University College London Hospitals
NHS Foundation Trust

# Consent to Participation in Research

## UCLH policy

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| **Policy number** | 007/CLN/T |
| **Issue number** | 6 |
| **Issue date** | 09/05/2023 |
| **Approved by** | SDT Policy Approval Sub Group (PASG) |
| **Responsible Director** | Director of Research |
| **Policy Author** | Associate Director, Research Governance and Operations (Joint Research Office) |
| **Review Body** | Senior Leadership Team (Joint Research Office) |
| **Documents to read in conjunction with this policy** | UCLH Consent Policy and Procedure<br>HRA guidance on informing participants and seeking consent |
| **Complete review by date** | 30/04/2026 |

***If reading a printed copy always check that it is the most recent approved version which can be found on the Policies page on the staff intranet (myUCLH).***

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| **List of reviewers & contributors**<br>*Include here whether Counter Fraud; Infection Control Team or Facilities Management (FM) were asked to review the policy and if comments were received* | *Research Quality & Safety Manager (Joint Research Office)*<br>*Research Audit & Quality Officer (Joint Research Office)*<br>*Associate Director Research Governance and Operations (Joint Research Office)*<br>*Associate Director Research Finance and Business Functions Director of Quality and Safety (Joint Research Office)*<br>*Information Governance Lead (Research) (UCLH Information Governance)*<br>*EPIC Electronic Health Records System Research Module team*<br>*Trust CQC and Quality Manager* | |
| *Summary of main points from consultation* | | |
| **Review body**<br>*Author to complete* | Joint Research Office Senior Leadership Team | January 2023 |
| **Date of meeting when policy approved by PASG** | 14/02/23 (stc) final approval by Chair 08/05/23 | |

**Review amendment log** – *must be completed each time the policy is amended*

| Version No | Date amendments made | Description of change |
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| 6 | January 2023 | *Update to reviewers and review groups.*<br>*Inclusion of emergency research procedures as exclusion to the policy..*<br>*Update to HRA links.*<br>*Inclusion of content from UCLH IG* |
| 5 | October 2019 | *Details from the "R&D: UCLH Standard Operating Procedure for Informed Consent" have been merged with this policy*<br>*-Additional definitions included to clarify key terms such as Investigator Site File and Delegation Log*<br>*-The HRA's guidance on adopting a proportionate approach to taking consent added*<br>*-The responsibilities of the HRA, CAG and Data Controller added with the latter introduced as part of the recently enforced EU General Data Protection Regulation (GDPR) 2018* |

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| | | *-Detailed guidance on the information to be conveyed to patients when introducing the study has been added*<br>*-The process for documenting consent has been expanded to include the use of EPIC, UCLH's electronic health record. Step by step processes for documenting the consent process and uploading the scanned signed consent form to EPIC have also been added.*<br>*-A step by step process for how to correctly supersede old trial documents has been added.*<br>*-Taking informed consent of incapacitated adults for CTIMP and non-CTIMP research has been further expanded to explain the key regulations involved (Mental Capacity Act and the Medicines for Human Use (Clinical Trials) Regulations 2004)*<br>*-Information regarding the consent for DNA analysis has been added to supplement human tissue research guidance*<br>*-Electronic methods for seeking informed consent has been added as the HRA and MHRA released a joint statement in 2018 regarding its use in research* |

## Environmental

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## 1. Summary

This policy sets out the requirement to ensure that legally valid consent is obtained when recruiting participants into research studies at University College London Hospitals (UCLH). It is recommended that this policy is read in conjunction with the Health Research Authority (HRA) guidance on informing participants and seeking consent and Consent and Participant Information Guidance.

## 2. Equality Impact Statement

The author of this policy has undertaken an Equality Impact Assessment (EIA) and has concluded that there is no negative impact on any of the protected equalities groups. The completed EIA form is available from the Policy Manager.

## 3. Introduction

Informed consent is the process by which a participant voluntarily confirms their willingness to participate in a particular study/trial, having been informed of all aspects of the study that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form (ICF). The consenting process must also be documented or recorded in the patient notes on the EHRS (where applicable) as an accurate account of when the patient was provided with the Participant Information Sheet (PIS), what discussions were had during the consent process, and when the patient/participant signed the ICF. The UK Policy Framework for Health and Social Care Research (3rd Edition, 2017) considers informed consent to be at the heart of ethical research. There is broad international agreement that it is morally, legally, and professionally unacceptable as per principles of Good Clinical Practice (ICH GCP E6, R2), the Medicines for Human Use (Clinical Trials) Regulations 2004, specifically Statutory Instrument (SI) 2004/1031 Schedule 1 Part 3 and the General Data Protection Regulation (GDPR), to perform a research-related procedure without first obtaining informed consent. This policy is designed to ensure that all researchers at UCLH obtain legally valid consent before recruiting participants into studies approved by the appropriate regulatory bodies and the Joint Research Office (JRO).

## 4. Objectives

This policy outlines the requirements for obtaining and documenting informed consent before recruiting participants into **approved** research studies at UCLH. 'Approved' research studies are considered to be any project in receipt of the appropriate regulatory approvals, e.g.:

- HRA Approval
- Research Ethics Committee (REC) Favourable Opinion
- Medicines and Healthcare products Regulatory Agency (MHRA) notice of acceptance/no objection (CTIMP and non-CE marked device studies only)
- UCLH Confirmation of Capacity and Capability (formerly 'UCLH NHS Permission').

All applicable approvals must be in place **prior** to research activity and patient consent commencing.

## 5. Scope

This policy applies to all substantive and honorary UCLH staff involved in studies which fall within the remit of the UK Policy Framework for Health and Social Care Research (3rd Edition, 2017), and its definition of 'research' (see 6. Definitions). Types of research studies can include:

- Interventional studies:
  - Clinical trial of an investigational medicinal product (CTIMPs)
  - Advanced therapy investigational medicinal product (ATIMPs)
  - Clinical investigation or other study of a medical device
  - Combined trial of an investigational medicinal product and an investigational medical device
  - Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice e.g. surgical procedures
  - Basic science study involving procedures with human participants

- Observational studies (Non-Interventional):
  - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
  - Study involving qualitative methods only
  - Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
  - Study limited to working with data (specific project only)
  - Research tissue bank (where consent is required)
  - Research database (where consent is required).

This policy does not apply to projects which fall outside of the UK Policy Framework's definition of research (e.g. clinical audits, service evaluations, standard care practice); staff should instead refer to the *UCLH Consent Policy & Procedure.* This policy does not apply to studies where consent is not required (or where the Confidentiality Advisory Group [CAG] has approved the project to obtain identifiable patient data for research purposes without consent).

This policy does not apply in cases of emergency research during national health emergencies such as national pandemics. In such circumstances, the Department of Health and Social Care and/or the Health Research Authority may issue guidance which allows for exemptions to consent under these extraordinary circumstances.

## 6. Definitions

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| Research | Research is defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research |

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| | (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of the UK Policy Framework for Health and Social Care Research. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework (*UK Policy Framework for Health and Social Care Research, 3rd Edition, 2017*). |
| Informed Consent | Informed consent can be defined as consent that is given freely after a person is informed of the nature, significance, implications and risks of the study. In order for consent to be legally valid, it must be given **voluntarily** by an appropriately **informed** person who has the **capacity** (or via a legally designated representative in the case of participants under the age of 16, vulnerable subjects or incapacitated adults), to consent to the research in question and the **right to withdraw** at any time, without reason. |
| Assent | Agreement given by a child/young person, or others who are not legally empowered to give consent. |
| Participant Information Sheet (PIS) | A document detailing all relevant information about the study, including all information discussed verbally. It is vital that potential participants are given ample time to read the PIS and to discuss the consent with others is they so wish. Information in the PIS must be comprehensible to lay-people without specialist education or technical background. The PIS must be identifiable by date and version number. The 'header' should have the UCLH Trust logo on the front page, and contact details of the research team. Other logos may be added as appropriate. The PIS is provided by the Sponsor to study teams and approved by REC, HRA and the JRO (as part of local capacity and capability reviews) prior to use. |
| Informed Consent Form (ICF) | A consent form should normally be used to record the consent process and a participant's agreement to take part in a study. The 'header' should have the UCLH Trust logo on the front page, and contact details of the research team. The consent form must be identifiable by date and version number. The signatories on the consent form should be those who are involved in the consent process such as the participant or the participant's legal representative/consultee and the researcher. Consent forms for a participant's legal representative should address them directly and should be written appropriately. The consent form must be clear that they are being asked for consent on behalf of the research participant. The ICF is provided by the Sponsor to study teams and approved by REC, HRA and the JRO (as part of local capacity and capability reviews) prior to use. |
| Investigator Site File (ISF) | The ISF is the Principal Investigator's (PI)/host site's file and contains patient identifiable information. At the beginning of a study, the ISF should be prepared and then subsequently updated throughout the lifetime of the study. The file should be stored in a safe and secure location with restricted access to staff personnel only. |
| Delegation Log | The study site delegation log is an essential study document to define and record the responsibilities of the research team authorised by the PI for the |

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| | effective delivery of a particular study. The delegation log is used as evidence to demonstrate how individuals are assigned to study tasks appropriate to their education, training and experience. It must be stored within the ISF. |

**Proportionate approach to seeking consent**

Per HRA guidance "Applying a proportionate approach to the process of seeking consent" and subsequent amendments, a proportionate approach to seeking informed consent should be adopted so potential participants are not faced with complex and lengthy information sheets. The approach involves assessing benefits and risks in order to adopt the most appropriate and practical method of seeking informed consent. Researchers and Research Ethics Committees (RECs) should always evaluate how the information is presented to participants and whether it is necessary, justified and proportionate. It is imperative that the methods utilised to obtain informed consent and the degree of detail provided should be proportionate to:

- The nature and complexity of the research
- The risks, burdens and potential benefits to the participants and/or society
- The ethical issues at stake

Considering the language used, the layout and format of the information, and whether any additional visual aids will be used during the consenting process can help provide the necessary information in a clear way without confusing the potential participant. This should facilitate genuine understanding of the study and its requirements. Further detailed information must be accessible to the potential participant, especially if the information has implications for whether they would want to participate or not in the research e.g. significant drug interactions. Please refer to the HRA guidance document for further information.

## 7. Duties and responsibilities

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| Person with duty of care to the patient | Ultimately it is the professional responsibility of the person with the duty of care towards the patient to ensure that the patient had given valid informed consent before being recruited into a research study. |
| Chief Investigator (CI) | The CI has overall responsibility for the conduct of the whole research study/trial in the UK. It is the Chief Investigator's responsibility to ensure that a procedure for obtaining legally valid consent is outlined in the study protocol. |
| Principal Investigator (PI) | The PI has responsibility for the study at site (e.g. UCLH). It is the PI's responsibility to ensure that a protocol with the appropriate regulatory and NHS approvals is in place before the research can begin. Should the individual agree to participate |

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| | in the study, it is the PI's responsibility to ensure that the General Practitioner and any other relevant health professionals involved in the individual's care are informed of the participation as appropriate, subject to the individual's consent for this information to be passed on. The PI can delegate consent responsibilities to other medically qualified research staff members. For non-medical research staff, consent can be delegated provided the criteria in Section 8.1 is met. The plan for obtaining informed consent, including delegation of responsibilities, must be agreed by the Research Sponsor, Research Ethics Committee and Health Research Authority. |
| Health Research Authority (HRA) | The HRA are an arm's-length body of the Department of Health and Social Care. The main purpose of the HRA is to protect, and promote the interests of patients and the public in health and social care research. They aim to ensure research is ethically reviewed and approved, promote transparency in research and provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects. |
| Research Ethics Committees (REC) | The REC is part of the Health Research Authority (HRA), and is responsible for safeguarding the dignity, rights, safety and wellbeing of research participants. The following must be approved by the REC as part of the study documentation:<br>• The process by which consent will be requested<br>• The content and format of the participant information sheet and consent form<br>• Special procedures for participants with difficulties concerning capacity, comprehension or communication<br>• Procedures for delegating consent, where applicable. |
| Confidentiality Advisory Group (CAG) | The CAG are part of the Health Research Authority (HRA). In exceptional |

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| | circumstances, they may grant authorisation to proceed without taking consent from participants. The CAG must be satisfied that there is no practical way to seek informed consent in the proposed study. Any authorisation granted will be temporary, for the time period specified in the application. More information about the role of the CAG is available at https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/ |
| Research Sponsor | The Research Sponsor has primary responsibility for ensuring that the design, conduct and reporting of the study meet appropriate standards, including those of informed consent. All research falling under the remit of the Secretary of State for Health must have a formal sponsor. |
| UCLH/UCL Joint Research Office (JRO) | The JRO (UCLH Research & Development) will ensure that appropriate authorisations are in place and that all appropriate Research Governance procedures have been followed before the study is allowed to begin recruiting participants. |
| Research Participants | By giving informed consent, participants take on responsibility to comply with the requirements of the research. They are free to withdraw their consent at any time, without reason. Please refer to Section 8, below. |
| Data Controller | The data controller determines the purposes for which and the manner in which any personal data are, or are to be, processed, including the data obtained during the informed consent process. The Sponsor generally determines what data is collected for a research study and therefore acts as the data controller in relation to the research data. |

## 8. Specific details to explain the policy

### General requirements for taking informed consent in research

- The research team member who is going to take informed consent must be employed by UCLH (substantive or honorary contract), and sufficiently knowledgeable and competent to recruit participants to that particular study. The role should be consistent with their professional role and guidelines.
- The line manager, chief investigator, principal investigator and (if applicable) academic supervisor must ensure that this criterion is met.
- The staff member should be willing to take on the additional responsibility for requesting and obtaining consent.
- The staff member must have received appropriate training for the role and have a sufficiently comprehensive understanding of the purpose, nature, benefits and risks of the research study/trial. All relevant training must be documented in the ISF (and staff training records, where applicable).
- An effective channel of communication must be maintained between all members of the research team throughout the period of the research study/trial.

### 8.1 Prior to taking informed consent

The PI must sign and date the Study Delegation Log (kept in the Investigator Site File [ISF] / Trial Master File [TMF] if they are also the CI) confirming that they are willing to delegate the responsibility of taking informed consent to appropriate members of their study team, who must also sign the Study Delegation Log. The PI is the person ultimately responsible for the participant's care and must have oversight of the informed consent process via an effective line of communication. The Delegation Log is a core document for each participating NHS site, and part of the HRA's UK Local Information Pack (https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx). The HRA have produced a Delegation Log template for use at NHS sites, however the sponsor may provide their own template to the study team.

If the informed consent process relates to any of the following types of studies, then informed consent must be taken by a medical professional (e.g. consultant/physician):

- CTIMPs
- ATIMPs
- Surgical procedures
- Medical device trials
- Any complex study where the research team request a medical professional to take informed consent.

For all other studies, the PI may delegate consent to an appropriately qualified and trained member of the study team, as recommended in ICH GCP E6 (R2) 4.8. If non-medical research staff (e.g. a Research Nurse or Clinical Trials Practitioner) are to accept responsibility for supporting the informed consent process, it is important that the following criteria are met:

- They are prepared to take on this additional responsibility and feel confident to take informed consent in line with their professional code of conduct (e.g. Nursing and Midwifery Council Code of Professional Conduct, ICH GCP etc.)
- They have a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities (where applicable) and the associated disease area, all of which must be documented in their training folder
- They should be qualified by experience and/or should have received appropriate training for this study (e.g. have attended the site initiation visit, where applicable)
- They are also required to provide a signed, dated and current version of their CV and valid GCP training certificate (where applicable, issued within 2 years) to be filed in the ISF/TMF and in the local central training file (where applicable)

The PIS and informed consent form must be identifiable by date and version number. Both must also be localised and printed on UCLH headed paper. Other logos may be added as appropriate. If UCLH is acting as a PIC, then study documentation will not need to be localised to UCLH.

### 8.2 Identifying Potential Research Participants

There are several ways to identify potential research participants at UCLH. UCLH patients may be identified as potentially eligible for a particular study by the care management team who has clinical responsibility for the patient. Other studies will identify participants through a variety of approved, study-specific means (including advertising) for consideration of study inclusion and referral.

Research participants will be assessed for their potential eligibility for a particular study by a healthcare professional that is authorised to recruit to the particular study. This assessment process should include checking the participant's medical history.

### 8.3 Approaching Potential Research Participants: Face-to-Face Consultation

Once a patient has been assessed and identified as potentially eligible for a particular study, they should be approached and introduced to the study. The person approaching the potential participant about a particular study must ensure they are familiar with all aspects of the study as described in the latest approved version of the protocol. 'Approved' means the protocol and study documents have received REC, HRA (and MHRA, where applicable) approvals, and UCLH Confirmation of Capacity & Capability. The process of approaching a potential participant can include sending the PIS prior to a face-to-face consultation or by conducting a face-to-face consultation and simultaneously providing the PIS to the participant. The verbal process used needs to be documented in the patient's medical notes. The approaching clinician is usually from the clinical team providing direct care to the patient. Where an approach is made by another group, ethical approval is required, alongside relevant UCLH honorary or other contracts. The patient would be expected to have consented to be contacted by a person outside of their direct clinical care team. During the verbal interview, the person taking informed consent must have the participant's medical notes, the current REC, HRA and R&D (and MHRA if applicable) approved versions of the PIS and ICF available. Other study documents, such as patient diaries and study schedule sheets, may also be used during the face-to-face consultation.

When describing the study, the person taking informed consent should explain the following:

- Background Information:
  - What the purpose of the study is and any background information that may be relevant
  - Why the potential participant has been approached
  - The number of people taking part in the study and how many have been recruited to date, if information available

- General Study Details:
  - Study design
  - Details of the drugs (or interventions) used, including any known safety profiles
  - An explanation of the placebo arm (if applicable)

- Operational Details of Study:
  - Duration of the study and the number of study visits involved, including where the participant will be seen and by whom
  - All procedures that are required as part of the study, such as blood tests, electrocardiograms etc.
  - The responsibilities of the participant if they choose to take part, particularly if the study duration is lengthy

- Participant Care:
  - Relevant sections of the participants medical notes and data collected during the study may be looked at by UCLH staff and individuals from external organisations (e.g., sponsors and regulatory authorities) for auditing and monitoring purposes.
  - The potential benefits and risks of participation in the study and any alternative treatments available to the participant
  - The participant enters the study voluntarily and can withdraw at any time without having to give a reason, or any prejudice to them or their future care
  - If the PI feels that the participant is not tolerating the study intervention/medication, the PI has the right to withdraw them from the study in the interest of the participant's safety
  - The availability of compensation should something go wrong
  - The contact details of the CI and the Trust Complaints e mail address should the participant wish to file a complaint
  - Any payments made for participation in the study or for out of pocket expenses (in instances where travel and accommodation expenses have been costed into the study contract)
  - The participant will have access to a 24 hour contact number should they need to contact the clinical team for medical emergencies whilst on the study
  - Contact details where the participant may obtain further information about the study e.g. the PI's number and/or the contact number for other members of the study team

- Under GDPR: Potential participants will need to be provided with transparency information about the Data Controller's[1] legal basis and details about how the participant's personal data will be processed. Where participant data cannot be identified on its own, or in combination with other accessible information, it is no longer deemed personal data and the GDPR transparency requirements do not apply. This information is usually included in the PIS, however may be presented separately in a transparency leaflet/information sheet. Further details regarding GDPR and how it affects research can be found on the HRA website.
- Should data be shared or requested from any organisation, the organisation must be listed within the sites and organisations within the approved study documentation. In addition, the patient should be informed their data is to be shared.

It is important that information is presented in a clear manner that is understandable to the potential participant. If they cannot understand the information, they cannot give their informed consent. As informed consent is voluntary, it must not be presented in a coercive manner, or with undue influence (e.g. fear of discrimination for refusal to participate, unrealistic expectations of benefits from participation, e.g. improved outcome from an experimental therapy or significant financial gain, excessive use of incentives, etc.). A verbal explanation of the above points must be given to the participant (plus family and friends if appropriate). This can be supplemented with diagrams if necessary to explain the study. Time for questions through the discussion must be given and questions adequately addressed. All potential participants should be provided with the PIS and allowed 'adequate time' to consider inclusion in the trial prior to providing written informed consent. It is commonly accepted that the participant should have a minimum of 24 hours between the date the PIS is provided to them and the actual verbal interview where the participant (and/or the participant's legally designated representative) signs the informed consent form. 'Adequate time' may be less if this is approved by the REC/HRA, and documented in the protocol.

For certain studies, during pre-screening, potential participants may also be asked to complete an additional informed consent form to provide their blood/tissue samples for use in Bio-Banking resources for future studies or metabolic profiling. If applicable, this should also be explained to the participant during the consenting process.

**Participants who do not speak English**

It is important that information is available in a language understandable to eligible research participants. The cost of translation should either be factored into the initial research grant application or, where the project is externally funded, resourced as any other clinical cost of research. The following steps should be taken for participants who do not speak English:

[1] The Data Controller is usually the Sponsor. Refer here for further details: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/data-controllers-and-personal-data-health-and-care-research-context/.

1. The trial's IRAS Application form should be reviewed for the requirements regarding interpreting services for patients who do not speak English or require interpreting assistance. The protocol should also detail whether non-English speaking patients are eligible or ineligible for participation in the study/trial.

2. It is recommended that if a patient who does not speak English is considered for participation in a trial, the site contacts the study sponsor to obtain a translated version of the PIS and ICF which they should submit to REC, HRA and local R&D for information, as part of the full documentation packages prior to use.

3. The UCLH Trust's independent Interpreting Service 'Language Line' should be used for participants who do not speak English. This service can be accessed via Epic and the SOP for this process can be found on the UCLH intranet. Ideally face-to-face interpreting is preferable to using the telephone interpreting service. Both of these services can be booked by calling Language Line. Face-to-face interpreting requires a minimum of 48 hours' notice but telephone interpreting is immediate. Appropriately translated and REC approved PIS and ICF should be used where available. These translated documents must be provided by the Sponsor. The interpreter should sign and date the consent form as a witness and it is recommended that the interpreter add their interpreter license number as a reference as well. Using family members as interpreters is not appropriate. The informed consent documentation in the participant's medical notes should state the name of the interpreter used and confirm any discussions that took place during the consenting process in order to ensure the participant was fully informed and understood the study requirements prior to completing the ICF.

For any questions or concerns relating to the proper consenting of a potential research participant who does not speak English, the PI/study team should contact the study sponsor directly for further direction and have written documentation from the sponsor clarifying any questions prior to proceeding with the potential research participant. All written correspondence should be saved in the Investigator Site File (ISF).

Researchers are able to utilise electronic methods for seeking, confirming and documenting informed consent in research studies. This may be utilised, in cases where face to face consenting is not viable, e.g. remote consultations or as a result of local infection control restrictions.

### 8.4 Documenting Informed Consent

**The PIS and ICF must be identifiable by date and version number. The PIS and ICF must be printed on UCLH headed paper. Other logos may be added as appropriate.**

To ensure adequate time for the potential participant to consider the study, a subsequent face-to-face consultation may be necessary where the informed consent form can be signed. Once the potential participant has had ample time to read the PIS and has had any questions regarding their participation answered satisfactorily, the person taking informed consent will ask the participant to clearly print their name, sign and date the informed consent form and initial any statements required by the informed consent form. Ticks or

crosses are not acceptable. The person taking informed consent must also clearly print their name, sign and date the informed consent form on the same day as the participant. If the protocol states any additional signatures are required then this process must be followed accordingly.

Once all parties have signed and dated the informed consent form:

- The signed original wet-ink form should be placed in the ISF, unless stated otherwise in the protocol. If signed consent forms are stored elsewhere, a File Note must be completed citing their location.
- Hard copy consent forms should be stored in line with UCLH information governance policy
- One copy of the signed informed consent form should be given to the participant.
- One copy of the signed informed consent form should be scanned and uploaded to the participant's electronic medical notes on the EHRS, along with the PIS.

If sponsors request signed informed consent forms via email or fax, the research team must ensure that these are anonymised and only the patient ID is provided on the informed consent form.

The informed consent process must be documented in a detailed and chronological manner within the participant's electronic medical notes on the EHRS. Where others, such as relatives or carers of patients lacking mental capacity (as defined in the Mental Capacity Act 2005), have played an active role in assisting the participant in understanding the study, then their involvement as an advocate or witness should also be documented in the participant's electronic medical notes on the EHRS. The PI/Sub-I is responsible for obtaining informed consent but the Research Nurse or Clinical Trials Practitioner may document the consent process by using a 'smart form' within the EHRS by adhering to the following steps:

a) Enter the Encounter with the participant
b) Enter the Research Consultation Navigator
c) Select the Research Consent Details link and a 'smart form' will appear
d) Choose 'New Consent' and enter the relevant study details and the version of the informed consent form
e) When complete, click 'Close'

Best practice dictates that consent should ideally be documented in the same encounter that it was taken in. Once the informed consent process has been documented within the participant's electronic medical notes, the signed paper consent form needs to be uploaded to the participant's electronic medical notes via the following steps:

a) Use Chart Search and type in 'Media Manager'
b) Search for the participant
c) To import a document, select the Scan/Import button
d) Place document in scanner, ensuring each page has the participant's details on it
e) Click on 'File' and then on 'Select Scanner' and to choose the relevant scanner
f) The consent form document will be uploaded as an Index Document

g) The Document Information prompt will be displayed: Select ‘Research Consent’ from the list and add details of the stud name and version of the consent form to the free text section

Further information regarding documenting the informed consent process and uploading the signed consent form can be found on the Trust’s intranet, myUCLH, within the Epic tip sheets for research. This is also covered during the Epic Research Add-on training module. An overview of the consenting process can be found in Appendix 1.

In the case of a patient being potentially screened and enrolled onto more than one trial within the same disease area, consultation and approval from both PIs and Sponsors is required. These discussions should be clearly documented within the patient’s electronic medical notes and should be handled on a case-by-case basis.

### 8.5 Informed Consent of Participants under the age of 16

For participants under the age of 16, the legally designated representative (often one of the parents/guardians) would sign the consent form on behalf of the minor. The **assent form** corresponding to their age range will be signed by the minor. During a clinical trial, if the minor reaches the age of majority, their express informed consent shall be obtained before the trial may continue.

As per The Medicines for Human Use (Clinical Trials) Regulations 2004, there is a hierarchy for determining who should be approached to give informed consent on behalf of a minor prior to their inclusion in the study (see Table 1 below). The provisions for informed consent by a legal representative only apply in the case of **emergency treatment** where no person with parental responsibility can be contacted prior to the proposed inclusion of the minor.

*In some instances, parental consent may not be required/appropriate for minors under the age of 16, depending on the nature of the study, and on the condition that this consent process has been justified and approved by an appropriate REC and HRA.

| | **Person Who May Give Consent** | **Definition** | **Comments** |
|---|---|---|---|
| 1 | Parent/Guardian | A parent or person with parental responsibility | Should always be approached when available |
| 2 | Personal Legal Representative | A person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the minor, and available and willing to do so. | May be approached if no person with parental responsibility can be contacted prior to the proposed inclusion of the minor, by reason of the emergency nature of the treatment provided as part of the trial. |

| | | | |
|---|---|---|---|
| 3 | Professional Legal Representative | A person nominated by the relevant healthcare provider (e.g. an acute NHS Trust or Health Board) who is not connected with the conduct of the trial. | May be approached if no person suitable to act as a personal legal representative is available. Informed consent must be given before the minor is entered into the trial. |

In addition, the process of taking consent includes the following conditions and principles which apply to the inclusion of a minor in a clinical trial:

- The parent/guardian or legal representative has had an interview with the investigator, or another member of the research team, in which opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
- The parent/guardian or legal representative has been provided with a contact point where further information about the trial may be obtained.
- The parent/guardian or legal representative has been informed of the right to withdraw the minor from the trial at any time.
- The parent/guardian or legal representative has given IC to the minor taking part in the trial.
- The parent/guardian or legal representative may, without the minor being subject to any resulting detriment, withdraw the minor from the trial at any time by revoking the IC.
- The minor has received information, according to their capacity of understanding, about the trial and its risks and benefits. The information must be given by staff with experience of working with minors.
- The investigator must consider the ability of a minor in forming an opinion and assessing the information provided. This applies both to the wish of a minor to refuse to take part, or to withdraw from the trial at any time.
- No incentives or financial inducements are given either to the minor or to the parent or legal representative, except the provision of compensation for injury or loss.
- The clinical trial relates directly to a condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

**Consent for under 16s in CTIMPs**

Children under the age of 16 are prohibited from giving consent to take part in a CTIMP as per The Medicines for Human Use (Clinical Trials) Regulations (2004). Only the above 3 groups within the table are eligible to provide informed consent on behalf of children under the age of 16.

**Consent for under 16s in non-CTIMPs**

Children and adolescents under the age of16 should be involved in the consent process in proportion to their capacity to understand. Children and adolescents must indicate assent

(i.e. that they have no objection to taking part in the research study); however full informed consent will normally be obtained from the parent or guardian.

Where the child or adolescent is judged to be Gillick competent (i.e. their knowledge and understanding is judged to be equivalent to that of an adult), they can legally consent on their own behalf. It is not recommended to apply the principal of Gillick competence to children under the age of 10. It is deemed good practice to encourage the child to agree to parental involvement. Information sheets appropriate for the child's age and level of development should be designed. These should normally be additional to an information sheet and consent form to be presented to the parent or guardian.

The HRA has produced guidance in regard to carrying out research with child and adolescent participants and it is recommended that this be read in full. The guidance is available at http://www.hra-decisiontools.org.uk/consent/principles-children.html.

### 8.6 Informed Consent of Adults lacking mental capacity

Non-CTIMPS:
One of the core principals of the Mental Capacity Act (2005) states that capacity should be assumed unless established otherwise. For a person to have capacity, the following conditions must be satisfied:

- The person must be able to absorb, comprehend and retain relevant information
- The person be able to use that information to arrive at a decision
- The person must be able to communicate that decision in some manner

Research involving adults unable to consent for themselves requires specific REC notice of favourable opinion from a recognised Mental Capacity Act Flagged REC. The research provisions of the Mental Capacity Act 2005, in particular Sections 30-34, apply to the conduct of intrusive research. According to Section 30 of the Act, research would be labelled as intrusive if taking informed consent would be legally required for participants with capacity. The Act is supplemented by a statutory Code of Practice which provides guidance on its use.

In order to comply with Section 32 of the Mental Capacity Act 2005, the PI must take reasonable steps to identity a "personal consultee". This can be defined as someone who is independent of the research study, knows the participant in a personal capacity and is able and willing to advise the PI about the participant's wishes in relation to joining the research study. If a personal consultee cannot be sought, a "nominated consultee" should be found. This person must be independent of the research study and appointed by the PI in accordance with the Mental Capacity Act's guidance on nominating a consultee for research involving adults who lack capacity to consent. It is important to note that the consultee does not give consent, only advice. The responsibility to decide whether the participant should be entered into the research study ultimately lies with the PI. The following conditions must be met:

- The consultee has had an interview with the PI, or another member of the research team, in which the opportunity has been given to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted
- The consultee has been provided with a contact point where further information about the trial may be obtained
- The consultee has been informed of the right to withdraw the potential participant from the trial at any time
- The participant has received information, according to his or her capacity of understanding, about the trial and its risks and benefits.
- The PI must consider the explicit wish of a participant capable of forming an opinion and assessing the information provided. This applies both to the wish of a participant to refuse to take part, or to withdraw from the trial at any time.
- No incentives or financial inducements are given either to the participant or to the consultee, except the provision of compensation for injury or loss
- There are grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the participant outweighing the risks or produce no risk at all
- The trial is essential to validate data obtained (a) in other clinical trials involving persons able to give informed consent, or (b) by other research methods
- The clinical trial relates directly to a life-threatening or debilitating clinical condition(s) from which the participant suffers.

It is deemed good practice for the PI to keep the consultee fully informed throughout the lifetime of the research study, especially if the study involves a series of procedures. If the consultee advises the PI that the participant should be withdrawn, the PI must withdraw the participant, provided that this would not produce a significant risk to the participant's health and wellbeing.

CTIMPs:

It is important to note that the Mental Capacity Act does not apply to Clinical Trials of Investigational Medicinal Products (CTIMPs) as outlined in Section 30. This is due to the fact that a separate provision has been created for including adults lacking capacity in CTIMPs in Schedule 1 of the Medicines for Human use (Clinical Trials) Regulations 2004 (S.I. 2004:1031) as amended by S.I.2006:1928, SI.2006:2984 and S.I.2008:941. Adults who are unable to provide legal consent to clinical trials may not be included if the same results can be obtained using adults capable of providing consent. The only exception to this is if there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. For CTIMPs, advocates are referred to as 'Legal Representatives'. Written consent of the patient's Legal Representative, given in co-operation with the treating Doctor, is necessary prior to participation in the clinical trial. Per Schedule 1 of the Medicines for Human use (Clinical Trials) Regulations 2004, the individual deemed to be the patient's Legal Representative must not be:

(a) the sponsor of the trial,
(b) a person employed or engaged by, or acting under arrangements with, the sponsor,
(c) the Principal Investigator or Sub-Investigator,
(d) a member of the research team

(e) a health care professional who provides care under the direction of the Principal Investigator or Sub-Investigator.

**Changes to capacity status over the course of the study**

In the event that the participant loses capacity after having consented to take part in the research study, the conditions of the Mental Capacity Act (2005) must be applied before the person is allowed to continue their participation. This may be especially pertinent to studies of progressive diseases. The Mental Capacity Act (2005) is not applicable if the protocol states that participants who lose capacity will be excluded from the study.

In the event that the Mental Capacity Act has been applied and the participant subsequently regains capacity, the participant must provide their own consent if they are to continue their participation in the research study. If consent is declined by the participant, any data already obtained must be destroyed and not used for the research project. Further advice may be sought from the REC or HRA (regarding GDPR transparency requirements).

Where the PI plans to include participants whose capacity status changes over the course of the study and where this was not included on the original application to the REC and HRA, the study must be resubmitted to the REC for approval under Section 30 of the Mental Capacity Act (2005).

**Research in Emergency Situations**

Section 32(8) of the Mental Capacity Act stipulates exceptional provisions for a person lacking consent to be entered into a research study prior to obtaining advice from a consultee. Such exceptions only apply in emergency situations. The following conditions must be met in order to execute Section 32(8):

- Urgent treatment is required and it would not be suitable to separate this from including the person in the research
- It is not considered practical to identify and consult a consultee prior to treatment administration

If capacity is regained, the PI must seek the participant's informed consent about their continued inclusion in the research study. If consent is refused when the participant regains mental capacity, any data gathered until that point must be destroyed. If capacity is not regained, a consultee must be identified and advice sought.

**8.7 Research with Human Tissue**

The Human Tissue Act (2004) requires consent to be obtained for the removal, storage and use of human tissue for certain scheduled purposes (activities), including research. Examples of human tissue that may be used for research purposes include blood samples, urine samples and biopsies. Scheduled purposes are divided into two groups:

- Part 1: General activities such as anatomical examination, transplantation or research in connection with disorders
- Part 2: Applies specifically to deceased subjects and activities could include a clinical audit, public health monitoring or quality assurance

When obtaining consent, the following must be explained to the potential participant:

- Any 'material' or significant risks associated with the method of obtaining the sample, how the sample will be used and any possible implications of using the sample
- Appropriate and clear information regarding the activities for which consent is required should be provided to the participant
- The potential value of providing generic consent to future research, especially if valuable human tissue is involved
- The implications of using identifiable tissue for research purposes e.g. the potential participant may be contacted by future researchers or be asked for access to their medical records
- If the research project is known or likely to involve genetic testing, the commercial sector or the use of human tissue in animals, this should be fully explained to the potential participant to ensure transparency
- Research tissue banks should ensure transparency by providing the potential participant with information regarding how much they charge private companies for human tissue samples, and to whom they will supply the samples
- Consent can be withdrawn at any time and its implications should be clearly outlined to the potential participant e.g. withdrawal of consent cannot be effective where the participant's tissue sample has already been used.

**Consent for DNA Analysis**

It is an offence to analyse DNA without consent. However, the storage of DNA is not subject to licensing, as it is not considered 'bodily material[2]' by the Human Tissue Authority (HTA). The results of DNA analysis can be used in research without prior consent if the bodily material from which the DNA is extracted satisfies all of the following points:

a) It has been extracted from a living person
b) The researcher is unable to identify the person from whom it has been obtained from
c) The tissue is used for a specific research project which is approved by a recognised REC

**Access to Tissue from the Deceased**

Under the Human Tissue Act, consent is required for the removal, storage and use of tissue samples from the deceased for the following scheduled purposes (activities):

[2] Bodily material is material which has come from a human body, and consist of or includes human cells. DNA in itself is not bodily material (Human Tissue Act 2004).

- Anatomical examination
- Research in connection with disorders or the functioning of the human body
- Establishing after a person's death the efficacy of any drug or other treatment administered to them
- Obtaining scientific or medical information, which may be relevant to any person including a future person

A full list of scheduled purposes can be found on the Human Tissue Authority website, as follows: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

Where tissue is planned to be taken from the deceased, consent can be sought from the following, in order of preference:

- Where an adult has provided consent for a specific scheduled purpose (activity), such as storage or use of tissue, to take place following their death, then that consent is considered sufficient and lawful
- Nominated representative: Appointment of this person and its associated terms and conditions may be made orally or in writing
- Person in a 'qualifying relationship': This is hierarchical in order of preference:
    - Spouse or partner (including civil or same sex partner)
    - Parent or child
    - Brother or sister
    - Grandparent or grandchild
    - Niece or nephew
    - Stepfather or stepmother
    - Half-brother or half-sister
    - Friend of long standing

**Consent Exceptions**

The Human Tissue Act was effective from 1st September 2006 and therefore it is not legally necessary to seek consent from tissue samples obtained prior to 2006. In addition, if more than 100 years have elapsed since a participant's death, consent to undertake research on their tissue is not required under the Human Tissue Act, regardless of the date of when the tissue was donated to research.

A further consent exception includes the following scenario, where all the below criteria apply:

a) The tissue obtained is from a living person
b) The researcher is unable to identify the person from whom it has been obtained from
c) The tissue is used for a specific research project which is approved by a recognised REC

Full details of the Human Tissue Act (2004) and its application to research can be found on the Human Tissue Authority website, as follows: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

### 8.8 Alternative Forms of Consenting Research Participants

Written consent should always be taken where possible. However, in some instances, written consent may not be appropriate for a particular research study/type. For example, an observational study may be collecting data from participants via the internet (e.g. via a survey/questionnaire), where face-to-face consenting is not possible or feasible. In such cases, consent is presumed to be implied upon the participant's submission of responses. This is acceptable only when it has been explicitly specified in the protocol, and reviewed and approved by the HRA, REC and participating NHS sites.

### 8.9 The Use of Confidential Patient Information Without Prior Consent

Under Section 251 of the NHS Act 2006, the common law duty of confidentiality can be lifted to enable disclosure of confidential identifiable patient information for medical research without obtaining patient consent. The Confidentiality Advisory Group (CAG) is an independent body whose main aim is to protect the interests of patients and the public while also facilitating the appropriate use of confidential patient information beyond direct patient care. CAG reviews research applications and advises the HRA whether there is sufficient justification to access the requested confidential patient information. Further details regarding CAG and the application process can be found on the HRA website, as follows:https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/

### 8.10 Electronic Methods for Seeking Informed Consent

The MHRA and HRA released a "Joint Statement on Seeking Consent by Electronic Methods" document in September 2018[3]. It is acceptable to use online text or multimedia as the main method of informing potential participants of a research study. For example, an electronic device such as a smartphone, tablet or computer may be used to convey information related to the study and to seek and/or document informed consent. However, researchers are cautioned as this may unintentionally discriminate against potential participants who cannot use such technology. Subsequently, alternative methods should be available for those unwilling or unable to use electronic methods. There are three groups of electronic signatures, as follows:

- Simple electronic signatures: This could be a finger-drawn signature, typed name or fingerprint scan
- Advanced electronic signatures: Uniquely linked to the signatory and therefore allows identification of the signatory
- Qualified electronic signatures: An advanced electronic signature that is created by a qualified electronic signature creation device and based on a qualified certificate for electronic signatures

[3] https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

The methods used to inform and document the consent of participants to CTIMP studies still need to comply with the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004, thus implementing the EU Clinical Trials Directive (2001/20/EC) in UK law.

### 8.11 Best Practices for Seeking Consent for CTIMP Studies

- Type A studies (the CTIMP involves risks no higher than that of standard medical care): Simple e-signatures involving the participant tracing their handwritten signature using a finger or stylus or biometric eSignatures should normally be used.
- Type B & Type C studies (higher risk than that of standard medical care): Typewritten or scanned images of handwritten signatures should not normally be used. Where consent is given remotely and the participant is required at some point to visit a study site for the purposes of the trial then verification can be done in person using information from official photo ID.

### Best Practices for Seeking Consent for non-CTIMP Studies

Any simple electronic signature is normally adequate for the majority of non-CTIMP research involving only negligible or minimal risk. Where the research involves more than minimal risk or burden, simple e-signatures that involve the participant tracing their handwritten signature using a finger or a stylus or biometric e-signatures should be considered as these allow for direct comparison with wet-ink signatures previously used by the participant. For postal/online surveys or self-administered questionnaire-based research where identifiable personal data are collected, then the participant must be able to actively signify their consent e.g. by providing an explicit consent statement and a tick box within the questionnaire. In such cases, a handwritten or biometric signature is not required.
The full statement can be found on the HRA website, as follows:
https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/.

### 8.12 Informed consent as an ongoing process

The research team involved in the study should understand that consent is a process which continues throughout the lifetime of the study. Every opportunity should be taken to discuss the nature of the study with participants and, where appropriate, their relatives and to answer any questions they may have. This is particularly important if there are changes to the study protocol or if new information is released which may affect a participant's willingness to continue their involvement in the study.

For any amendments affecting the PIS and informed consent form, the sponsor must request recruited participants to be re-consented with the approved updated version in addition to their original informed consent form in order to continue their involvement in the study. The re-consenting process and newly signed informed consent form and PIS must be scanned and uploaded to the participant's electronic medical notes on EPIC, and stored in the ISF. The new PIS and ICF template documents must be stored in the ISF, with previous versions marked as superseded.

When a new PIS or ICF has been approved and is ready to use, the following steps must be followed to ensure the old version of the respective document is correctly superseded:

- Strike a single line diagonally across the front page of the old document
- At the top of the old document, state the version number of the new document which the old document will be superseded by
- State the date of when the old document was superseded at the top of the old document
- State the name of the person who is superseding the old document at the top of the old document

An overview of the re-consenting process can be found in Appendix 2.

## 9. Training requirements

All staff involved in consenting participants for research purposes must be appropriately trained and experienced. It is the PI's responsibility to ensure this is in place, and that consenting activities are delegated to appropriate research staff. Consent training is provided by the NIHR (https://learn.nihr.ac.uk/).

## 10. Dissemination & Communication

This policy will be disseminated to all PIs of currently open research studies, and made available on the Joint Research Office's website. This policy will also be available on the R&D myUCLH page.

## 11. Monitoring and Audit

| What in the policy is going to be monitored | Monitoring method | Who will lead the monitoring ? | How often? | Where will it be reported? |
|---|---|---|---|---|
| A sample of UCLH research studies/trials taking informed consent, and approved via the Joint Research Office will be audited to ensure that:<br>PIS and ICF must be identifiable by date and version number<br><br>PIS and ICF must be printed on | Audits of Investigator Site Files, Participant Information Sheets, and completed participant Consent Forms. Copies of REC, HRA and R&D approval confirmation will be | Research Quality & Safety Manager (Research Quality & Safety team, Joint Research Office) | Annual | UCLH Quality & Safety Committee |

| | | | | |
|---|---|---|---|---|
| UCLH headed paper<br><br>Consent form must be signed and dated by the participant<br><br>Consent form must be signed and dated by the person taking consent (and advocates where applicable), and the date of this is consistent with the participant date of signature<br><br>All ICF questions must be answered via participant initials<br><br>The original completed consent form must be stored in the Investigator Site File and uploaded to the patient's Epic record<br><br>Confirm the PIS and consent form signed are the correct date version as per REC, HRA and R&D approvals<br><br>Master copies of the ICF and PIS (current and superseded) are stored in the Investigator Site File | reviewed to ensure participant document used has been appropriately approved. | | | |

## 12. References

1. Confidentiality Advisory Group (CAG) of the Health Research Authority - https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/
2. Department of Health UK Policy Framework for Health and Social Care Research (2017, Version 3.3) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
3. General Data Protection Regulation (2018) - https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN
4. Health Research Authority and Medicines and Health products Regulatory Agency, Joint statement on seeking consent by electronic methods (2018) - https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/
5. Health Research Authority, Informing Participants and Seeking Consent - https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/
6. Human Tissue Act (2004) - http://www.legislation.gov.uk/ukpga/2004/30/contents
7. Human Tissue Authority, Code E: Research (2017) - https://www.hta.gov.uk/sites/default/files/Code%20E.pdf
8. Mental Capacity Act (2005) - http://www.legislation.gov.uk/ukpga/2005/9/contents
9. The International Conference on Harmonisation GCP Guideline (ICH GCP) E6 (R2) 2017 - https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice
10. The Medicines for Human Use (Clinical Trials) Regulations (2004) - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
11. HRA decision tool on consent & patient information guidance https://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf

## Appendix 1: An Overview of the Consenting Process

### 1. Approvals Required PRIOR to Recruitment:

- HRA
- REC Favourable Opinion
- MHRA notice of acceptance/no objection (applicable to drug/device trials only)
- Other study-specific approvals e.g. Confidentiality Advisory Group (CAG), etc.
- UCLH Confirmation of Capacity & Capability – issued by the JRO (representatives of UCLH R&D)

### 2. Study Open at UCLH

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### 3. Delegation Log & Training Log Updated

- Please ensure all staff members working on the study are appropriately delegated and listed on the Delegation Log. The PI must countersign each staff member's entry on the Delegation Log within 1 month of the staff member signing the Delegation Log.
- Training records must also be signed and updated to ensure all staff members working on the study have been appropriately trained on the protocol and study conduct.

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### 4. Patient Identification

- This should be conducted by specific staff member(s) who have been delegated this duty on the Delegation Log

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### 5. Verbal Interview with Patient

- Conduct a face-to-face consultation with each active participant to ensure he/she is made aware of any changes and are able to ask any questions in order to make an informed decision regarding whether to provide consent or not
- For further information regarding the face-to-face consultation, please refer to Section 8.3 of this policy

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### 6. Documenting Informed Consent

- The signed original wet-ink form should be placed in the ISF, unless stated otherwise in the protocol. If signed consent forms are stored elsewhere, a File Note must be completed citing their location.
- One copy of the signed informed consent form should be given to the participant.
- One copy of the signed informed consent form should be scanned and uploaded to the participant's electronic medical notes on EPIC, UCLH's electronic health record system, along with the PIS:
    - Enter the **Encounter** of the patient
    - Enter the **Research Consultation Navigator**
    - Select the **Research Consent Details** link and a **Smart Form** will appear
    - Select '**New Consent**' and enter the relevant study details and the version of the consent form

## Appendix 2: An Overview of the Re-consenting Process

### 1. Amendment/Urgent Safety Measure Implemented at UCLH

- Ensure UCLH Study Team aware of amendment/urgent safety measure requirements, especially the need to re-consent patients, if appropriate

### 2. New versions of the Informed Consent Form and Patient Information Sheet Localised to the UCLH Header

- File blank template in Investigator Site File

### 3. Supersede Old Versions of the Informed Consent Form and Patient Information Sheet in the Investigator Site File

- Strike a single line diagonally across the front page of the old document
- At the top of the old document, state the version number of the new document which the old document will be superseded by
- State the date of when the old document was superseded at the top of the old document
- State the name of the person who is superseding the old document at the top of the old document

### 4. Supersede Old Versions of the Informed Consent Form and Patient Information Sheet in the Investigator Site File

- Strike a single line diagonally across the front page of the old document
- At the top of the old document, state the version number of the new document which the old document will be superseded by
- State the date of when the old document was superseded at the top of the old document
- State the name of the person who is superseding the old document at the top of the old document

### 5. Re-consent All Active Patients at Next Available Opportunity

- Conduct a face-to-face consultation with each active participant to ensure he/she is made aware of any changes and are able to ask any questions in order to make an informed decision regarding whether to continue to provide consent or not
- For further information regarding the face-to-face consultation, please refer to Section 8.3 of this policy

### 6. Documenting Informed Consent

- The signed original wet-ink form should be placed in the ISF, unless stated otherwise in the protocol. If signed consent forms are stored elsewhere, a File Note must be completed citing their location.
- One copy of the signed informed consent form should be given to the participant.
- One copy of the signed informed consent form should be scanned and uploaded to the participant's electronic medical notes on EPIC, UCLH's electronic health record system, along with the PIS:
    - Enter the **Encounter** of the patient
    - Enter the **Research Consultation Navigator**
    - Select the **Research Consent Details** link and a **Smart Form** will appear
    - Select '**New Consent**' and enter the relevant study details and the version of the consent form