Standard Operating Procedure

S15 – Informed Consent Version 7	
Post holder responsible for Procedural Document	Helen Quinn, Director of Research & Development
Author of Standard Operating Procedure	Samantha Keenan, Lead Research Nurse
Division/ Department responsible for Procedural Document	Research & Development
Contact details	samantha.keenan@nhs.net
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Author & Position	Samantha Keenan, Lead Research Nurse
Signature	SKeenan
Date	3.5.2023
Approver & Position	Helen Quinn, Director of Research & Development
Signature	
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Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0 Final	04 March 2011	Research Nurse	Process documented
2.0 Final	20 March 2014	Lead Research Practitioner	Updated terminology and addition of requirements in process
3.0 Final	October2017	Lead Research Nurse	Revised process to include re-consenting; Update into Trust template
4.0 Final	19 December 2019	Team Lead	6.1.5 revision
5.0 Final	15 October 2020	Team Lead	Update into current SOP template
6.0 Final	18 March 2021	Lead Research Nurse	Incorporating HTA referencing in section 6
7.0 Draft	?? ?? 2023	Quality Assurance Manager	Ensuring the SOP covers the procedure for Eastern and Northern Services.

Associated Trust Policies/ Procedural documents:	S26 Training for Research Staff Royal Devon Consent Policy Consent to examination or treatment
Key Words:	R&D SOP Template Work Instruction

In consultation with:

- Band 6/7 Research Nurses
- Clinical Trials Group
- Governance Oversight Group
- Core team meeting
- Quality Assurance Group

Contents

KEY POINTS OF THIS PROCEDURAL DOCUMENT:

- The investigator/research team obtaining and documenting informed consent should comply with the applicable regulatory requirement(s).
- Study participants should not be recruited until all regulatory approvals are in place.
- It can be appropriate for the Chief Investigator (CI) or Principal Investigator (PI) to delegate the process of informed consent to other members of the research team.
- Participant information should be provided to potential study participants in both an oral and written form.
- The person receiving informed consent must ensure they are completely familiar with all aspects of the clinical trial.

1. INTRODUCTION

1.1 Informed consent in the context of a research study is a process of information exchange, which involves the giving of information, the discussion and clarification of the information and the receiving of the participant's verbal and written consent. Participants must have given their informed consent prior to participating in any study procedures. The process of obtaining informed consent should be documented in the participant's medical records and a copy of the signed consent form inserted.

1.2 In obtaining and documenting informed consent, the investigator/research team should comply with the applicable regulatory requirement(s) (e.g. REC, HRA, and MHRA if applicable), and should adhere to the principles of Good Clinical Practice (ICH GCP E6, R2) and the UK Policy Framework for Health and Social Care Research.

2. PURPOSE

The purpose of this document is to set out the process of receiving informed consent from research participants within the Royal Devon Trust including all sponsored and hosted studies

Study participants should not be recruited until all regulatory approvals are in place. For confirmation please email rduh.research-eastern@nhs/net

3. SCOPE

This SOP applies to all research staff obtaining informed consent from a study participant.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
ICH	International Conference on Harmonisation
NMC	Nursing and Midwifery Council
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research & Development
REC	Research Ethics Committee
Royal Devon	Royal Devon University Healthcare NHS Foundation Trust
SOP	Standard Operating Procedure

5. DUTIES AND RESPONSIBILITIES OF STAFF

This SOP is applicable for all clinical trials sponsored and hosted by the Trust and also for non-Trust sponsored trials which do not have their own procedures for consent. This SOP relates to participants who are able to give informed consent for participation in a clinical trial and also sets out the consent procedures for more vulnerable participants (minors and incapacitated adults).

It is the responsibility of the person receiving valid informed consent to ensure that all the applicable regulatory approvals are in place prior to any research activity taking place for that study.

You should refer to the Health Research Authority (HRA) website. For further information on consent form layout and requirements for participant information sheets.

It is important that this SOP be read and understood before study personnel start receiving consent, but it should also be referred to if any doubt arises regarding the process of informed consent during the study.

6. PROCEDURES

6.1 How to Delegate Responsibility for Informed Consent

6.1.1 It is anticipated that for some studies it will be appropriate for the Chief Investigator (CI) or Principal Investigator (PI) to delegate the process of informed consent to other members of the research team. Where an ethically approved protocol allows other members of the research team to take consent, this will be permitted within the Trust under the following criteria:

- The designee is prepared to take on this additional responsibility AND feels confident to receive informed consent in line with their Code of Professional Conduct i.e. NMC or other professional organisational guidelines (if applicable).
- S/He has a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease

area. The designee should be fully aware of the risks and potential benefits of taking part in the clinical trial. S/he should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.

- The delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log.
- The process has been approved by the relevant Research Ethics Committee (REC) and Trial Sponsor.
- An effective line of communication is maintained back to the CI/PI who is ultimately the person responsible for the participant's care and for ensuring that participants have fully understood what they are consenting to.

6.1.2 It should be noted that receiving informed consent is a separate procedure from checking eligibility, and where eligibility must be confirmed by the PI or a registered doctor, this cannot be delegated to a research nurse or practitioner but must be conducted and documented prior to receiving informed consent.

6.1.3 Any other research personnel involved in giving information during the informed consent procedure should also sign and personally date the informed consent form.

6.1.4 All persons who obtain written informed consent must have a copy of their signed and dated CVs in the Study Site File and must have completed the Study Delegation Log/Site Responsibility Log, which is also signed and dated by the CI/PI.

6.1.5 All persons obtaining written informed consent must have appropriate training and/or documented competency sign off. If this is a CTIMP this needs to be a registered health care practitioner and within their scope of practice. The role should be delegated by the Principal Investigator of the study and recorded on the delegation log

6.2 Information for the Participant

6.2.1 Participant information should be provided to potential study participants in both an oral and written form.

6.2.2 ICH GCP (4.8.10) describes what you should explain to the research participant during the discussion prior to them consenting to participate in a trial and what should be contained within the written informed consent form (or any other written information relating to the trial).

You should check that the oral information reflects any written information provided to participants, both of which should include explanations of the following:

- A statement that the trial involves research.
- The purpose of the trial.
- The trial treatment(s) and the probability for random assignment to each treatment.
- The trial procedures to be followed, including all invasive procedures.

- The participant's responsibilities.
- Those aspects of the trial which are experimental.
- The reasonably foreseeable risks or inconveniences to the participant and, when applicable, to an embryo, foetus or nursing infant.
- The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- Alternative procedure(s) and course(s) of treatment that may be available and their important potential benefits and risks.
- The compensation and/or treatment available to the participant in the event of trial-related injury.
- The anticipated prorated payment, if any, to the participant for participating in the trial.
- The anticipated expenses, if any, to the participant for participating in the trial.
- That the participant's participation in the trial is completely voluntary and that the participant may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant would otherwise be entitled and without affecting their future care.
- That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorising such access.
- That the participant's General Practitioner will also be informed in writing of their participation in the study, if required. By signing the informed consent form, the participant or the participant's legal representative is authorising such access.
- That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.
- 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.
- The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.
- The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated.
- The expected duration of the participant's participation in the trial.
- The approximate number of participants involved in the trial.

6.3 The Receiving of Consent

6.3.1 The person receiving informed consent must ensure they are completely familiar with all aspects of the clinical trial as described in the latest version of the protocol and approved by the REC. Consideration should also be given as to whether it is even appropriate to approach a particular individual with a request to participate in a study. Those receiving consent should consider

whether there are factors present which may impair a participant's capacity at that time point.

6.3.2 The person receiving informed consent must have to hand copies of the participant information sheet and informed consent form for the study using the current version approved by the REC, together with any documents that the participant may need to use e.g. diaries.

6.3.3 All prospective study/research participants should be given information regarding the study in a suitable area. Respect and dignity of the participant should be taken into consideration prior to the consent process being performed and a private area sought if required.

6.3.4 Participants who potentially fulfil the inclusion criteria will be identified and approached. A verbal explanation of the study must be given to the participant (and friends and family if appropriate), and if necessary diagrams may be used to explain the study. Time for questions throughout the discussion must be given and questions adequately addressed.

6.3.5 The person taking informed consent should then provide the participant with a written information sheet (which should be localised to participating site).

6.3.6 Participants should be given adequate time, usually at least 24 hours, unless otherwise stated in the protocol, to read the information sheet and to discuss with any family and friends (except in the case of acute/ emergency studies), prior to agreeing to participate. The participant should not be coerced to participate in the study.

6.3.7 Once the participant has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then the person taking informed consent will ask them to sign the written informed consent form relating to the study. The informed consent form must be personally signed and dated by the person receiving consent and the participant. Each should also clearly print their name by their signature. The boxes at the side of each statement on the written informed consent form should be initialled by the participant.

6.3.8 Once all parties have signed the informed consent form, the participant should receive a copy of the signed and dated consent form, information sheet and any other written information provided to the participants. The original should be placed in the Site File/Trial Master File, with a copy in the participant's medical notes if applicable.

6.3.9 Documentation of any study procedure should be attributable, legible, contemporaneous, original, accurate, and complete. Therefore, the timing and signing of the consent form, relative to study enrolment and the initiation of study procedures, is subject to audit by regulatory bodies. It is essential to record dates correctly on the Informed Consent form and in the participant's medical notes. The staff member receiving consent should clearly document the process of Informed Consent undertaken with the participant in the participant's medical notes.

6.3.10 The consent form must be signed by the study participant, or their legal representative, before any aspect of their involvement in the study begins.

6.3.11 With the introduction of seeking and documenting informed consent electronically (e-consent) guidance should be taken from the Research and Development Manager and the joint statement with the Medicines and Healthcare products Regulatory Agency (MHRA), setting out the legal and ethical requirements for seeking and documenting consent using electronic methods. This will be documented with a file note explaining the agreed procedure.

Further information re e-consent can be found within 'The Statement' included within the MHRA e-consent blog available via the hyperlink.

6.4 Ongoing Procedure throughout the Study

6.4.1 he informed consent process does not cease once the consent form has been signed; informed consent to remain in the study should be checked with the participant at each subsequent visit. The practice of giving information about the study to participants should be an on-going process performed by all members of the research and/or multidisciplinary team (as appropriate). This is particularly significant with the introduction of protocol amendments and the availability of important new information that may be relevant to the participant's willingness to continue participation in the study. In these circumstances it may require the study participant to re-consent on the amended consent form in order to continue involvement in the study. If the participant is re-consented to a study this must be documented in the participant's medical notes and a copy of the new informed consent form should be given to the participant, a copy uploaded to EPIC and the original placed in the TMF/ISF. For Healthy Volunteer studies, where medical notes may not be appropriate or available, the information regarding re-consent should be filed in the TMF/ISF.

6.4.2 All participants must be provided with contact details where they may obtain further information about the study. This will either be the CI/PI's number or a contact number of a member of the study team.

6.5 Withdrawal of Participants:

Where a participant withdraws from a study or the PI/treating clinician responsible for the participant's care decides it is in the best interest of the participant to withdraw them from a study, please ensure the following:

- The withdrawal process and reasons for withdrawal are fully documented in the medical notes.
- The withdrawal process in the study protocol is referred to and acted upon
- Document if the participant withdraws consent for all study follow-up or confirm if they are willing to continue to have retrospective or future details sent to the sponsor.
- The Sponsor is informed of the process and the reasons through study specific withdrawal forms or SAE forms as required.

6.6 Consent of Minors

6.6.1 In accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 a minor means a person under the age of 16 years and will be treated as such until they turn 16. Where a minor reaches the age of 16 during the conduct of a clinical trial they should be re-consented (using the appropriate participant information sheets and informed consent forms) where their participation on the clinical trial is continued.

6.6.2 There are a number of separate factors that must be considered when taking assent from minors (to participate in a clinical trial) in addition to the above criteria for persons able to provide informed consent. Assent is defined as the child or young person's permission or affirmative agreement to participate in research and requires that children have an understanding of the research process and are informed about what they are expected to do.

- It is essential that the clinical study relates directly to a clinical condition from which the minor suffers or is of such a nature that the study can only be carried out on minors.
- It is important to show that there will be some benefit for the group of participants involved in the study and that the clinical study is necessary to validate data obtained in other clinical studies involving persons able to give assent or by other research methods.
- The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development. Continuous monitoring throughout the study of such risks and/or distress must take place. The interests of the minor must always prevail over the interest of science.
- A full explanation of the study including the objectives, risks, inconveniences and all the conditions associated with the study must be given to the person with parental responsibility for the minor in order that they provide informed consent for the minor to participate in the study. If they are unable to be contacted due to the emergency nature of the treatment provided as part of the study, then a legal representative for the minor must have had an interview with the CI/PI or another member of the study team in which they have been given the opportunity to understand the objectives, risks and inconveniences and be able to provide consent to the minor taking part. A contact number for the research team must be given in order for them to obtain further information regarding the study should they wish to do so.
- It is important for the minor to be given information regarding the study according to his/her level of understanding (from staff who have experience in dealing with minors) and the person taking assent must respect their wishes. In cases where the child has been involved and is judged competent to give assent then he/she should also sign the form. It is also good practice to document the child's view where they are not judged competent to give assent.
- The person with parental responsibility for the minor, and the minor themselves, must be made aware that they can withdraw from the study at any time without any detriment to future care.

- No incentives or financial inducements must be given except for compensation in the event of injury or loss.

See Appendix 1 for Hierarchy of Informed Consent for a Minor, as detailed in the MHRA Grey Guide 2013.

6.7 Participants with Language, Communication Problems/Comprehension

6.7.1 The legal position is that adults must be presumed capable of taking decisions unless the opposite has been demonstrated. This applies just as much to people with learning disabilities as to any other adult. Where there are comprehension or communication difficulties then participants must be given all appropriate help to enable them to make their own decisions e.g. using visual aids, sign language etc.

6.7.2 If a decision is taken to enrol participants with communication problems or comprehension difficulties then investigators must have a clear plan about how these matters will be managed and documented in the consent process. For example, if the difficulties are due to visual impairment then the information sheet can be read to the potential participants and audio recorded at the same time to provide a copy for the participant to keep.

6.7.3 Where there are communication difficulties, a relative or an independent participant's advocate should be involved in the consent process. The latter's role is to help the prospective participant express their views. Therefore, two types of information sheet may be required: one for the relative and one for the participant. The latter should be designed to overcome or minimize some of the communication problems, for example, a pictorial information sheet for the research participant. Sufficient time must be allowed for the person seeking consent to explain and discuss the proposal with the participant and the relative or advocate, and for the relative or advocate to discuss with the prospective participant.

6.7.4 Best endeavours will be made to provide consent forms and participant information sheets translated into another language where required. If this is not possible a translator will sign the consent form indicating that they have been present and involved during the process.

6.7.5 For the consent to be valid the research participant must always be able to communicate their decision. If the person is unable to sign or to mark the consent form so as to indicate his/her consent, then consent may be given orally in the presence of at least one witness, usually a relative or patient advocate. The role of the relative or advocate in the consent process, for example, acting as a witness or explaining the trial to the participant, must be documented in the medical records. Consent could also be recorded to provide a complete record with a copy of the tape for the participant.

All hospital staff who provide information and request consent from participants with communication problems or comprehension difficulties must be appropriately trained and experienced with such participants.

The Research Ethics Committee and the Sponsor must agree the plan, including the delegation of responsibilities.

6.8 Adults lacking Capacity

6.8.1 The definition of an incapacitated adult under the Medicines for Human Use (Clinical Trials) Regulations 2004 is *"an adult unable by virtue of physical or mental incapacity to give informed consent"*.

6.8.2 For Clinical Trials the Medicines for Human Use Act supersedes the instructions in the Mental Capacity Act 2005.

6.8.3 For all Non-CTIMP studies, the Mental Capacity Act 2005 must be followed.

6.8.4 Legally, adults must be assumed to be capable of taking decisions unless the opposite has been demonstrated for a particular decision. Where doubt exists, the CI/PI or another experienced clinician/practitioner should formally assess the capacity of the individual to make an informed decision about participation in a research project. This assessment and the conclusions should be recorded in the medical records. A participant is deemed to lack legal capacity to consent or refuse only when they cannot be helped to reach their own decision with memory aids or sign language for example.

6.8.5 When taking the decision about the enrolment of an adult who is unable to provide informed consent for his/herself (for participation in a clinical trial) it is important that the CI/PI ensures that:

- The study relates directly to a life threatening or debilitating clinical condition from which the participant suffers and that there are grounds for expecting that the study procedure/intervention to be tested in the study will produce a benefit to the participant, outweighing the risks or producing no risks at all.
- The clinical study must be essential to validate data obtained in other clinical studies involving persons able to give informed consent or by other research methods.
- The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the participant and continuous monitoring throughout the study of such risks and/or distress must take place. The interests of the participant must always prevail over the interest of science.
- No one can currently consent to research on behalf of an incapacitated adult. The research investigator must however identify a legal representative who can be consulted about the involvement of the participant in the study. If no suitable personal legal representative (e.g. relative) is available then a professional legal representative may be approached (e.g. doctor primarily responsible for medical treatment or a person nominated by the trust). However, this representative must not be connected with the conduct of the trial in any way. Where a legal representative has been appointed, they must have an interview with a member of the study team to understand the objectives, risks, inconveniences/discomforts and associated conditions for the study and be provided with a contact number for the study team should they wish to ask further questions about the study. The legal representative

must be informed of their right to withdraw the participant at any time resulting in no detriment to care or treatment for the participant.

- Participants should not be enrolled into the trial if it is contrary to a formal advance decision or any other form of statement made in advance by the participant whilst competent. This does not have to be in writing and an investigator should take reasonable steps to find out if there are any advance wishes by consulting relatives. Any participant's 'dissent' must always be respected throughout, especially in non-therapeutic research, even if they do not have the legal capacity to refuse.
- The participant must also be given information regarding the study according to their level of understanding. For those participants able to form an opinion based on the information provided, their wish to participate must be respected by the person taking consent.
- The role of the patient's advocate, their relationship to the participant and the response of the participant should be documented. The opinion of the patient's advocate about enrolment should be formally documented and a written and signed statement obtained.
- No incentives or financial rewards must be used to influence a participant to participate (or the participant's legal representative to agree to participation on their behalf) in a study other than provision for compensation in the event of loss or injury.

6.9 Consent in Emergency situations/Deferred Consent

6.9.1 In emergency situations, where prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent is not possible, and the participant's legally acceptable representative is not available, enrolment of the participant should require measures described in the protocol and/or elsewhere, with documented favourable opinion by the REC to protect the rights, safety and well-being of the participant and ensure compliance with applicable regulatory requirements.

6.9.2 The participant or their legal representative should be informed about the study as soon as possible and consent to continue and other consent as appropriate should be requested.

6.10 Consent to research using human tissue and samples

All research involving the acquisition of human tissue and samples should be undertaken in accordance with the HTA Code of Practice: Guiding Principles and the Fundamental Principle of Consent. The consent should make it clear to the participant what will happen to their samples and if they are being asked to gift their samples for research other than the study to which they are consenting and if so how long the samples will be held for and that they will be disposed of appropriately at the end of this period of time.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Members of staff delegated to take consent should be qualified by experience and/or should have received appropriate training for this study.	Delegation Log Training Log entries CV.
2.	Participants should be given adequate time, usually at least 24 hours, unless otherwise stated in the protocol, to read the information sheet and to discuss with any family and friends (except in the case of acute/ emergency studies), prior to agreeing to participate.	View copy communication with participant (check with study staff where this is located) and cross check with date of consent.
3.	The informed consent form must be personally signed and dated by the person receiving consent and by the participant, each should also clearly print their name by their signature and the boxes at the side of each statement on the written informed consent form should be initialled by the participant	Spot check a cross section of consent forms.
4.	The staff member receiving consent should clearly document the process of Informed Consent undertaken with the participant in the participant's medical notes.	Medical notes.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)

Health Research Authority

The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument **2006/1031,** implemented on the 1st May 2004 as amended

The Mental Capacity Act 2005

Appendix 1 – Hierarchy of Informed Consent for a Minor (taken from the MHRA Grey Guide 2013)

Person who may give consent	Definition	Commentary
Parent	A parent of person with parental responsibility in law.	Should always be approached if available. Under the Children Act 1989, parental responsibility may be acquired by an unmarried father, step-parent, second female parent or appointed guardian.
Personal legal representative	A person not connected with the conduct of the trial who is: • suitable to act as the legal representative by virtue of their relationship with the minor, and • available and willing to do so.	May be approached if no person with parental responsibility can be contacted prior to the proposed inclusion of the minor, by reason of the emergency nature of the treatment provided as part of the trial. The investigator must be satisfied that the person has sufficient knowledge of the minor and an interest in their welfare.
Professional legal representative	A person not connected with the conduct of the trial who is: • the doctor primarily responsible for the medical treatment of the minor, or • a person nominated by the relevant health care provider (for example, an acute NHS Trust or Health Board)	May be approached if no person suitable to act as a personal legal representative is available. Informed consent must be given before the minor is entered into the trial. Care organisations should have arrangements for appointing professional legal representatives where required.