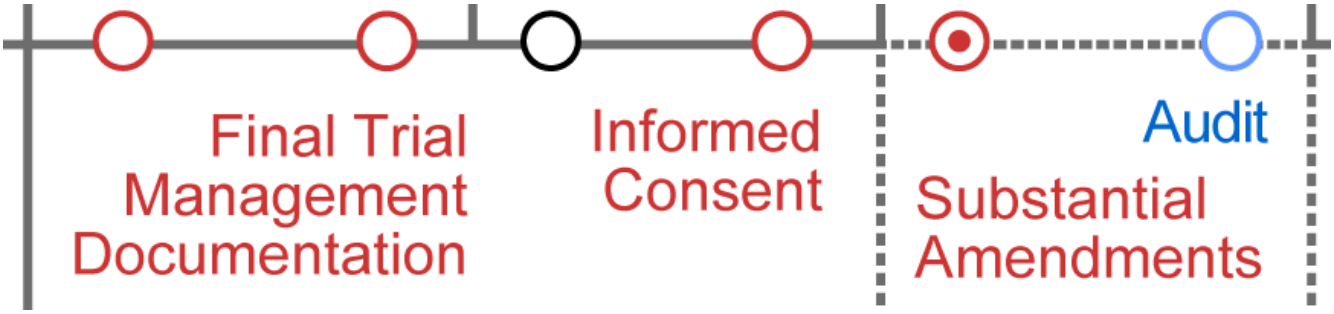
Informed Consent



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.

Informed Consent

Informed consent is a legal and ethical requirement for research involving human participants. For consent to be valid, it must be voluntary, given by a person with capacity to consent, and based on sufficient information to make an informed decision. If new information arises during a study that may affect participants' willingness to continue, they should be re-consented using updated, ethics-approved documents.

Simplified Approaches to Seeking Consent

The amended Clinical Trials Regulations introduce flexibility in how informed consent may be obtained, for example, by using a simplified approach for low-risk/low-burden trials of authorised medicinal products routinely used in the UK, where no additional, non-routine interventions or diagnostic procedures are performed. One example would be to obtain verbal consent, provide the participant with information to take away, and document the consent discussion in the medical records. The use of simplified consent must be justified and

approved by a Research Ethics Committee (REC).

Participant Information Sheets and Consent Forms

The Health Research Authority (HRA) online consent guidance provides templates for preparing participant information sheets and consent forms suitable for different types of research, including pragmatic trials (.PDF).

Researchers should use these resources early in study design and, where possible, co-design or review consent materials with public contributors. Electronic consent (e-Consent) is increasingly being adopted, and the HRA and Medicines and Healthcare products Regulatory Agency (MHRA) have published a joint statement on the use of e-Consent.

Trials Involving Incapacitated Adults

The amended Clinical Trials Regulations outline provisions for trials involving incapacitated adults in emergency settings, permitting enrolment prior to obtaining consent (see Section 21 of the HRA Guidance (.PDF)). Part 5 of Schedule 1 of the Clinical Trials Regulations specifies the conditions and principles that must be satisfied.

Learning modules for consent involving incapacitated adults, 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

A minor as a person under the age of sixteen. Table 1 of the HRA guidance (.PDF) (.PDF) describes the hierarchy of consent for minors, outlining who may give consent on their behalf.

Children and young people should be involved in the consent process to the extent appropriate to their age, understanding, and willingness to engage.

Guidance published by the Nuffield Council on Bioethics (.PDF)includes information on consent in trials involving minors.

Emergency Research Involving Minors

The amended Clinical Trials Regulations permit the inclusion of minors in emergency trials without prior consent, provided that consent is sought from a person with parental responsibility or a legal representative as soon as possible after enrolment (see Section 16 of the HRA Guidance (.PDF)). Further methodological guidance is available from the University of Liverpool's Institute of Population Health (.PDF): Research without prior consent in critically ill children.

Non-CTIMP Research

For non-CTIMPs, the HRA's consent guidance explains consent processes for incapacitated adults and for children and young people, with links to nation-specific legislation across the UK.

Access to Patient Information for Research Without Consent

In certain studies, it is lawful and ethical to access confidential patient information without consent when there is a strong justification. Section 251 of the NHS Act 2006 enables the Secretary of State for Health to set aside the common-law duty of confidentiality for defined medical purposes. The HRA oversees this process through the Confidentiality Advisory Group (CAG), which reviews applications and provides expert advice.

Data Protection and Transparency

Under the UK GDPR, organisations are required to publish transparency information when processing personal data for health and care research. The HRA website provides model transparency wording for public-sector sponsors to use in participant information sheets and comprehensive data protection and confidentiality guidance for researchers.

Further Reading

- NIHR Be Part of Research: Resources for participants that explain consent and the role of a legal representative.
- HRA Guidance (.PDF) (.PDF): Applying a proportionate approach to the process of seeking consent.
- Nuffield Council on Bioethics (.PDF): Guidance on involving children in research.
- University of Liverpool's Institute of Population Health (.PDF): Research without prior consent (deferred consent) in trials investigating the emergency treatment of critically ill children

- NIHR Learn: Training modules for informed consent, including trials involving incapacitated adults and minors
- The Clinical Trials Transformation Initiative (CTTI): Guidance and tools related to informed consent
- The PeRSEVERE Project: Guiding principles to help ensure withdrawal and other trial participation changes are prepared for and managed