

Document Title: Informed Consent for a Research Study – Adults with Capacity

Document Number: 007

Version:	2
Ratified by:	R&D Committee
Date ratified:	21/12/2017
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Date issued:	05/02/2018
Review date:	05/02/2021
Target audience:	All research staff
Intranet:	NA
Key related documents:	Royal Free Hospital Policy for Consent to Examination or Treatment SOP005 GCP Training SOP008 Obtaining Informed Consent for a Research Study - Children SOP009 Obtaining Informed Consent for a Research Study – Incapacitated Adults RFLRDDOC0007 PIS non CTIMP template RFLRDDOC0008 ICF non CTIMP template RFLRDLOG0004 Staff Delegation of Duties Log
This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017) The Mental Capacity Act (2005)

Date equality analysis completed.	21/12/2017
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Version Control

Version	Date	Author	Status	Comment
1	01/07/2014	Alison Allen	Final	New Document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04/10/2017	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) Include the requirement to document in the source data giving the PIS to patient prior to the screening visit

Contents

Section		Page
1	Introduction	5
2	Objective	5
3	Definitions	5
4	Scope	7
5	Equality statement	7
6	Duties	7
7	Details of procedure	7
8	Policy	14
9	Risk management/liability/monitoring & audit	14
10	Forms/templates to be used	14
11	Flowcharts	14
Appendices		
Appendix (1)	SOP reading log	15
Appendix (2)	Equality analysis guide and tool	17

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.
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 from a study participant. This involves informing the participant by means of a verbal explanation and written patient information.

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

4. SCOPE

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

For taking of consent in minors please see SOP008 and for consent for adults who lack capacity, including emergency situations, see SOP009

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.

It is the responsibility of the Chief Investigator and anyone delegated the responsibility of taking informed consent to read, understand and follow this SOP.

7. PROCEDURE

Person Responsible	Task
PI or delegated team member	7.1 Informed Consent – the Basics All potential participants should be given information about the study prior to inclusion in the study. The dignity of the potential participant should be taken into consideration, and a private area used for the consent

	<p>process if required.</p> <p>The PI, research delivery team or delegate should document in the source data e. medical notes when the participant was given the patient information sheet and any discussions to demonstrate that the participant were given ample time to consider the information and their participation in the trial prior to attending their screening visit.</p> <p>Subjects who potentially fulfil the inclusion/exclusion criteria will be identified and approached and a verbal explanation of the study must be given to the potential participant (or friends and family if appropriate) by the researcher. If necessary, diagrams or pictures should be used to explain the study. For example, it is much easier to show a picture of a person lying in an MRI than it is to write a description of this. Time for questions throughout the discussion must be given and questions adequately addressed.</p> <p>The informed consent process should not end once the Informed Consent Form has been signed. The practice of giving information about the study to participants should be an ongoing process performed by all members of the research team and any associated healthcare professionals.</p> <p>This is particularly important if protocol amendments are introduced, or if important new information that may be relevant to the participant’s willingness to continue taking part in the study or wellbeing is discovered. In these circumstances it may be necessary to re-consent the participant using an amended Participant Information Sheet and consent form, to continue their involvement in the study.</p> <p>The timing of the signing of the Consent Form, relative to study registration and the initiation of study procedures, is subject to audit by regulatory/approval bodies. It is therefore essential to record dates correctly on both the Informed Consent form and in the subject’s medical notes.</p> <p>The consent form must be signed by the study participant before any aspect of their involvement in the study begins.</p>
<p>PI or delegated team member</p>	<p>7.2 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</p>

	<p>documents the subject may need to use e.g. subject diaries. 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 been discussed. 7. That their data and/or samples may be included or used in further ethically approved research studies <p>The HRA have template consent forms and guidance 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>PI or delegated staff member</p>	<p>7.3 Documenting consent and eligibility</p> <p>Prior to recruitment to a study, the individual taking consent must explicitly record in the source documents which inclusion and exclusion criteria are satisfied; it is not sufficient to include a statement that all criteria have been met. It is advisable</p> <p>This is particularly important when the criteria rely on investigator judgement (e.g. that the individual has the capacity to consent) or where the absence of a condition is required (e.g. that there is no history of mental health conditions, or no history of drug abuse).</p>
<p>PI or delegated staff member</p>	<p>7.4 Taking consent from Adults with the capacity to consent.</p> <p>Patients who potentially fulfil the inclusion/exclusion criteria will be identified and approached. The doctor/research nurse who offers a patient a specific</p>

	<p>trial should ensure the patient fulfils the eligibility criteria by checking the patient's medical history and checking which medication they are currently taking.</p> <p>This should be documented in the patient's notes. Time for questions throughout the discussion must be given and questions adequately addressed.</p> <p>When describing the study the person seeking consent should explain:</p> <ol style="list-style-type: none">1. What the purpose of the study is and any background information that may be relevant.2. Why the participant has been approached3. Details of the study design and details of any drugs used (including any known safety profiles). If there is a placebo arm or randomisation involved then these procedures should be explained.4. The number of people taking part in the study and how many have been recruited to date.5. The duration of the study and the number of study visits involved. It should be explained where the subject will be seen and by whom.6. All procedures, such as blood tests, electrocardiograms (ECGs) etc. that are required as part of the study should be included and explained in lay language e.g. "10mls (2 teaspoons) of blood."7. The potential benefits and risks of participation in the study, and any alternative treatments available to the subject should be discussed.8. The availability of compensation should something go wrong.9. That the participant enters the study voluntarily and can withdraw at any time without any prejudice to them or their future care. Similarly if the Investigator feels that the study medication is not suiting the participant that they have the right to withdraw them from the study in the interests of their safety.10. That a detailed discussion of the participant's medical history (including disclosure of all medication they are taking) will be required should they agree to participate.11. If there are any payments made for participation in the study or for out of pocket expenses.12. The responsibilities of the participant if they choose to take part, particularly if the
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	<p>study duration is lengthy.</p> <p>13. That giving informed consent does not necessarily mean the participant will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria e.g. a study specific diagnostic test.</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>Once the above information has been verbally discussed with the subject, the participant should be provided with a written Participant Information Sheet about the study (on localised Trust headed paper).</p> <p>The participant should be given adequate time to read the Participant Information Sheet and to discuss with any family and friends (if applicable), prior to agreeing to participate. There are no statutory requirements specifying how long potential subjects should be allowed to consider the trial. This will depend on the need for treatment – for example, the decision to enter into a clinical trial in an emergency setting may need to be made in a very short timeframe – but it should be clearly defined in the REC application. Patients should not be coerced in any way to participate in the study.</p> <p>The participant should not be coerced to take part.</p> <p>Once the participant has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then they should be asked to sign the written Informed Consent Form relating to the study.</p> <p>Each box following each statement on the consent form should be personally initialled by the participant to affirm agreement with the corresponding statement.</p> <p>The Informed Consent Form must be personally signed and dated in ink easily visible on photocopies by the person seeking consent, the CI/PI or Co-Investigator (if different) and the participant. Each should also clearly print their name by their signature.</p>
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	<p>Once all parties have signed the written Informed Consent Form, the participant should receive a signed and dated copy, together with a participant Information Sheet and any other written information provided to the participants. The original copy of the above must be placed in the participant’s medical notes (scanned into the applicable section if the medical notes are electronic) or study notes (for healthy volunteer studies) and a copy kept by the study team in the Site File.</p> <p>The patient’s notes should make the process of IC transparent. This information should be presented in the patient’s medical notes in a detailed and chronological order.</p> <p>Please read/review the RFH policy for consent to examination or treatment.</p> <p>http://freenet/trustpolicies.asp#documentsc</p> <p>All participants must be provided with 24 hour contact details where they may obtain further information about the study (only applicable for CTIMP studies). This will either be the CI’s number or a contact number of a member of the study team.</p>
<p>PI or delegated team member</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</p>

	<p>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). lp</p>
<p>PI or delegated team member</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 approval is not required should be obtained. 3. The participant information sheet and consent form explains the actual or potential use of tissue samples. 4. Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet. <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>PI or delegated team member</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</p>

	<p>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>
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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

RFLRDDOC0007 PIS non CTIMP template

RFLRDDOC0008 ICF non CTIMP template

11. FLOWCHART

SOP 007: Informed Consent for a Research Study – Adults with Capacity

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<https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

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	Obtaining Informed Consent – Adults with Capacity
Briefly describe its aims and objectives:	This SOP describes the procedure for obtaining written informed consent from a study participant. This involves informing the participant by means of a verbal explanation and written patient information.
Directorate and Lead:	Rachel Fay, R&D Manger, R&D Office
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017) 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	

SOP 007: Informed Consent for a Research Study – Adults with Capacity

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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