

Document Title: Obtaining Informed Consent: Adults Who Lack Capacity

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Version Control

Version	Date	Author	Status	Comment
1.0	01/07/2014	Alison Allen	Final	New Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	09/10/2017	Lucy Parker	Final	Update to new SOP template. Addition of withdrawal of consent Additional of consent to supply relevant material to external organisations Replacement of Research Governance Framework with UK Policy Framework for Health and Social Care (2017)

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1. INTRODUCTION

Informed consent (IC) in the context of a research study, is the process by which a competent subject voluntarily confirms his or her willingness to participate in a particular study and the associated documentation, after having been informed of, and having comprehended all aspects of the study that are relevant to their decision to participate. It is morally and professionally unacceptable to perform any research related procedure on someone without first obtaining their informed consent.

Informed consent is a four step process which involves:

1. The giving of information.
2. The discussion and clarification of the information and.
3. Taking the subject's verbal and written consent.
4. Documenting the process of consent

All participants entering into a clinical study/research project must have given informed consent before any aspect of the project starts (interventional or non-interventional) and the original signed version should be filed in their medical records (or scanned in if the records are electronic) or study notes (for healthy volunteer studies) together with a copy of the Participant information Sheet (PIS). A copy of the signed consent form should be given back to the participant together with the PIS and a copy retained in the study file.

2. OBJECTIVE

This SOP describes the procedure for obtaining written informed consent for a study subject who lacks capacity to consent for themselves.

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 dealt with appropriately, in accordance with the legal and regulatory framework.

To describe the procedure to be followed 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 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.

3. DEFINITIONS

RF Royal Free London NHS Foundation Trust

Responsible Personnel -The Declaration of Helsinki states that the person seeking informed consent should be a qualified physician: 'The physician should then obtain the subject's freely given informed consent, preferably in writing' (1996 version). However ICH GCP guidelines state that 'The investigator, or, a person designated by the Investigator should fully inform the subject' (ICH GCP 4.8.5) and the written

informed consent form should be signed and dated by the 'person who conducted the informed consent discussion'.

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a study-by-study basis. If staff other than the Chief Investigator (CI) or Principal Investigator (PI) are to accept responsibility for the informed consent process, it is important the following criteria are met:

1. They are prepared to take on this additional responsibility AND feel confident to seek informed consent in line with their professional organisational guidelines e.g. if a Clinical Research Nurse (CRN), taking of Informed Consent in line with the Nursing and Midwifery Council Code of Professional Conduct
2. They have a full understanding of the study, potential risks/benefits and the associated disease area. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
3. This delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log (title can vary from Sponsor to Sponsor, but is essentially a log that captures each member of the study team and their individual responsibilities in the management and conduct of the study and is signed and dated by the CI/PI). The RF R&D Office has a template delegation log available on their website (RFLRDLOG0004). Alternatively, researchers can contact their assigned RF R&D Office Research Portfolio Manager, who will be able to send them the template.
4. The process has been approved by the relevant Research Ethics Committee (REC)
5. An effective line of communication is maintained back to the CI/PI who is the person ultimately responsible for the subject's care.
6. Where the taking of informed consent is the role of someone who is not medically qualified doctor it is expected that a medically qualified doctor who is part of the trial team is readily available during or following the consent process if the subject required or requests further discussion relating to the medical care to be provided as part of the trial

It is ultimately the responsibility of the CI/PI to ensure that subjects have fully understood what they are consenting to, and it is usual practice for the CI/PI or Co-Investigator to sign/countersign the Consent Form.

It is best practice for any other research personnel involved in giving information during the informed consent procedure to sign and date the Informed Consent Form, e.g. if a translator was used, they should also sign and date the consent form.

All those responsible for obtaining written informed consent must have a copy of their signed and dated CVs in the Trial Master File (TMF), and must have completed the study Delegation Log/Site Responsibility Log, which must also be signed and dated by the CI. For CTIMPS, all those taking consent must have valid GCP certificates within the last two years (See SOP005 GCP Training)

Informed Consent has been defined as follows "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 Guideline for Good Clinical Practice E6 (R1)(1996), 1.28

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 encompass situations where it is not possible to obtain informed consent for participants to be involved in Medicinal Clinical Trials. The Regulation describes provisions relating to giving informed consent on behalf of adults who are unable to consent for themselves (referred to as “incapable adults”), including the role and responsibilities of legal representatives. 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’.

Mental Capacity Act 2005 The Act applies to research involving adults over the age of 16 in England and Wales, except Clinical Trials of Investigational Medical Products (CTIMPs) covered by the Regulations. -

4. SCOPE

This SOP will cover the procedure of obtaining written informed consent from a study participant. Specifically, Adults who lack Capacity and consent for relevant material as defined under the Human Tissue Act to be supplied to an external organisation.

This SOP only relates to obtaining consent where the participant does not have Capacity to consent for themselves.

For Adult participants with capacity please refer to: SOP007- Obtaining Informed Consent for a Research Study – Adults

For Children, please refer to: SOP009 –Obtaining Informed Consent for a Research Study – Children.

5. EQUALITY STATEMENT

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust’s commitment. You are responsible for ensuring that the trust’s policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (2).

6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

The delegation of IC to an appropriate, suitably qualified member of the research team should be considered on a study-by-study basis, taking account of local circumstances and be in accordance with ICH GCP Guidelines.

7. PROCEDURE

Person Responsible	Task
PI or delegated team member	<p>7.1 Informed Consent Form Contents</p> <p>Copies of the Participant Information Sheet and Informed Consent Form must be approved by the REC and should be used, together with any documents the subject may need to use e.g. subject diaries. There should be a separate information sheet for the person who will be giving consent or assent on behalf of the participant.</p> <p>The Informed Consent Form must be checked for the following:</p> <ol style="list-style-type: none"> 1. It should be on localised Trust headed paper. 2. The correct title, date and version number for the study is clearly visible and relates to the written Information Sheet given to the participant. 3. A statement to say the participant has had the study explained to them and by whom. The risks, benefits and alternative treatments have been discussed and all the subject's questions have been satisfactorily answered. 4. A statement that their participation is voluntary and they are free to withdraw at any time, without the loss of any treatment to which they would otherwise have been entitled. 5. A statement that their medical records may be reviewed by authorised personnel and that confidentiality will be maintained at all times. 6. That compensation arrangements have

	<p>been discussed. 7. That their data and/or samples may be included or used in further ethically approved research studies</p> <p>If the study is a clinical trial, there must also be a discussion around arrangements for continued IMP access post trial, and made clear that there is no guarantee a drug will be approved for non-trial use. If it is known that a drug will be made available via an extension protocol or compassionate use programme, this should also be made clear. All of this should also mentioned in the PIS</p> <p>The RF R&D Office has template consent forms available on their website. Alternatively, researchers can contact their assigned RF R&F Office Research Portfolio Manager who will be able to send them the templates.</p>
	<p>7.2 CTIMP Studies</p> <p>Only medical professionals can gain consent from participants who lack capacity for CTIMP trials. The following principles need to be observed in this situation:</p> <ul style="list-style-type: none"> • 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 Medicines for Human Use (clinical trials) Regulations 2004 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. <ul style="list-style-type: none"> (a) A personal legal representative is a person not connected with the conduct of the trial who is: <ul style="list-style-type: none"> (i) suitable to act as the legal representative by virtue of their relationship with the adult, and (ii) available and willing to do so. (b) A professional legal representative is a person not connected with the conduct of the trial who is: <ul style="list-style-type: none"> (i) the doctor primarily responsible for

	<p>the adult’s medical treatment, or (ii) a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).</p> <ul style="list-style-type: none"> • 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 subject from the trial at any time. • The legal representative gives informed consent for the subject to be included in the trial
	<p>7.3 Non CTIMP Studies</p> <p>The Mental Capacity Act (2005) applies to research that is not a Clinical Trial covered by the Regulations.</p> <p>The researcher must consult with appropriate people about whether the person who lacks mental capacity should be included in the research.</p> <p>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.</p> <p>If there is no-one appropriate to consult, the researcher must nominate a consultee. The consultee must have no connection with the research. The researcher must provide the consultee with information about the research and ask them:</p> <ul style="list-style-type: none"> • Whether the person should take part, and 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. <p>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.</p> <p>If the person gives any indication that they do not wish to</p>

	<p>continue to be involved with the research, they must be withdrawn.</p>
	<p>7.4 Emergency Situations and Incapacitated Adults</p> <p>7.4.1 CTIMP Studies</p> <p>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.</p> <p>The Regulations allow incapacitated adults to be entered into a trial prior to consent being obtained from a legal representative provided that:</p> <ul style="list-style-type: none"> • 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 subject (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 subject must be withdrawn from the trial. <p>7.4.2 NON CTIMP STUDIES</p> <p>Anyone responsible for caring for a person must give them urgent treatment if they need it.</p> <p>The research proposal should make clear how researchers will deal with urgent decisions which may be needed during the research.</p> <p>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.</p>

	<p>7.5 Patients Who do not Speak English (RF Site)</p> <p>The interpreting service exists for patients who speak little or no English and who require communication support. All requests for interpreting are managed by the Patient Advice and Liaison (PALS) team. The office is located on the ground floor of the main RFH building, next to main reception. The service uses external agencies to provide both face-to-face and telephone interpreting. Telephone interpreting should be used for all appointments 40 minutes or under.</p> <p>To use telephone interpreting please call 0800 028 0073, provide the operator with details of the service booking the interpreter together with the language, your details and the ID code 269237. You will be connected to an interpreter within 40 seconds.</p> <p>Face-to-face interpreters have to be booked five working days in advance as interpreters are not employed direct by the trust. Please note that all face-to-face booking must be made through PALS and not with the interpreter or agency direct. However, it is worth checking with PALS whether an interpreter is possible even if the timeframe is less than 5 working days.</p> <p>Please note that the PALS department closes at 5pm therefore any bookings received after 4.30pm that day will be processed the next day. If cancelling a booking then please e-mail the details to rfh.PALS@nhs.net. The PALS office is closed at weekends and request forms submitted after 4pm on Friday will not be processed until the following Monday (excluding Bank Holidays).</p>
	<p>7.6 Consent to supply relevant material to external organisations</p> <p>Most external organisations require assurances that informed consent has been appropriately and legally obtained.</p> <p>If tissue samples are to be stored for future use and/or external collaboration there are key points that should be included in the Participant Information Sheet and clauses added to the consent form:</p> <ol style="list-style-type: none"> 1. Consent should be in writing from the donor, legal representative or next-of-kin as appropriate. 2. Ethics approval or a statement that

	<p>approval is not required should be obtained.</p> <p>3. The participant information sheet and consent form explains the actual or potential use of tissue samples.</p> <p>4. Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet.</p> <p>Researchers should consider which clauses in relation to future use should be made optional so that the participant can participate in a study without having to consent to their samples being used for future use.</p>
	<p>7.7 Withdrawal of consent</p> <p>Many studies will have participants “drop out” of participating in the study. Indeed, many studies plan for a certain percentage of their participants to remove themselves from the study. It is important therefore, to have a process in place for recording the removal of consent from a study.</p> <p>Researchers are allowed to ask the participants for the reason of withdrawal of consent. This may help the design of the study, e.g. if they are dropping out because they feel there are too many visits or too many questionnaires to complete, the study team may then going through the correct procedure for amending the study design. However, the participant does not have to give them a reason.</p> <p>There are a number of options available should a participant choose to stop taking part in the study. Are they going to give permission for all of their data and samples to be collected until the point of withdrawal to be used or do they wish everything to be removed? There should be a discussion with the participant and their wishes recorded in their notes and in the study records.</p> <p>If the participant wishes all data/samples to be removed/destroyed then their wishes must take precedence over the wishes of the researcher.</p>

8 POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

9 RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director should be gained before any action is taken.
- SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
- The R&D Office is responsible for the ratification of this procedure.

10 FORMS/TEMPLATES TO BE USED

None applicable

11 FLOWCHART

None applicable

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APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	Informed Consent for Adults who lack Capacity		
Briefly describe its aims and objectives:	This SOP describes the procedure for obtaining written informed consent for a study participant who lacks capacity to consent for themselves.		
Directorate and Lead:	Rachel Fay, R&D Manager, R&D Office		
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 The Mental Capacity Act 2005		
Is the Trust Equality Statement present?	Yes	No	if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Age	None identified	R&D administrative document	NA	NA	This SOP includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
Disability	None identified	R&D administrative document	NA	NA	
Gender Reassignment	None identified	R&D administrative document	NA	NA	
Marriage and Civil Partnership	None identified	R&D administrative document	NA	NA	
Pregnancy and maternity	None identified	R&D administrative document	NA	NA	

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Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Race	None identified	R&D administrative document	NA	NA	
Religion or Belief	None identified	R&D administrative document	NA	NA	
Sex	None identified	R&D administrative document	NA	NA	
Sexual Orientation	None identified	R&D administrative document	NA	NA	
Carers	None identified	R&D administrative document	NA	NA	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	10/11/2017
R&D Committee	Royal Free London NHS Foundation Trust	21/12/2017

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V2.0, 09 OCT 2017

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