated non-medical benefits or rewards; any expenses the participant may be expected to

bear. The details of compensation for trial-related injury, including contact details. The ways in which the participant's data (including medical records) will be accessed by the study team, and other researchers in the future
    - That they will be provided with updated information throughout the study as needed
    - The HRA UK GDPR transparency wording should be used.

5.2 Participant information - format

The information provided should be in a level of detail commensurate with the study's complexity, risk, time commitment, and moreover its intended audience. Technical terminology should be minimised, and where needed, explained on its first use. Unfamiliar devices or equipment can be explained with photos. The HRA has certain specific Participant Information Design and Review Principles which should be separately reviewed by the study team, and must be incorporated into the documentation. These principles can be briefly, though incompletely, summarised under the following six headings:

- Public contributors are involved in the design and review process
- The information provided is "succinct" and "proportionate"
- Language is "as clear as possible"
- The information is provided in a suitable format
- The format is such that it aids comprehension
- The information is "tailored" to its intended audience

The HRA also provides Participant Information Quality Standards, which, again, the participant information must meet. Those relevant to *how* the information is presented can be incompletely summarised as follows:

- Explaining acronyms and abbreviations at their first use
- Using British English throughout
- Captions, 'alt-text', transcripts and subtitles are provided for images, graphics and videos

There is no legal requirement that the participant information be written, but HRA guidance states that "it is normally considered best practice and advisable" to have written information, alongside multimedia formats if necessary. Physical formats should be available to those unwilling or unable to use online or multimedia formats. Where the person responsible for the participant's involvement does not read the relevant language, (for instance, because they read an alternative language, or because they do not read) the information should be provided in another way – whether that is verbally, in translation, or so on.

That the person responsible for the participant's involvement has been provided with this information is not, by itself, sufficient for their informed consent. Rather, they must *understand* that information. Typically, this involves an opportunity to discuss it with a member of the study team, and the CTIMP legislation specifically states that the person responsible for the participant's involvement must have had "an interview with the investigator, or another member of the investigating team". Even where this is not explicitly required, the need for the person responsible for the participant's involvement to be *informed* (rather than just *in possession of*

information) will typically require giving them an opportunity to discuss the research with someone associated with, and knowledgeable about, the study. This will often happen just prior to the consenting process *as such*.

5.3 Discussions

For research involving more than a simple questionnaire, or other limited interaction: it will generally be expected that there will be a documented conversation after the provision of information and before the signing of consent, usually immediately before. The conversation should include an opportunity for the potential participant to ask any questions, and for them to be answered fully.

The researchers must allow sufficient time after the provision of information for the person responsible for the participant's involvement to read and absorb it. This generally means a minimum of 24 hours, though this may vary based on the degree of intervention, the complexity of the information, and the circumstances of recruitment. The intention should be clearly detailed in the ethics application. The REC will determine whether the planned process is sufficient.

The conversation should be with someone who has adequate knowledge of the research to answer questions, and who understands (per the HRA) at least the following:

- "[the] protocol and the potential implications it may have on the people to be involved
- [the] alternatives that may be available to potential participants, this may include treatment alternatives;
- [how] to communicate effectively with potential participants, including explaining complex scientific / medical concepts;
- [how] to optimise the voluntary nature of decision making, avoiding undue influence."

Where a translator or other intermediary is required (e.g. because the potential participant does not speak English, is not able to read the information, etc. – not because of age or diminished mental capacity), the process should ensure, and demonstrate, that all information in the PIS has been provided to the potential participant in a manner that they can understand and that it is the potential participant themself who decides whether to participate.

Translation for consent purposes should be provided by a translator who is independent of both the study and the participant – this usually means a professional service, such as Language Line. The process should be confirmed by a witness, who is able to read the PIS and, in the case of translation, understand the relevant language. They confirm that the potential participant was provided with all of the information in the PIS, understood it, and voluntarily agreed to participate. The witness must be independent of the study (i.e. not on the delegation log) – they could be the translator, a friend or relative, or a member of staff who is not involved with the study.

The person taking the consent following the interview should be an appropriately trained and delegated member of investigator team. Typically in CTIMPs this should be a doctor or dentist. Deviations from this expectation should be discussed with the Research Governance Team, and approved by the MHRA. Where someone less familiar with the scientific and medical

details of the research is taking consent, someone who fully understands this information should be readily available throughout.

5.4 Consent Form Confirmations

The precise content of the consent form will depend on the nature of the study and associated human participant involvement. A typical consent form, however, may ask the person responsible for the consent form to confirm at least some of the following:

- The person responsible for the participant's involvement understands what will happen to the participant in the course of the study (and per HRA guidance, that:)
    - That they have read, watched or otherwise understood the information provided in the information sheet or equivalent media, where the date and version of this information is specified.
    - That they have had an opportunity to discuss the participant's involvement with the PI or appropriate delegate
    - They understand that the participant's involvement is voluntary and can be withdrawn at any point, without compromising their medical care or legal rights
- The person responsible for the participant's involvement understands what will happen to the participant's data
    - They understand what data of the participant's may be accessed, and by who; they consent to this.
    - They understand that the participant's anonymised data may be shared to support other research and researchers in the future, including researchers outside of the UK and EEA.
    - They understand that the participant's GP may be informed of their involvement in the study
    - They understand what will happen to the participant's data if the participant withdraws from the study.
- The person responsible for the participant's involvement understands what will happen to the participant's tissue
    - They understand the types of samples to be collected.
    - They understand the specific ways in which the participant's tissue may be put to use within this research project.
    - They understand the 'broader' or more 'generic' ways in which the participant's tissue may be put to use in future research – including DNA analysis or the creation of cell lines.
    - They understand that their tissue is given 'as a gift' and they will have no rights to any eventual profits that might result from the research.
- The person responsible for the participant's involvement agrees to the participant's involvement in all of the above.

5.5 Signature / Confirmation

It is a requirement of the **Medicines for Human Use (Clinical Trials) 2004 Regulations** that in CTIMPs the consent form is signed (unless "the person is unable to sign or to mark a document so as to indicate his consent", in which case, see below). It is not a requirement for non-CTIMPs, though a joint HRA-MHRA statement specifies that it is still best practice, and

"investigators should document consent unless not doing so can be justified (and approved by a REC)".

The use of electronic signatures is acceptable in both CTIMPs and non-CTIMPs. The process should conform with SOP 17 Electronic Signatures.

5.6 Emergency Settings

In research relating to emergency medicine; if the participant is temporarily incapacitated or otherwise unable to consent, and would in other circumstances be able to do so, it may be appropriate, with advance REC approval and oversight, to enter participants into research without their prior consent.

In this case, ICH GCP requires that the participant must be approached at the earliest opportunity, typically upon recovery, and their consent sought. If consent is denied, the participant must be withdrawn from the research and any associated research data destroyed.

If potential participants would not usually consent for themselves, due to age or lack of capacity, then parental consent or an appropriate person's assessment must be sought as soon as possible. If emergency protocols *and* third-party consent/assessment are likely to be involved (e.g. for an emergency paediatric care study, or for a stroke study in which potential participants might not regain full capacity), this should be clear in the REC application and the intended process approved.

6. Related documents

Internal documents

RG SOP 6 – Sponsoring a study

External documents

The Medicines for Human Use (Clinical Trials) Regulations (2004)

The Mental Capacity Act (2005)

The Children Act (1989)

The Human Tissue Act (2004)

HRA UK Policy Framework for Health and Social Care Research

HRA and MHRA joint statement on seeking consent by electronic methods

HRA Participant Information Quality Standards

HRA Participant Information Design and Review Principles

ICH E6 (R3) GCP

MRC – HRA Consent and Participant Information Guidance

NIHR – How to conduct research involving interpreters and translators