THE St Luke's WILKES INSTITUTE

Research & Innovation Office

Standard Operating Procedure

Informed Consent Process

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Standard Operating Procedure: Research & Innovation Office

Informed Consent Procedure

Contents

Acronyms

CAG - Confidentiality Advisory Group
CI – Chief Investigator
CTIMP - Clinical Trial of an Investigational Medicinal Product
CV- Curriculum vitae
HRA – Health Research Authority
HTA – Human Tissue Act
ICHGCP - International Conference on Harmonisation of Good Clinical Practice
IRAS - Integrated Research Approval System
MHRA - Medicines & Healthcare Products Regulatory Agency
MRC - Medical Research Council
NIHR - National Institute for Health & Care Research
NRES - National Research Ethics Service
PI- Principal Investigator
REC- Research Ethics Committee
SOP – Standard Operating Procedure
SLH- St Luke's Hospice

Introduction

Informed consent is the process by which a person voluntarily confirms their willingness to participate in a research study having been informed of all aspects of the study that are relevant to their decision to participate.

Informed consent is an ongoing process. It involves giving information to the person, discussing and clarifying the information, seeking the participant's documented consent, and subsequently providing any new information that might affect the person's willingness to continue to participate in the study.

Consent is documented by means of a written, signed and dated informed consent form, or alternatively in an electronic format as approved by the Health Research Authority (HRA).

Further information on designing appropriate patient information and consent forms is available on the HRA website. In obtaining and documenting informed consent, the Research Team must comply with Good Clinical Practice and with the ethical principles that have their origin in the Declaration of Helsinki.

Purpose

To describe the processes for seeking informed consent to enter a research study, and for documenting that consent has been obtained.

Roles & Responsibilities

Duties within the organisation

It is the responsibility of St Luke's Hospice Research & Innovation Office to make SOPs available to all research active staff working on hospice approved research studies. It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Hospice SOPs are available to research staff. It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are

available to research staff. It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example, those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Hospice SOP it is the responsibility of the CI or PI to resolve these with the Research & Innovation Office prior to starting the study.

It is the personal responsibility of all staff to follow the Hospice (or the designated alternative organisations) procedural documents. St Luke's Hospice Research & Innovation Office is responsible for managing Hospice SOPs including their approval, dissemination, and archiving. All Hospice SOPs will be published on the Hospice Research website.

Specifics of this SOP

Overall responsibility for all elements of research activity, including seeking informed consent, rests with the local Principal Investigator (PI). It is considered best practice that only those involved directly with the participant's care, and with good knowledge of the study, should seek consent.

In particular, 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 person / potential participant may require.

If the task of seeking informed consent is delegated to other member(s) of the research team, it is the responsibility of the PI to ensure that the individual(s) is/are suitably trained and qualified. In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) the person seeking consent should normally be a qualified physician, unless agreed by the main Research Ethics Committee and the Research Governance Sponsor.

Where applicable, it is the responsibility of the PI to ensure that the delegation of the task of seeking consent is clearly documented. It is the responsibility of the person seeking consent to ensure that they have provided a copy of their signed and dated CV for the Investigator Site File and have completed and signed the Delegation of Duties Log.

It is the responsibility of the person seeking consent to ensure they are fully familiar with all aspects of the study as described in the latest version of the protocol and approved by the Research Ethics Committee (REC) & Health Research Authority (HRA).

Seeking Informed Consent

It is strongly advised to review and consider the "HRA and Medical Research Council - Consent and Participant Information Guidance" as referenced in Section 6 below.

This provides information on the regulatory framework, and various scenarios that may be encountered, dependent on individual project types. It is worth noting that the regulations do differ depending on which of the devolved nations the research is taking part. However, key principles will be outlined in the sub-sections below.

General Principles

All information presented to people in relation to the research in any format (written documents, digital media etc.), including the Participants Information Sheet (PIS) consent form and any study advertisements, must have prior ethical and regulatory approval as described in the hospice research policy and should be version numbered and dated.

Prior to signing the consent form, the potential participant should be given the opportunity to consider their involvement and ask questions with appropriate members of the research team, and if required, should be given further opportunity to consider their involvement.

The potential participant should be provided with ample time and opportunity to read the written PIS and to discuss the study with family or friends before being asked to sign the Consent Form. Generally, this should be with as much time as reasonably required for that particular project type and documented on the IRAS application and approved by the Research Ethics Committee and Health Research Authority.

Consent forms must be completed prior to any study-related procedures being conducted. The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to scrutiny. It is therefore essential to record dates correctly on both the consent form and in the

participant's medical notes, and to ensure this fall in line with Sponsor and protocol expectations.

If the potential participant does not speak English or has hearing loss and requires an interpreter, it is best practice to use an independent translator or family member. Any information imparted to the potential participant (written or verbal) should not contain any language that causes the potential participant to waive (or appear to waive) any legal rights, or that releases (or appears to release) the investigator, institution or sponsor from liability for negligence.

Neither the Investigator nor any member of the clinical research team should coerce or unduly influence, by any means, a person to participate or to continue to participate in a trial. A full list of information that should be included in any explanation to a potential participant, as specified by GCP Guidelines can be found in Appendix A. The practice of giving information about the study to participants should be an ongoing process performed by all members of the research and/or multidisciplinary team.

Adults lacking capacity

Studies governed by the Medicines for Human Use (Clinical Trials) Regulations 2004

The Medicines for Human Use (Clinical Trials) Regulations 2004 (CT Regulations) allow for the inclusion in a clinical trial of an incapacitated adult, who is unable to consent, or who has given consent prior to the onset of incapacity.

The assessment of capacity should be completed by a medic at the start of the trial and clearly documented in the medical notes and source data. There should be grounds for expecting that administering the medicinal product (if applicable) to be tested in the trial will produce a benefit to the subject outweighing the risks, or produce no risk at all.

The clinical trial should relate directly to a life-threatening or debilitating clinical condition from which the subject suffers. In the case that an individual is unable to consent due to physical or mental incapacity then a legal representative should be approached to give informed consent.

A "legal representative", in relation to an adult unable by virtue of physical or mental incapacity to give informed consent, and who is being considered as a participant for a clinical trial, is:

A person who, by virtue of their relationship with the adult is suitable to act as their legal representative for the purposes of the trial and is available and willing to so act.

Or, if no such person is identified:

The doctor primarily responsible for the medical treatment of the adult;

Or,

A person nominated by the relevant health care provider.

A legal representative should not be connected with the conduct of the trial. If an incapacitated adult has, prior to the onset of incapacity, refused to give informed consent to taking part in a clinical trial, then that individual cannot be included as a participant in a clinical trial.

Clinical Trial Regulations allow for the inclusion of an incapacitated adult as a matter of urgency where it is not reasonably practicable to identify a legal representative. However, this is only if inclusion in the trial is carried out in accordance with a procedure/protocol that has received prior approval by a Research Ethics Committee.

Studies not governed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

For non-Clinical Trials, advice should be sought from a consultee on whether an adult lacking capacity to consent would wish to be included in the research study or not.

Consultees are not asked to give consent on behalf of the adult, but rather to provide an opinion on the views and feelings of the potential participant.

Consultees in England and Wales can be one of the following:

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Personal consultee.

i.e. a person who cares for the adult lacking capacity or is interested in that person's welfare but is not doing so for remuneration or acting in a professional capacity.

If a personal consultee is not available or unwilling to give advice then a nominated consultee i.e. a professional who is independent of the study can do so.

The consultee must be told that they are being asked to advise on the views and feelings they believe the adult would have towards participation in the study. They cannot be pressured to provide this advice and must be informed that they are free to decide whether they wish to provide this advice or not. Sufficient information must be given (see Section 3.1 above), to ensure that they are provided with understandable information to be able to make an Informed choice.

If a Participant Regains Capacity

If it is likely adult participants might regain capacity during the study, a plan should be made on how they will be involved in the ongoing consent process. In most cases, it is appropriate to ask them to give their own consent when and if they are able. If it is intended to ask participants who regain capacity for their ongoing consent the following must be done:

• Inform the legal representative (Clinical Trials of Investigational Medicinal Products (CTIMPs) or consultee (other intrusive research) of this at the outset.

• Prepare an appropriate Participant Information Sheet and consent form for when capacity is regained, which should fully explain what has happened thus far, and then inform what you are seeking consent for.

If the participant consents to continue in the study then they should sign a consent form to indicate this. However, it must also be anticipated that the participant may wish to withdraw their consent. This can either be from any further involvement, or from any retrospective involvement whilst they lacked capacity. Researchers must therefore be prepared to explain what they can expect with regards to their data and ongoing treatment for example. It is advisable to anticipate this at each stage in the project. Any data collected up to and including that point should not be included in any analysis, unless this has prior approval by a REC. It may be, for example, that the point at which capacity is regained has happened after data has been fully

anonymised and analysed and so it would neither be possible nor practical to withdraw it.

Note: The decision by the participant to withdraw outweighs any prior decision made by a legal representative or consultee

If a Participant loses Capacity During the Research

If there is a significant risk of participants losing capacity during a study, researchers should consider discussing ongoing options with them during the initial consent to be involved in the study, and include information in the Participant Information Sheet.

For Clinical Trials, consent to participate in a study is presumed to remain legally valid after the loss of capacity (provided the protocol does not change significantly). For all other research, researchers will need to consider whether a participant would remain or be withdrawn from the study. There are only a very limited set of circumstances where an earlier consent in common law endures a loss of capacity.

If the intention is that the participant would remain in the study and would be required by the protocol to undergo further interventions and procedures then this constitutes "intrusive research" for the purposes of the Mental Capacity Act 2005. This would require approval from an appropriate REC and advice would need to be sought from a consultee.

Researchers have a legal obligation to carefully consider a request made by a representative or consultee to withdraw someone from a study after they have lost capacity. They must consider their current situation, including possible benefits and harms that might arise as a consequence of their continued participation.

In situations where the potential for losing capacity was discussed as part of the original consent researchers should still review how best to proceed if the participant does subsequently lose capacity. The original consent given by participants should not automatically be considered absolute.

In all studies, the current circumstances of the participant must be considered. Researchers should consult with carers and take note of any signs of objection or distress from the participant. They must consider withdrawing a participant if they raise any objections.

If the protocol changes during a study or researchers plan to obtain further consent from participants during a study, they must ask the legal representative for their consent / or consultee for advice, on behalf of any adults who have lost capacity.

Documenting Informed Consent

In line with ICH GCP guidelines:

The consent form must be on the headed paper of the Hospice where the participant is being recruited. It must refer to the version number and date of the PIS that the potential participant has been given.

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

The potential participant should initial (**rather than tick**) against each statement on the consent form to indicate their agreement. This must not be completed by the Investigator on behalf of the potential participant.

The consent form must be signed and personally dated by the potential participant (or legal representative or consultee) and the authorised person who conducted the informed consent discussion. The form should be signed by both parties on the same date unless specified otherwise in the Protocol and approved by the REC. Each person should also clearly print their name by their signature. The Investigator must not complete any of the information on behalf of the participant.

The process of seeking informed consent must be documented in the participant's patient record detailing the study title and/or acronym, the version number and date of the relevant PIS, and the date that consent was obtained. The entry should be dated and signed by the person authorised and responsible for conducting the informed consent process.

Two copies of the original signed and dated consent form should be made, the original should be filed in the Investigator Site File (a scanned copy can be placed in the electronic patient record), and a copy given to the participant. It is worth noting that where required by the study Protocol, a copy is additionally provided to the participant's GP.

Participants should be given copies of all relevant, updated, and new information regarding the study throughout their participation once this information has received REC approval.

NB: If approved by the REC/HRA, e-consent is a viable option in certain circumstances. In UK law 'writing' is defined as 'typing, printing, lithography, photography and other modes of representing or reproducing words in a visible form'. Electronic signatures can include signatures that are:

- Tick box plus declarations
- Typewritten
- Scanned
- An electronic representation of a handwritten signature
- A unique representation of characters
- A digital representation of characteristics, for example, fingerprint or retina scan
- A signature created by cryptographic means For further guidance, read the joint HRA and MHRA e-consent statement, referenced below.

Re-Consent

Consent is an ongoing process and should verbally be sought at each visit. However, if significant amendments to the research protocol throughout the course of the study result in changes that may affect a potential participant's continued involvement in the study, then potential participants must be asked to re-consent to these alterations.

A revised PIS and Consent Form, appropriately version numbered and dated, must be provided to the participant. All revised documentation must be approved by the HRA/University Ethics Committee and C&C confirmation of no-objection should be obtained from the R&IO before their use.

The participant must be informed of the new information in a timely manner and communication of this information documented in the participant's medical notes.

The participant must be given ample time to consider their continued involvement and to ask questions before being asked to sign the revised Consent Form.

A copy of the revised documentation must be provided to the participant and placed in the medical record and Investigator Site File.

References

HRA/MRC: Principles of Informed Consent:

https://www.hra-decisiontools.org.uk/consent/principles.html

Health Research Authority:

https://www.hra.nhs.uk/

HRA and Medical Research Council - Consent and Participant Information Guidance:

https://www.hra.nhs.uk/documents/294/informed-consent-in-ctimps.pdf

HRA and MHRA Statement on e-consent:

https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhraeconsent-statement-sept-18.pdf

ICH Good Clinical Practice Guidelines:

http://www.ich.org/products/guidelines.html

Declaration of Helsinki:

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association

The Medicines for Human Use (Clinical Trials) Regulations 2004 (Plus subsequent amendments):

http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Appendices

Appendix 1: Information to be provided to potential trial participants

According to ICH GCP (4.8.10) the discussion prior to a participant consenting to participation in a trial and the patient information sheet or any other written information relating to the trial should contain the following (unless otherwise approved by a Research Ethics Committee):

1. A statement that the trial involves research.

2. The purpose of the trial.

3. The trial treatment(s) and the possibility of random assignment to each treatment; diagrams may be useful.

4. The frequency of all trial procedures to be followed, including all invasive procedures.

5. The responsibilities of the participant.

6. The experimental aspects of the trial.

7. Any foreseeable risks or inconveniences for the trial participant.

8. The reasonably expected benefits, if any, should be explained. If there is no clinical benefit intended, the participant must be made aware of this.

9. Alternative treatments and procedure(s) that may be available and the potential benefits and risks.

10. The compensation and/or treatment available to the participant in the case of any injury relating to the trial.

11. Anticipated pro-rated payment, if any, to the participant for participating in the trial.

12. The anticipated out of pocket expenses, if any, to the patient for participating in the trial.

13. That the participant's participation in the trial is completely voluntary and that the participant can withdraw or refuse to participate, or withdraw from the trial at

any time without penalty or loss of benefits to which they would otherwise be entitled and without affecting their future care.

14.That authorised representatives from regulatory bodies, pharmaceutical company (or other commercial company, if appropriate to the study) will be given access to the participants' records for the purpose of verification of the trial procedures and data collected without violating the confidentiality of the participant. If applicable, that the participant's General Practitioner will also be informed in writing of their participation in the study. By signing the informed consent form, the participant is authorising such access.

15. That records identifying the participant will be kept confidential and will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential.

16. That the participant /legal representative will be informed in a timely manner if any information becomes available that may be relevant to the participant's willingness to continue to participate in the trial.

17. The person(s) to contact for further information regarding the trial (if possible record a 24hour phone number where the participant can receive advice out of office if required).

18. The foreseeable circumstances under which the participant's participation in the trial may be terminated.

19. The expected duration of the participant's participation in the trial

20. The approximate number of patients involved in the trial