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RESEARCH, CONSENT AND MENTAL CAPACITY: STANDARD OPERATING PROCEDURE

Introduction and Aim

Informed consent is defined in ICH-GCP as: "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.

All clinicians responsible for dealing with consent and capacity issues in research must work at all times within the UK policy framework for health and social care research v3.3 and the UHB Research Governance Policy (UHB099).

The same legal principles apply when seeking consent from participants for research purposes as when seeking consent for investigations or treatment.

The main focus of this SOP is to aim to ensure that staff are suitably qualified and experienced to deal with consent and capacity issues and to describe the procedure for obtaining informed consent from participants.

Objectives

- To describe general issues around the consent process in research, where these differ from standard clinical practice.
- To ensure that consent and capacity issues in research are addressed appropriately, in accordance with the legal and regulatory framework.
- To describe the procedure for obtaining consent from an adult, where the adult has mental capacity to give or refuse consent to participating in research and to ensure that research is undertaken lawfully where the adult lacks mental capacity to consent to or refuse consent to participate in the research.
- To describe the procedure for obtaining consent from children, or from those with parental responsibility for them to participate in research
- To outline the different practices which apply to dealing with consent/capacity issues with regard to Clinical Trials of Investigational Medicinal Products (CTIMPs) and other types of research (non CTIMPs)

Scope

This procedure applies to staff in all locations including those with honorary contracts

Equality Health Impact Assessment	An equality impact assessment has been carried out on the Research Governance Policy under which this Procedure falls. No adverse impact has been identified.
Documents to read alongside this	- Cardiff and Vale University Health: Board Consent to Examination or Treatment Policy (UHB100)

Procedure	- Cardiff and Vale University Health Board: Research Governance Policy (UHB 099) - Health and Care Research Wales Good Clinical Practice (GCP) Training Requirements (all-Wales) SOP Number 2
Approved by	Research Governance Group (RGG)

Accountable Executive or Clinical Board Director	Research Governance Group (RGG)
Author(s)	Research Governance Co-ordinator Mental Capacity Act Manager

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	02/10/2012	*TBA*	*New document*
2	23/04/2013		Page 8, section 5.6: addition of . Valid Informed Consent in Research: Training Provider: NISCHR CRC
3	16/07/13		Section 5.2: re-written to reflect updated requirements for ethical review in the harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees. There are now a numbers of exemptions to the requirement for NHS ethical review, and rather than this policy attempting to provide a comprehensive list of those study types requiring NHS ethical review, the reader is directed to the National Research Ethics Service guidance document for further information.

4	13/03/14	16/05/14	Throughout: links to external websites and documents, as well as contact details, added and updated, accordingly Section 5 :clarification on who may take informed consent, which types of training are necessary and how this process should be documented. Section 5.4 clarifies that it is it the responsibility of the PI to ensure the person to whom taking informed consent is delegated is suitable. Also in this section, the requirement to complete the 'Delegation of Consent' form is changed from mandatory to optional, as this is a duplication of information already recorded in the Study Delegation Log. Section 6.4 contains minor clarification of informed consent in minors.
5			- Transferred onto current UHB template. -References to NISCHR changed to Health &Care Research Wales -References to NRES changes to HRA -Reference to new competency document for non medical staff who take consent. -Reference to new Clinical Trials Regulation -Clarifications and updated references throughout
6		24/04/2018	Updated to reflect replacement of research governance framework with UK policy framework for health and social care research Updated password for UHB consent training

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1.0 Responsibilities

Executive responsibility for this SOP lies with the Medical Director.

All healthcare staff who have contact with participants whilst undertaking Research have a responsibility to familiarise themselves with and follow the content of this SOP and to ensure that they remain up to date with regard to the law, case law and guidance regarding research, consent and mental capacity. This is also the professional requirement for those who are registered with professional bodies.

Where staff are unsure about the legal aspects of consent and capacity in a particular case, they must seek advice from the Mental Capacity Act Manager / Patient Safety Team in the first instance.

The R&D office is responsible for ensuring that this SOP is updated as necessary: that relevant training is available and to provide information and support to staff as required.

The Research Governance Group is responsible for monitoring, reviewing and where necessary, approving amendments to this SOP.

2.0 General Principles

2.1 Definitions of different kinds of research

For the purpose of this SOP, research studies can be divided into two categories: Clinical Trials of Investigational Medicinal Products (CTIMPS) and all other kinds of research (non-CTIMPS).

These two types of study are governed by differing legislation and this may affect the study design.

For the purpose of compliance with this SOP the researcher should make an early decision as to whether the study is a CTIMP or a non CTIMP.

The Medicine and Healthcare products Regulatory Agency (MHRA) have produced an algorithm to aid researchers in making this decision.

It is available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf

The MHRA has an email advice line available via their website should researchers still be unsure after reviewing the algorithm. However, it is advisable that the PI/CI first contacts their Trial Sponsor to gain advice.

All CTIMPs should be conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and their subsequent amendments, herein after referred to as 'Regulations'

It is important to note that these Regulations will be replaced by The EU Clinical Trials Regulation 536/2014 which will come in force during 2019 (exact date remains unknown on the day of publishing of this SOP).
The current legislation will be repealed on the day the new Regulation becomes applicable, although it will still apply three years from that day to:

- Clinical trials applications submitted before the new Regulation becomes applicable
- Clinical trials applications submitted within one year after the Regulation becomes applicable if the sponsor opted for the old system

More detailed information, updates and the Regulation itself can be found at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp
Those carrying out Clinical Trials should check the site regularly for updates and to ensure they are aware of the entry into application.

2.2 Ethical and organisational approval for studies

Where required, written evidence of favourable opinion from the appropriate NHS Research Ethics Committee (REC) must be obtained prior to commencing research. Information on the requirements for ethical review by Research Ethics Committees can be found on the HRA website
http://www.hra.nhs.uk/

2.3 Designing the Study

As part of the study/protocol design for both CTIMPs and non-CTIMPs, the issues of consent and capacity must be addressed. The skills and training requirements for individuals who will be taking consent should be considered in the study design.

The points listed below may differ depending on whether the study is a CTIMP or a non-CTIMP and are covered in detail in Section 4, but also need to be considered as part of the study/protocol design:

- The different legislative frameworks covering CTIMPs and non-CTIMPs

- If those with/without capacity are to be included, what information must be included in the protocol
- The documentation which is to be completed when assessing capacity
- Research in emergency situations including retrospective consent from previously incapacitated adults

The study design should also consider the points in the following sections.

3.0 Procedure

- Some types of research involving non-invasive surveys or questionnaires may not require a formal consent process to be undertaken. Voluntary completion of a research questionnaire, after receiving all the relevant information required to make an informed decision regarding participation, may constitute implied consent to participate in the study. This process should be detailed in the protocol and should be reviewed and approved by an ethics committee.

- Staff involved in the clinical care of a potential participant must make the initial approach to identify whether an individual would be willing to talk to or receive further information from a research team.

- Where a potential participant is approached about a study in clinic this should be documented in the participant source documents. The version number of any Participant Information Sheet (PIS) and the Informed Consent Form (ICF) given should be noted.

- When informed consent is given, this should also be documented in the source data. If consent is given on the same day as any study activities are performed, the time, as well as the date of consent should be documented to demonstrate that consent was given before any study activities took place. Copies of the original signed and dated Consent Form (and accompanying PIS) should be made. Unless otherwise required in the Protocol, the original signed copy should be filed in the Investigator Site File or project file, with one copy given to the participant and the second copy should be filed in the medical notes.

- Throughout the study, where relevant new or updated study information becomes available, participants and all members of the research team should be kept updated and new Consent Forms completed where appropriate. Copies of earlier versions of PIS or Consent Forms should be retained in the study file.

- Arrangements should be made, where necessary, for professional translation/interpreters to provide assurance that access to studies is equitable. Family members or relatives must not be used as translators

in research studies. Health and Care Research Wales Permissions Service provides Welsh translation services for research documentation if required.

Guidance and standard templates for the study documentation, including the PIS and ICF can be found at:
http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

3.1 Responsibilities for Consent

The Chief Investigator (CI) has overall responsibility for the design, conduct and reporting of the research project whereas the Principal Investigator (PI) is responsible for research processes at a particular site. These responsibilities, including consent and capacity, may be delegated to other members of the study team including medically qualified staff, nurses, and other healthcare professionals, scientists and psychologists etc.

3.2 Delegation of Consent

The General Medical Council (GMC) recommends that when Doctors delegate the task of informed consent, it is their responsibility to ensure that the person to whom the task is delegated:

- is suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment and understands the risks and acts in accordance with guidance as set out in GMC 'Seeking Patients Consent; The Ethical Considerations.'

Additionally, an addendum to ICH-GCP E6 (R2) became active on June 14th 2017. Included in the addendum are the following requirements:

- The investigator is responsible for supervising any individual or party, to whom investigator delegates trial-related duties and functions conducted at the trial site, and
- If the investigator retains the services of any individual or party to perform trial-related duties and functions, the investigator should ensure this individual or party is qualified to perform those trial-related duties and functions and should implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated. Therefore, it is the responsibility of the PI to ensure the suitability and capability of the person who has been delegated these duties and this should be documented according to the wishes of the study sponsor.

Where responsibility for consent has been delegated by the PI, the following conditions apply:

- The delegation of responsibility should be recorded on the Study Delegation Log (SDL) and agreed by the individual accepting responsibility. The Log should be stored in the Investigator Site File (ISF).
- Individuals must not accept responsibility for any part of the consent process unless they are trained and competent to do so.
- Any relevant professional Codes of Conduct should be adhered to
- All individuals who will be taking consent should receive study specific training such as that provided by the sponsor at the Initiation, or via the CI/PI. All training should be documented, signed by the PI, and evidence placed in the ISF.
- The competence of the individual responsible for taking consent and considering capacity should be assessed by the PI before they are delegated this duty and added to the SDL. In the case of individuals who would usually take consent as part of their normal duties, this assessment may be made from the PI's prior knowledge of that individual or for those who do not routinely take consent, after the PI is satisfied that the individual has completed appropriate training. (Please see section 3.4 for training requirements) The PI should document his/her assessment and competency of the individual as per sponsor requirements.
- The criteria for assessing and recording competence to obtain consent will be study specific. For convenience, a template form is provided in Annex 2 which lists the main criteria that should be considered when delegating informed consent. This form is not mandatory, but may be personalised and used in addition to the SDL, for those who may find it useful. Where completed, a copy of this form should be filed in the ISF.
- In addition to the above, a tool to assist researchers to assess the competency of those inexperienced in taking consent is available. (Informed consent Competency Assessment Version 1.0 – July 2014 the UKCRF Network Informed Consent Competency Assessment Workstream- part of the UKCRF Network Education & Training Group). Although not mandatory, it may be used where required.

3.3 Circumstances When Responsibility Should Not Be Delegated

Responsibility for consent should not be delegated from the CI/PI in any case where

a) a 16-17 year old appears not to have capacity to consent
b) a child under 16 years is not competent to give consent
c) it is not clear that the person with parental responsibility is acting in the child's best interests

The exception to this is where an individual other than the CI/PI would normally take consent and carry out a procedure/assessment as part of

standard clinical care, then they may also take consent for research involving the same procedure/assessment.

In any case where it is felt that an adult appears not to have capacity to consent then, having provided appropriate support to the person to help them make the decision for themselves without success, a formal mental capacity assessment must be undertaken in accordance with the Mental Capacity Act 2005. These processes must be recorded in the clinical notes.

3.4 Training

Whilst it is recognised that consent is covered under GCP training, the UHB expects that core areas of training will be observed.

(i) Protocol specific training: All individuals responsible for obtaining consent within research must undertake protocol specific training. A record of the training should be kept in the ISF - for example, a copy of the slides used, a meeting agenda and a signed attendance list should be kept in the ISF

(ii) Consent training: All individuals who do not obtain written informed consent as part of their normal duties should either undertake the online consent training provided by the UHB, as described in the UHB Consent policy UHB100 – http://www.beinformedplus.com/login. (Organisation Code=CAV, Password= UHB2017 NB Case is important.), or have completed the Valid Informed Consent in Research: **Training Provider:** –Health and Care Research Wales https://www.healthandcareresearch.gov.wales/

(iii) Mental Capacity Act training is mandatory for the UHB's clinical staff

Nurses/Midwives requiring further information regarding the delegation of consent should contact their line manager in the first instance, then contact the R&D office or a member of the R&D senior team for advice.

4.0 Mental Capacity and Research

4.1 Adults (aged 16 years and over) with mental capacity to decide to participate in research

CTIMPs:

- The consent procedure should comply with the principles outlined in the ICH-GCP guidelines, the HRA guidelines and applicable Regulations.
- Subjects should be given sufficient time to make a decision with regard to entering a clinical trial.
- If a capable adult gives informed consent to take part in a CTIMP and subsequently becomes unable to give informed consent by virtue of

physical or mental incapacity, the consent previously given when capable remains legally valid.

- If a capable adult does not consent to participate and subsequently loses mental capacity to give informed consent, the refusal is legally binding. He or she cannot then be entered into the trial by seeking consent from a legal representative

Non CTIMPs:

- The consent procedure should adhere to the general principles outlined in the HRA guidelines.
- Subjects should be given sufficient time to make a decision with regard to entering a research study.
- Where a participant loses mental capacity to decide about taking part in the research during the course of the research, he must be withdrawn from the research, unless the research proposal explicitly addresses this issue and the proposal has been granted REC approval. Alternatively, researchers can apply for REC approval to continue to include such subjects.

4.2 Adults (aged 16 years and over) who lack mental capacity to decide to participate in research

CTIMPs:

- Incapacitated adults should not be included in research if the same results could be obtained using adults capable of giving consent
- Schedule 1 of the Regulations outlines the factors which must be taken into consideration when obtaining consent for an incapacitated adult to participate in research and provides details on the process of involving a personal or professional legal representative to obtain consent on behalf of such individuals
- A personal legal representative is a person not connected with the conduct of the trial who is:
    (a) suitable to act as the legal representative by virtue of their relationship with the adult, ***and***
    (b) available and willing to do so.
- A professional legal representative is a person not connected with the conduct of the trial who is:
    (a) the doctor primarily responsible for the adult's medical treatment, or
    (b) a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).
- A professional legal representative may be approached if no suitable personal legal representative is available.
- The legal representative must be properly informed by the researcher about the trial

- The legal representative must also have been provided with a contact point where further information about the trial can be obtained
- The legal representative must be informed of the right to withdraw the participant from the trial at any time
- The legal representative gives informed consent for the to be included in the trial

Non CTIMPs:

- The Mental Capacity Act 2005 applies to research that is
    - (a) Intrusive (if the participant had capacity, the researcher would need to obtain their consent to involve them)
    - (b) Involves people who lacks mental capacity to decide whether or not to take part in the research, and
    - (c) Is not a Clinical Trial covered by the Regulations

- The Mental Capacity Act 2005 Code of Practice must be complied with
- The researcher must consult with appropriate people about whether the person who lacks mental capacity should be included in the research
- An appropriate person (the consultee) must be involved in the person's care, interested in their welfare and be willing to help, for example a family member. The consultee must not be a paid or professional care worker.
- If there is no-one appropriate to consult, the researcher must nominate a consultee using the following Department of Health guidance: *http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_083133.pdf*
- The consultee must have no connection with the research.
- The researcher must provide the consultee with information about the research and ask them:
- whether the person should take part, and
    - (a) what they think the person's feelings and wishes would be, if they still had capacity to decide
- If the consultee does not think that the person would have agreed to take part in the research, then they must not be included.
- **Note that, in contrast to CTIMPs, consent cannot be obtained from consultees. Rather, advice should be sought from them, but the decision to include a participant rests with the Principal Investigator.**
- If the person gives any indication that they do not wish to continue to be involved with the research, they must be withdrawn.

4.3 Emergency situations & incapacitated adults

CTIMPs

- There is provision within the Regulations relating to research involving incapacitated adults in emergency situations. When urgent treatment is to be given to an incapacitated adult as part of the trial, time may not allow for obtaining written consent from the legal representative.
- The Regulations allow incapacitated adults to be entered into a trial prior to consent being obtained from a legal representative provided that:
- Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency, but
- it is not reasonably practicable to obtain informed consent prior to entering the subject, and
- the action to be taken is carried out in accordance with a procedure approved by the ethics committee.
- Where an incapacitated adult is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent either from the participant(if capacity has been recovered) or from a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the participant must be withdrawn from the trial.
- Please refer to Schedule 1 of the Regulations for further information.

Non CTIMPs:

- Anyone responsible for caring for a person must give them urgent treatment if they need it.
- The research proposal should make clear how researchers will deal with urgent decisions which may be needed during the research.
- Where an adult who lacks capacity needs urgent treatment and researchers want to include them in a research study, the researchers must get agreement to include the person in the research from a registered medical practitioner, *or* follow a procedure that the REC agreed at the approval stage.

4.4 Children (aged under 16 years)

CTIMPs

- The Regulations outline how minors can lawfully be included within research. The Regulations also provide details on the process of involving a legal representative to obtain consent on behalf of minors, where because of the emergency nature of the treatment to be provided as part of the trial, it is not possible to obtain consent from a person with parental responsibility. The legal representative may be a personal legal representative who is a person not connected with the conduct of the trial who is:

(a) suitable to act as the legal representative by virtue of their relationship with the minor, and

(b) available and willing to do so.

- If no person suitable to act as a personal legal representative is available then a professional legal representative may be appointed. This must be a person not connected with the conduct of the trial who is:

(a) the doctor primarily responsible for the medical treatment of the minor, or

(b) a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).

- Written consent must be given by a parent or those with legal responsibility for the minor, but minors should also give their assent (the voluntary permission given by one who is old enough to understand and know if they want to take part or not).
- Where the parent is competent to decide for their child but unable to read or write, an impartial witness could sign the consent form to say that the information sheet has been read to the parent and verbal consent has been given.
- The child (where appropriate) and the person with parental responsibility/legal representative must be properly informed by the researcher about the trial
- They must also be provided with a contact point where further information about the trial can be obtained
- The child and the person with parental responsibility/legal representative must be informed of the right to withdraw from the trial at any time
- The legal representative must give informed consent for the minor to be included in the trial

Non CTIMPs:

- As with consent to treatment, the *Gillick* test of competence to consent to participate in research in the UK should be applied. This can be summarised: a child who has sufficient maturity and intelligence to be capable of understanding the treatment and making a decision based on the information provided will have capacity to consent to treatment and care. Children (i.e. those under 18 years of age) who are felt to be competent to understand the research proposal and thus make decisions can give consent on their own behalf.

- If a competent child consents to taking part in research, a parent cannot usually override that consent. However, parents' agreement may be necessary if children are to be seen at the parents' home or elsewhere if it is not a place where the child can be expected to go without parental agreement. Advice regarding such circumstances can

be sought from the UHB Senior nurse for R&D or The Mental Capacity Act Manager for UHB.

- Further guidance is available on the HRA website. The HRA guideline makes specific comments on the type of information which may be provided for different age groups and different levels of understanding.

4.5 Emergency Situations (Minors)

CTIMPs

- Where the treatment to be given to a minor as part of the trial needs to be administered urgently, time may not allow for the written consent of a person with parental responsibility or a legal representative to be obtained first.
- Minors may be entered into a trial prior to informed consent being obtained provided that:

a) Having regard to the nature of the trial and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency, but
b) It is not reasonably practicable to obtain informed consent prior to entering the subject, and
c) The action to be taken is carried out in accordance with a procedure approved by the ethics committee.

- Where a minor is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from a person with parental responsibility or a legal representative as soon as practicable after the initial emergency has passed. Where consent is withheld, the participant must be withdrawn from the trial.

Non CTIMPs:

- Children should be given urgent treatment if they need it. The research proposal should make clear how researchers will deal with urgent decisions which may be needed during the research.

For a brief summary, please refer to the table detailed in Annex 3

5.0 Consent to collect human tissue for research purposes

The Human Tissue Act (2004) focuses on the fundamental principle of consent for storage and use of any tissue taken from a living person. One of the 'scheduled purposes' for which tissue (including blood) may be taken with consent is 'research in connection with disorders or functioning of the human body'. However, the Act allows research without consent on 'residual tissue' provided the samples are anonymised and the research has REC approval.

For further information, please contact The UHB Governance Officer, Human Tissue Act.

Advice may be sought from the UHB R&D Office or Cardiff University Research and Innovation Service (RIS) depending on the person's substantive employer.

6.0 Implementation

The Clinical Board R&D Leads must ensure that all relevant personnel within their Clinical Boards are aware of this SOP and the implications for their practice. There are no additional resources required for implementation of this SOP.

7.0 Distribution

Cardiff and Vale UHB research personnel via the UHB intranet and through Clinical Board R&D Leads.

ANNEX 1 - Abbreviations and Definitions

CI – Chief Investigator
CRF – Case Report Form
CTIMP – Clinical Trial of an Investigational Medicinal Product
GCP - Good Clinical Practice
GMC - General Medical Council
HTA – Human Tissue Act
HRA - Health Research Authority
ICF - Informed Consent Form
ICH - International Conference for Harmonisation
ISF – Investigator Site File
MCA – Mental Capacity Act 2005
PI – Principal Investigator
PIS – Participant Information Sheet
R&D - Research and Development
REC – Research Ethics Committee
SDL - Study Delegation Log
SOP - Standard Operating Procedure
UHB - University Local Health Board

The Chief Investigator (CI) is the clinician with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites.

The Principal Investigator (PI) is responsible for the research site. For multi-site studies, there should be one PI for each research site. In the case of a single site study, the CI and the PI can be the same person.

Medical Staff – A qualified Physician or Dentist.

Non-Medical Staff – Healthcare professionals and other professional groups such as Nurses (including Research Nurses, Specialist Nurses), Midwives, Physiotherapists, Podiatrists, Radiologists, Dieticians, Psychologists, Social Scientists, Biomedical Scientists, etc (this list is not exhaustive).

ANNEX 2 - Template for Delegation of Informed Consent Responsibilities for Research

Title of Study: R&D Number/IRAS Number

Name (BLOCK CAPITALS) _____

As Principal Investigator for the above study, I confirm that the above named

	Initial Boxes
• Has obtained certification either by completing an on-line training package or attending face to face training on valid informed consent in research *(Please circle whichever applies)*	
• Has undergone protocol specific training and can fully inform the potential participant of the nature of the study and associated risks/alternative treatment options.	
• Has completed an appropriate competency package in receiving consent for the above study (if required)	
• Recognises and practises within own limits and professional boundaries and professional Code of Conduct	
• Is aware that they may be subject to observation of their practice whilst taking consent, on a random basis and will comply with any audits undertaken on the consent process	

I have delegated responsibility to *[Insert Name]* to receive informed consent for this study and have recorded this on the Study Delegation Log

Name of Principal Investigator (PRINT) _____

Signature _____ Date _____

Acceptance of delegated responsibility

Name (PRINT) _____

Date

Signature _____ _____

1 copy for Investigator Site File, 1 copy for training file

To download a working copy of this form, please follow this link: ANNEX 2 Template for Delegation of Informed Consent Responsibilities for Research (TR-RG-014)

ANNEX 3 Consent-Capacity Guidance Table

SUBJECT	CTIMP	Non-CTIMP
Adult with mental capacity	Adult gives consent	Adult gives consent
	If then loses mental capacity to consent, can remain in the trial	If then loses mental capacity to consent, must be withdrawn unless ethical approval has been explicitly given for the adult to remain in the study
Adults who lack mental capacity	Must not be included in trial if the same results could be obtained using adults capable of giving consent	Must not be included in research if the same results could be obtained using adults capable of giving consent
	Legal representative must give consent	Researcher must consult with an appropriate person (consultee) about whether or not adult should be included. Consultee does NOT give consent. Decision lies with researcher
Emergency situations where the adult lacks mental capacity	Incapacitated adults can be included in trial, but consent must be obtained from either the adult or the representative as soon as practicable	Researchers must get agreement to include the person in the research from a registered medical practitioner, *or* follow a procedure that the REC agreed at the approval stage
Children aged under 16 years	Consent must be given by someone with parental responsibility for the child or, in an emergency where it is not possible to obtain consent from a person with parental responsibility, consent must be obtained from a legal representative	Consent can be given by a *Gillick* competent child, or if the child is not competent, by a person with parental responsibility for the child

Emergency situations and children	Where a minor is recruited in an emergency situation without prior informed consent, steps must be taken to seek informed consent from a person with parental responsibility or a legal representative as soon as practicable after the initial emergency has passed	Children should be given urgent treatment if they need it. The research proposal should make clear how researchers will deal with urgent decisions which may be needed during the research