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STANDARD OPERATING PROCEDURE

Informed Consent for Research

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RESEARCH AND INNOVATION

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BACKGROUND

Informed consent is 'A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate'. Informed consent is documented by means of a written, signed and dated 'informed consent form' (ICH E6 (R2) Guideline for Good Clinical Practice, 2017).

Informed consent is an on-going process. It involves giving information to the participants, discussing and clarifying the information, receiving the subjects' written consent and subsequently providing any new information that might affect the subject's willingness to continue in the study.

PURPOSE

This Standard Operating Procedure has been written to give guidance to study personnel at Lancashire Teaching Hospitals NHS Foundation Trust on how to obtain a participant's consent to participate in a research study and for documenting that consent has been obtained.

SCOPE

It is important that all study personnel use the same procedure to obtain informed consent from participants prior to conducting any study related procedures as detailed in the research study protocol. This is to ensure study personnel comply with ICH E6 Guidelines for Good Clinical Practice and with the ethical principles that have their origins in the World Health Organisation's *Declaration of Helsinki*.

This SOP applies to participants over 16 years of age. When potential participants may lack the capacity to understand information or make a decision, great care should be taken in obtaining meaningful informed consent (RCN, 2011). Along with the Protocol, REC and Sponsor approved documentation the Trust's policy for implementing the Mental Capacity Act and obtaining authorisation for Deprivation of Liberty (Section 6) needs to be followed if the participant lacks capacity.

PROCEDURE

1. WHO?

- The investigator is responsible for ensuring all participants involved with a research trial / study have been fully informed of the study and have consented to take part in the research study. This duty can be delegated to suitable study personnel providing they have signed the research study delegation of duty log (RD-TMP-04 Delegation of Duties Log).

- It is the Principal Investigator's responsibility to be satisfied that the delegated person is appropriately qualified and has the necessary skills and experience to undertake the informed consent process and to be able to adequately describe and discuss with a potential participant the risks and benefits associated with participation in the study.

- Those seeking consent must have sufficient knowledge of the study procedures and the investigational medicinal product (if applicable), and must understand the risks involved in order to provide any information the participant may require.

- In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) the person seeking consent should be a medically qualified person, except in certain circumstances as listed below.

- For some studies, the investigator may choose to delegate the process of obtaining informed consent for research to another healthcare professional (most commonly a research practitioner). However, the study team need to confirm that the Study Sponsor supports that consent is taken by delegated individuals and that the Health Research Authority (HRA) / Research Ethics Committee (REC) have also approved the consent process.

- For some studies it may be acceptable for a nurse who has undertaken the appropriate training, is within the scope of their job roles and is supported by the host site and delegated by the PI to consent to CTIMPs, where appropriate approvals via the HRA / REC and the Sponsor. This would usually include evidence that the PI or a medic has confirmed eligibility in writing prior to consent and is on hand to answer any questions that may arise from the patient.

It is important to ensure that all who are delegated the duty are:

- Appropriate by their own knowledge of the study.
- Knowledgeable of optional treatments.
- Aware of their own limitations.
- Willing to undertake the delegated duty and are fully aware of their own responsibility.
- Delegated by the study Investigator.

2. WHEN?

- Informed consent must be sought from research participants prior to conducting any trial/study related procedures.

- Some trials / studies may have more than one consent time point. Some trials / studies may require consent for the screening stage of the study and then consent for the actual trial / study if the patient fulfils the eligibility criteria after screening assessments. Study personnel must comply with the approved study protocol as to when informed consent should be taken.

- As new information is identified or amendments are made to the protocol, it may be necessary to amend the patient information sheets with this new information. These information sheets should be approved by HRA / REC before being given to the patients and the consent process being followed again.

3. HOW?

1. The investigator or delegated person is responsible for ensuring informed consent is obtained from research participants according to the approved research study protocol.

2. All information presented to the participants in relation to the research study in any format, including the Patient Information Leaflet, consent form and any study advertisements, must have prior HRA/REC approval and should be version numbered and dated.

3. The participant must be allowed ample time and opportunity to read the information leaflets and to discuss the study with family and friends before being asked to sign a consent form. Generally, this should be at least 24 hours, unless agreed with the HRA/REC and the study team during feasibility as stipulated in the study protocol.

4. The time and date of when the study information has been presented to the patient must be recorded in the participants medical notes and any study related documentation. This could be presented using the informed consent summary templates (RD-TMP-03 a, b, c available on the intranet Template Documents | Lancashire Teaching Hospitals Intranet (lthtr.nhs.uk)

5. The participant should be given the opportunity to ask any questions to the appropriate members of the study team and if required must be given further opportunity to consider their involvement, and to ask any further questions.

6. Consent forms must be completed before any study related procedures are conducted. The investigator or delegated person must record dates correctly on the consent form.

7. The investigator, delegated persons or members of the study team must not coerce or unduly influence a participant's decision of whether to participate or to continue to participate in a research study.

8. The consent form must be printed with Lancashire Teaching Hospitals NHS Foundation Trust logo header.

9. The consent form must make reference to the version number and date of the Patient Information Leaflet that the participant has been given.

10. The consent form must only be completed once the person seeking consent is satisfied that the subject has been fully informed and understands what study participation entails.

11. The participant should initial each of the boxes, using black ballpoint pen on the HRA/ REC approved consent form, confirming each of the statements.

12. The participant should write their own name, the date and signature in the presence of the person receiving consent (unless ethically approved process states otherwise). The investigator or delegated person must not complete any information on behalf of the study participant.

13. The investigator or delegated person must document in the medical notes how the participant meets the eligibility criteria.

14. The investigator or delegated person should document the process of Informed consent in the participant's medical notes, detailing the study title and/or acronym, the version number and date of the relevant Patient Information Leaflet and consent form used. The entry must be signed and dated by the investigator or delegated person. This can be done using the Informed Consent templates (RD-TMP-03 a, b, c).

15. The investigator or delegated person must file the signed consent form in accordance with the research study protocol. If there is no specific guidance within the protocol two consent forms must be signed; one to be filed in the patient's medical notes along with a copy of the Patient Information Leaflet and one in the site file. A copy must be given to the participant.

16. The investigator or delegated study personnel should provide participants with copies of all ethically approved relevant, updated and new information regarding the study throughout their participation.

17. If there is new information about the trial / study, the consent process must start again and the patient must re-consent.

18. The investigator or delegated trial / study personnel must reconfirm a participant's willingness to continue in the study at every study visit and this must be documented in the participant's medical notes.

4. TELEPHONE CONSENT

There may be times, such as during times of a global pandemic, that the only feasible way of obtaining consent for research studies is to do this virtually or by telephone. In this event, sponsors will need to submit an amendment to the protocol to enable consent via virtual methods such as telephone or video call to the HRA / REC. HRA/REC approval must be obtained prior to consenting patients via virtual methods or telephone. To protect the research participants from exposure to infectious diseases, they will not be required to come to the department.

Learning from the recent pandemic has changed how many sponsors will to run their studies. As such there may an increase in the number of telephone or virtual consents in the future.

See Appendix 2 for a step-by-step guide to the process.

5. WITNESSED VERBAL CONSENT

There may be times, such as during a period of infection, that witnessed verbal consent can be obtained. For example, the contagious nature of the COVID-19 virus means that documentation handled by the patient must not leave the bed space. Infection, Prevention and Control processes must be followed and it may be that remote or witnessed consent is acceptable, where HRA/ REC approval has been granted. Witnessed verbal consent will be taken from the patient by the principal or Co- investigator in the presence of a professional witness (i.e. a nurse caring for patient). The patient must be fully informed of the study and given the opportunity to ask questions. Once satisfied that this is the case, the professional witness will be asked to sign and date the consent form

outside of the patient's bed space and a copy will be provided for the patient. This process will be documented in the patient's clinical records as normal.

6. eCONSENT

In September 2018, the MHRA and HRA issued a joint statement on seeking consent by electronic methods. The primary focus is clinical trials of investigational medical products (CTIMPs) but the principals can be applied to all research studies. Electronic methods may be used for seeking, confirming and documenting informed consent.

Information about a trial / study does not have to be in writing but can be provided to potential participants using electronic methods. Whichever method is used, HRA/REC approval needs to have been obtained prior to taking consent.

Informed consent must be recorded 'in writing', but electronic methods for documenting consent can be considered to be in writing. A copy of the signed consent form, either physical or electronic should be provided to the participant.

Electronic signatures can include signatures that are:

- tickbox plus declarations
- type written
- scanned
- an electronic representation of a handwritten signature
- a unique representation of characters
- a digital representation of characteristics such as a fingerprint or retina scan
- a signature created by cryptographic means

In UK law 'writing' is defined as 'typing, printing, lithography, photography and other modes representing or reproducing words in a visible form'. Provided that the method used to record consent is able to represent or reproduce words in a visible form it will satisfy the requirement to be in writing. It does not have to be on paper. The MHRA allows the use of electronic signatures but the type will depend on the specific context of the trial.

For the majority of non-CTIMP research involving only negligible or minimal risk, any simple electronic signature is normally adequate. Where research involves more than minimal risk, burden or intrusion, simple eSignatures that involve the participant tracing their handwritten signature using a finger or stylus or biometric signatures should be considered as they allow for direct comparison with eSignatures / and or wet ink signature previously used by the participant

If at all uncertain, further guidance from the Sponsor and Centre for Health Research and Innovation should be sought.

7. OTHER RELATED PROCEDURES

RD-TMP-04 Delegation of Duties Log

RD-TMP-3a Informed-Consent-Summary-Adult_v1.5_10-10-18

RD-TMP-3b Informed-Consent-Summary-Child_v1.0_10-10-18
RD-TMP-3c Informed-Consent-Summary-Health Volunteer_V1.0_10-10-18
ICH GCP E6 (R2) EMA/CHMP/ICH/135/1995 (2017)
MHRA / HRA Joint Statement on seeking consent by electronic methods (September 2018)
RCN (2011) Informed Consent in health and social care research, 2nd edition, London UK.
TP-139 Mental Capacity Act and Deprivation of Liberty Policy (Trust policy)

CONSULTATION WITH STAFF AND PATIENTS

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Controlled Copy Authorisation			
Copy Number	For printed or copied versions		
Location			
Authorised signature		**Date**	
Print-out only valid with original authorised signature			

APPENDIX 1

Information to be provided to potential subjects

According to ICH GCP E6 (R2)(section 4.8.10) the discussion prior to a subject consenting to participation in a trial and the patient information sheet or any other written information relating to the trial should contain the following:

a) A statement that the trial involves research.
b) The purpose of the trial.
c) The trial treatment(s) and the possibility of random assignment to each treatment.
d) The trial procedures to be followed, including all invasive procedures.
e) The subject's responsibilities.
f) Those aspects of the trial that are experimental.
g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, foetus or nursing infant.
h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
j) The compensation and/or treatment available to the subject in the case of any trial-related injury.
k) The anticipated prorated payment, if any, to the subject for participating in the trial.
l) The anticipated expenses, if any, to the patient for participating in the trial.
m) That the subject's participation in the trial is voluntary and that the subject can withdraw or refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
n) That the monitor(s), the auditor(s), the REC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the Guideline for Good Clinical Practice applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorising such access.
o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
p) That the subject or the subject's legal representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue to participate in the trial.
q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
s) The expected duration of the subject's participation in the trial
The approximate number of subjects involved in the trial.

APPENDIX 2

Telephone consent flow diagram

Eligible participants will be approached during virtual clinics and offered to receive a Patient Information Sheet (PIS) either by post or email.

Once the participant has received, and has been given time to read through the PIS, they will be followed up via phone call to ask if they have had chance to read through and if they have any questions.

NB: the protocol may state how long the participant needs to have to consider the research study.

Once contact has been made, an appointment will be made to go through the consent process over the phone, or by other virtual methods.

If the participant wishes to go ahead with the research, a consent form will be posted out to them with a cover letter, explaining that they should contact the research nurse on receipt of the paperwork. The participant will be sent a stamped and addressed envelope to return to the research department.

Once an appointment has been established the PI or Sub-I, or delegated research nurse will consent the participant as they would in a face to face appointment as per GCP, following the steps set out in RDCLI12 3.HOW. The process must be fully documented in the participants' medical notes. (RD-TMP-03 a, b, c). If the participant is a healthy volunteer, the documentation will be kept in the relevant section of the site file.

Once the consent form has been completed, the participant will be asked to post the consent form back to the research facility. They will post this back in the envelope provided.

Once the consent form is received, the research nurse or delegated other will sign the consent form and a copy will be filed in the patients CRF. A completed copy will also be sent to the participant, either by post or by email. If the participant is a healthy volunteer, a copy of the consent form will be kept in the relevant section of the site file.