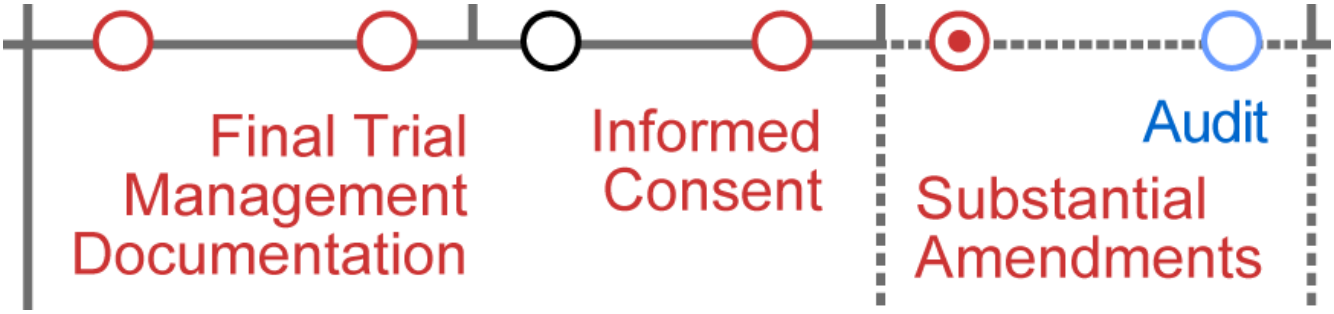
Routemap

Informed Consent



Trial Recruitment Phase

Informed Consent follows the Trial Begins station and precedes the Ongoing Management & Monitoring station. Obtaining informed consent is a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

Trial participants must give their informed consent before they are entered into a trial*. Consent should be obtained before the first trial-specific activity is undertaken. For Clinical Trials of Investigational Medicinal Products (CTIMPs), Schedule 1 of the Clinical Trials Regulations (as amended) are the requirements for consent.

During a trial, the willingness of participants to continue should be reaffirmed periodically. If significant new information becomes available, participants should be reconsented using revised (and re-approved) consent documents so that, if applicable, their continued consent is confirmed.

**For certain emergency trials involving vulnerable participants (minors or incapacitated adults - see below).*

Participant Information Sheets

The HRA's online consent guidance provides templates for preparing participant information sheets and consent forms suitable for different types of research, including a template for pragmatic trials (.PDF). Ideally, consent documents

should be co-designed or reviewed by patients. Sponsors are increasingly adopting electronic methods to seek consent (eConsent), and the HRA and the MHRA have published a joint statement on its use.

Trials involving incapacitated adults

For CTIMPs, Schedule 1 of the Clinical Trials Regulations (as amended) defines a legal representative, and Table 2 of the HRA guidance outlines the hierarchy of consent for incapacitated adults using personal or professional legal representatives. The provisions in England, Wales and Northern Ireland differ from those in Scotland.

Trials involving incapacitated adults in the emergency setting: The Medicines for Human Use (Clinical Trials) (Amendment No. 2) Regulations 2006 made provisions for trials involving incapacitated adults in emergency settings in which participants can be entered into a trial before informed consent is obtained (see Section 21 of the HRA Guidance). Incapacitated adults should receive information at their level of understanding. If participants can form an opinion and assess the information, their explicit wishes should be considered. Part 5 of Schedule 1 of the Clinical Trials Regulations provides a list of conditions and principles that must be in place.

Learning modules for consent involving adults with without capacity, and consent in the emergency setting can be accessed through NIHR Learn. Further resources to support the conduct of trials involving adults with impaired capacity can be found on the Consult Website.

Trials involving minors

The Clinical Trials Regulations define a minor as a person under 16. Table 1 of the HRA guidance (.PDF) describes the hierarchy in which to determine who should be approached to give informed consent on behalf of a minor. Where minors can express their own views on a study, they should be involved in a way that is appropriate to their understanding and development and the extent to which they wish to engage. Guidance published by the Nuffield Council on Bioethics provides more information on consent in trials involving minors.

Trials involving minors in the emergency setting: The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008 have made provisions for trials involving minors in emergency settings in which minors

can be entered into a trial without prior consent. The Regulations require a person with parental responsibility or a legal representative to provide consent as soon as possible after entry into the trial (see Section 16 of the HRA guidance (.PDF) for further information). Part 4 of Schedule 1 of the Clinical Trials Regulations provides a list of conditions and principles that must be in place. Information from the Institute of Population Health at the University of Liverpool on research without prior consent in the emergency treatment of critically ill children can be found below.

Learning modules for consent in paediatric research can be accessed through NIHR Learn.

Non-CTIMP Research

For research other than CTIMPs, the HRA's online consent guidance provides information about consent in incapacitated adults and children and young people in the four UK nations.

Access of Patient Information for Research Without Consent

In certain research studies, there may be sufficient justification to access confidential patient information without consent. Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes. The HRA took responsibility for Section 251 and established the Confidentiality Advisory Group (CAG).

General Data Protection Regulations (GDPR)

The GDPR requires organisations to publish transparency information when processing personal data for health and care research. Suitable transparency terms for public sector sponsors to use in participant information sheets can be found on the HRA website, along with comprehensive guidance.

Further Reading:

- HRA Guidance (.PDF): Applying a proportionate approach to the process of seeking consent.
- The Clinical Trials Transformation Initiative (CTTI), a US public-private partnership, has produced guidance and tools relating to informed consent.
- The PeRSEVERE project has developed guiding principles to help ensure withdrawal and other trial participation changes are prepared for and managed to protect participants' interests and trial integrity.

Research articles:

The MRC-NIHR Trials Methodology Research Partnership (TMRP) have resources relevant to consent:

- The Quintet Recruitment Intervention (QRI) aims to facilitate informed decision making by patients about RCT participation
- This review introduces qualitative research techniques and explains how this approach can be used to understand, and improve, recruitment and informed consent for trials.
- This paper (.PDF) describes three key techniques that recruiters can use to address patients' treatment preferences to facilitate recruitment and informed consent.
- This article (.PDF) identifies broad practices that support or hinder equipoise communication.
- The DevPICv2 (.PDF) provides a measure of informed consent that can be applied directly to recruitment appointments where trial participation is discussed to evaluate the quality of recruiter information provision and evidence of patient understanding.
- The Q-QAT (Quanti-Qualitative Appointment Timing) (.PDF) is a simple technique to identify key challenges to recruitment that stem from how the RCT and treatments are portrayed to patients in recruitment appointments.
- Russell and colleagues identify key populations that are underserved by research, where methodological and ethical challenges around consent are encountered, and call for future research.

The TMRP have specific resources for people with communication, hearing, sight & other physical disabilities

- The Consent Support Tool has been developed specifically to facilitate involvement of people with communication disorders in health research studies.

- The Collaboration of Aphasia Triallists (CATS) host resources to support researchers develop accessible consent forms.
- There are examples of good practice available through collaborations such as the patient information sheet access group.
- Many charities and third sector organisation provide resources to support consent processes across health and research e.g. Autistica.

TMPR resources for trials involving incapacitated adults

- This website from the CONSULT project brings together resources to support researchers conducting research with adults who have impaired capacity and summaries of the legal frameworks.

The University of Liverpool, Institute of Population Health:

- The Connect Study Guidance (.PDF) provides further information about research without prior consent (deferred consent) in trials investigating the emergency treatment of critically ill children.
- The ENHANCE Guidance explores potential communication strategies with bereaved families when their relative has died following enrolment into an emergency/critical care trial, without prior informed consent.
- Resources include example staff training video and an animation to help explain to children and young people about their participation in research when they were very poorly.