Reference Number: *UHB 147* **Version Number:** 7.1	**Date of Next Review: 18/10/2025** **Previous Trust/LHB Reference Number:** *N/A*

INFORMED CONSENT IN CLINICAL RESEARCH

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 should be an on-going process of information exchange and protect the rights, well-being and autonomy of the research participants.

It is a legal requirement as stated in the Declaration of Helsinki, adopted by the World Medical Association in 1996 and Good Clinical Practice (ICH-GCP), and forms the foundation of ethical research.

The aim of this SOP is to describe the process for obtaining informed consent from those wishing to participate in clinical research.

Objectives

- To describe general issues around the consent process in research, where these differ from standard clinical practice.
- To describe the procedure for obtaining consent from adults, including considering mental capacity and the legislation by which it is governed
- To describe the procedure for obtaining consent from children, or from those with parental responsibility for them to participate in research
- To signpost to relevant information, advice and templates to aid the researcher

Scope

This procedure applies to all staff in locations throughout Cardiff and Vale University Health Board who will be obtaining informed consent as part of their research role, including those operating under honorary contracts or research passports,

Equality Health Impact Assessment	An equality impact assessment has been undertaken on the Research Governance Policy (UHB099), under which this Procedure falls. No adverse impact has been identified.
Documents to read alongside this Procedure	- Cardiff and Vale University Health Board: Consent Examination or Treatment Policy (UHB100) - Cardiff and Vale University Health Board: Research Governance Policy (UHB 099) - UK Policy Framework for Health and Social Care Research Training requirements for Research Staff, including GCP (UHB317)
Approved by	Cardiff and Vale UHB Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Team Mental Capacity/Patient Safety Manager

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	02/10/2012	U/K	*New document*
2	23/04/2013	U/K	Page 8, section 5.6: addition of . Valid Informed Consent in Research: Training Provider: NISCHR CRC
3	16/07/13	U/K	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		U/K	- 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
7	14/07/21	16/12/21	-Title change as feedback suggests the previous title is a little confusing. Previous title 'Research Consent and Mental Capacity - Updated throughout to make more user friendly by signposting researchers to the most recent Government/HRA website information and current advice. - New section on remote consent added - Removal of general information which is repeated in detail throughout the previous versions and across multiple SOPs and guidances. - Reworded throughout to enable better readability and flow. - Updated training information added - Creation of index for hyperlink addresses
7.1	18/10/2022	10/11/2022	-Documents to read alongside section updated to include Training requirements for Research Staff, including GCP (UHB317)Section 4 Updated to reflect new CVUHB e-learning on informed consent, as included in UHB 317 Following discussion at JRGG meeting, clarification was added to section 6.6 – Consent in Minors.

Contents	**Page number**

1.0 Abbreviations

CI	Chief Investigator
Clinical Trials Regulations	Medicines for Human Use (Clinical Trials) Regulations (2004) and associated amendments
CTIMP	Clinical Trial of Investigational Medicinal Product
CVUHB	Cardiff and Vale University Health Board
EHR	Electronic Health Record
HCRW	Health and Care Research Wales
HRA	Health Research Authority
ICF	Informed Consent Form
ICH GCP/ GCP	International Conference on Harmonisation guidelines for Good Clinical Practice
ISF	Investigator Site File
MCA	Mental Capacity Act (2005)
MHRA	Medicines and Healthcare Products Regulatory Authority
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure

2.0 Responsibilities

The Chief Investigator (CI) has overall responsibility for the design, conduct and reporting of the research study, including the consent process.

At the research site, the Principal Investigator (PI) has overall responsibility for ensuring that informed consent is obtained and documented for all participants enrolled in the study in accordance with the protocol, approved study documentation and ethical approval. However, all staff who obtain consent to research as part of their role are responsible for attending relevant informed consent and study specific training and obtaining consent only if they feel confident and competent to do so. They should be familiar with the Protocol and associated disease area.

3.0 Delegation of Consent

CI/PIs may delegate responsibility for the informed consent process to an appropriately qualified member of the research team.

Conditions for Delegation of Consent are set out in

- GMC Guidance - Decision Making and Consent and
- ICH-GCP E6 (R2)

It is made clear that it is the responsibility of the PI to ensure the suitability and capability of the person to whom consent has been delegated and that this should be documented according to the wishes of the study sponsor.

3.1 How to delegate responsibility for taking informed consent

It is the responsibility of the CI/PI to ensure that the designee:

- is prepared to take on this additional responsibility and feels confident to take informed consent in line with the NMC Code of Professional Conduct or other professional organisational guidelines.
- has a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease area, as appropriate.
- is fully aware of the risks and potential benefits of taking part in the research study.
- is qualified by experience and/or should have received appropriate training for this study. All training should be documented, and evidence placed in the Investigator Site File (ISF).

In addition:

- the delegation of responsibility should be documented on the Study Delegation Log (SDL).
- the consent process should have been approved by the relevant Research Ethics Committee (REC), Study Sponsor and NHS organisation hosting the study.
- an effective line of communication back to the CI/PI who is ultimately responsible for the patient's care and for ensuring that

participants have fully understood what they are consenting to, should be maintained.

3.2 Assessing Suitability

For those who would usually take consent as part of their usual duties, the assessment of suitability of the designee for obtaining informed consent, may be made from the PI's prior knowledge of that individual. For those who do not routinely take consent, this assessment should ensure the PI is satisfied that the individual has completed appropriate training. 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, an example template which lists the main criteria to be considered when delegating informed consent is provided in Appendix 02. This template is not mandatory, but may be personalised and used if found to be useful. Where completed, it should be used in addition to the SDL and a copy should be filed in the ISF.

A word version of the template: TPL/003/05 Template for Delegation of Informed Consent Responsibilities for Research, which can be edited to personalise to studies, may be downloaded from the R&D pages of the Cardiff and Vale UHB (CVUHB) Intranet, or obtained on request from R&D.

Signed and dated CVs and evidence of valid Good Clinical Practice (GCP) certificates, where appropriate, should be available in the ISF and the SDL must have been completed.

4.0 Training

The Cardiff and Vale UHB requires any research personnel who do not receive informed consent as part of their usual duties to have completed an approved informed consent training course, as detailed below, before they are permitted to receive informed consent in clinical research studies.

In all cases, as well as Good Clinical Practice and protocol specific training, it is strongly recommended that all staff complete the following:

CAV e learning on ESR:

- Mandatory training: Mental Capacity Act
- 000 NHS Wales - Decision Making and Consent in Wales

  or

- Health and Care Research Wales Valid Informed Consent training

Any other e learning relevant to their role:

Those working with a vulnerable patient group may access additional online informed consent training, for paediatrics and adults lacking capacity via the NIHR Learn portal. It is advised that researchers consider completing this training where applicable. Please visit: https://learn.nihr.ac.uk/ to set up a free user account.

- NIHR Learn:
  - Informed consent in paediatric research
  - Informed consent in emergency settings
  - Informed consent with adults lacking capacity
- ESR:
  - 000 Mental Capacity Act: Research Involving People Who Lack Capacity

It is the responsibility of the PI to ensure that those to whom the consent process has been delegated are adequately qualified by experience or training. For more information on CVUHB training requirements please see 'Training Requirements for Research Staff, including Good Clinical Practice (GCP) (UHB317)

5.0 Establishing Capacity

Mental Capacity is the ability of a person to make decisions that may have legal consequences for themselves and/or for others affected by the decision. Prior to obtaining consent the researcher must establish that the participant has capacity to provide consent at the time that the decision must be made. In order to have capacity, a potential participant should be able to:

- understand information presented to them
- retain information
- consider and evaluate the options
- communicate their decision (this may not necessarily be via speech or writing)

If there are concerns or uncertainty regarding a participant's capacity, expert advice must be sought.

Adults lacking capacity may only be approached for studies where provision is made in the protocol and approved by REC. In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) the Medicines for Human Use (Clinical Trials) regulations (2004) and associated Amendment Regulations should be followed. In non-CTIMP studies, the Mental Capacity Act (2005) (MCA) should be used to guide the process. In all studies the presumed will of the participant should inform any decisions made on their behalf.

The Health research Authority (HRA) have published guidance on informed consent, which addresses the inclusion of vulnerable participants in studies,

and includes template Patient information Sheets and Informed Consent Forms.
If researchers are unsure about the legal aspects of consent and capacity in a particular case, they should seek advice from the Mental Capacity Act Manager / Patient Safety Team.

6.0 Procedure

The consent process should be detailed in the protocol, reviewed and approved by REC. Details of the consent process should include the provision of study information to potential participants and the minimum length of time they will have to consider their participation in the study. It should also include information on vulnerable groups to be included, and detail the method of consent or study inclusion in these groups. Potential participants should have the opportunity to discuss this with their friends and/or family, General Practitioner or anyone else, should they wish.
The language used in both oral and written information should be clear and concise using layman's terms wherever possible.

Detailed guidelines for preparation of information sheets and consent forms can be found via the Consent and Participation Guidance pages of the HRA website. These templates should be used and adapted to the particular study.

6.1 Obtaining Informed consent

- When including NHS patients in the study, the initial approach, to ascertain whether an individual would be willing for the research team to discuss the study with them, or to receive further information, should be made by a member of the patient's clinical care team.
- Where a potential participant is approached about a study in a clinic setting, this should be documented in the participant notes or source documents. The version number of any Participant Information Sheet (PIS) and the Informed Consent Form (ICF) given should be noted.
- As well as providing a PIS, study information should be presented verbally to the participant by the appropriate study team member, using non – technical language and other resources as appropriate. Other resources, as per protocol and appropriate approvals may include video, diagrams, consent script or frequently asked questions documents.
- The participant must be given adequate time to consider the information in line with the study protocol. There should be opportunity for participants to ask question to aid their understanding of the study and any risks involved, before they make their decision.

- When informed consent is given, this should 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.
- Unless otherwise required in the protocol, the original signed copy of the ICF should be filed in the ISF. The participant should be given a copy of the PIS and signed ICF to keep and a copy should be placed in the participant's medical records. In the case of healthy volunteers where no medical records are available, documentation of the informed consent discussion should be available in source data or within the participant's study notes in line with the process documented in the protocol.
- Unless otherwise indicated in the protocol, both the participant and the person obtaining consent must initial, sign and date the ICF. Each person's name should be clearly printed and each person must date his or her own signature only.
- Neither the investigator nor any member of the clinical research team should coerce or unduly influence any person to participate or to continue to participate in the trial. It should be made clear that declining to take part in the study will not affect their future care or treatment and that they are free to withdraw from future involvement with the study at any stage without providing a reason.
- At follow up visits, research staff should verbally check if the participant is willing to continue in the study and the response recorded
- Should new information become available during the course of the study which results in an amendment, participants will need to make an informed decision regarding whether they wish to continue in the study. Participants should be provided with a copy of any updated PIS, ICF and other participant facing information before attending their next study appointment. At the study appointment they will need to be re-consented using the new HRA, Health and Care Research Wales (HCRW) and REC approved paperwork in line with the protocol Copies of earlier versions of PIS or ICFs should be retained in the study file.

6.2 Implied Consent

Some types of research involving non-invasive surveys or questionnaires may not require a formal consent process. 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 REC.

6.3 Remote/Virtual Consent

Remote/virtual methods for seeking, confirming and documenting informed consent are becoming more common. For studies obtaining consent using a remote process, i.e. over the telephone or using audio- or video-conferencing or another web-based platform, the protocol should describe the process that will be used (e.g. how and when the consent documentation will be sent to the participant and how/where the consent discussion will take place). In addition, the protocol should describe how consent will be documented remotely. In studies where a remote/virtual consent process is implemented the study specific guidance should be followed in line with the REC and HRA/HCRW approved study protocol.

The HRA and Medicines and Healthcare products Regulatory Agency (MHRA) have published a joint statement on seeking consent by electronic methods (September, 2018). Whilst the statement focuses primarily on clinical trials, the basic principles can be applied to all research conducted within the UK when consent is sought via electronic means.

Investigators should align with local practice at site for e-consultations when setting up a remote/virtual consent discussion. For instance, 'Attend Anywhere' is an online service which is utilised in routine practice for video call appointments at CVUHB. Whichever method is used, it should facilitate thorough and interactive communication that enables the potential participant to understand what participation would involve. It should also allow for the confirmation of the participant's identity, particularly where the discussion and documentation of consent are carried out by electronic means at a distance. In trials where face-to-face verification is not possible, for example where the trial is to be conducted entirely remotely, the participant's identity may be verified visually via a video link (and asking the patient to confirm their name and date of birth) or other means.

Potential participants (and/or their legal representative where appropriate) should be provided with access to written information about the study for the purpose of seeking informed consent, either as a physical hard copy or digital download prior to consent discussion. Participants can then use this in conjunction with the discussion to help them reach an informed decision.

Participants (and legal representatives where appropriate) should also be provided with a copy of (or have access to) their signed and dated consent form (either electronically or on paper). All consent documentation will need to be printed for storage in the ISF (and patient medical records). Any other storage requirements will be dictated by the protocol.

6.4 Consent in vulnerable groups

Enrolling participants with impaired capacity to decide may be acceptable where research is necessary to promote the health of that particular group, and cannot be performed on legally competent people instead.

Where a person does not have capacity to make decisions, the law provides safeguards and protection, including giving limited powers to third parties to

take decisions on their behalf. The MCA provides a statutory framework to empower and protect vulnerable people who may not be able to make their own decisions. It sets out who can make decisions in which situations and how they go about it.

Non-CTIMPs

Researchers should work in line with the MCA and the MCA code of practice when consenting patients to non-CTIMP research.

Legally, adults must be assumed capable of taking decisions unless the opposite has been demonstrated for a particular decision and at that given time.

Where doubt exists, a formal assessment of the capacity of the individual must be undertaken in line with the MCA and local Policy. This should be recorded in the medical records.

Where the participant does not have capacity, the researcher must take reasonable steps to identify a personal consultee or nominated consultee as defined in the MCA, to give advice.

If the consultee believes that the patient would refuse consent, they must not be included in the research.

Examples of personal and nominated consultees and guidance on the process can be found on the Principles of Consent pages of the HRA website.

In clinical research, the MCA can be seen to work in tandem with the Clinical Trials Regulations, which prevail in CTIMPs.

CTIMPs:

It is not always possible to obtain informed consent to enrol participants into CTIMPs. The Clinical Trials Regulations and associated amendments describe provisions relating to giving informed consent on behalf of adults who are unable to consent for themselves including the role and responsibilities of legal representatives. Under the Clinical Trials Regulations, the definition of a legal representative depends on whether the subject is a minor or an adult with incapacity. The definition may also vary in different parts of the UK.

Common to the definition of the legal representative in any scenario is that the individual concerned must not be “a person connected with the conduct of the trial”. This is defined as:

- The sponsor of the trial
- A person employed or engaged by, or acting under arrangements with, the sponsor and who undertakes activities connected with the management of the trial
- An investigator for the trial
- A healthcare professional who is a member of an investigator’s team for the purposes of the trial

- A person who provided health care under the direction or control of a person referred to above, whether in the course of the trial or otherwise.

The consent obtained from the legal representative should follow the usual requirements of obtaining informed consent.

Please refer to the Consent and Participant Information Guidance pages of the HRA Website for the most up to date information on obtaining informed consent in vulnerable groups, and in different parts of the UK, where laws may differ.

6.5 Emergency situations

The Clinical Trials Amendment Regulations (2) (2006) made additional provision relating to CTIMPs involving Adults Lacking Capacity in emergency situations. The amendment allows Adults Lacking Capacity to be entered into a trial prior to consent being obtained from a legal representative provided that:

- With 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 participant, and
- The action to be taken is carried out in accordance with a procedure approved by the research ethics committee.

Where an adult lacking capacity 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.

For non-CTIMP studies there is a similar process, involving consultations with personal or nominated consultees to gain their advice, but the nature of consultations should be in compliance with the MCA and the MCA Code of Conduct. Guidance on how to proceed in such situations is available on the HRA website.

Those responsible for obtaining consent in studies which include vulnerable participants must familiarise themselves with the relevant legislation before the study starts.

6.6 Consent in children and young people (minors)

Here you will find specific guidance on consent by and on behalf of children and young people in England, Wales and Northern Ireland. If you are consenting minors in Scotland, please refer to the HRA Guidance: Principles of consent: Children and Young People (Scotland)

In most cases, children and those with parental responsibility should be involved in the research consent process. While consent may be given by those with parental responsibility, the child or young person's competence to weigh the risks and benefits and any extra time needed for them to do this must be considered. The wishes of the child or young person regarding participation in the research must be considered.

Non-CTIMPs

In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent for research. Hence, children can give consent to participate in research themselves provided they have the capacity to do so. Children and young people's competence may be reflected in their ability or otherwise to understand and assess risk.

To give consent, the child must be able to understand the nature and consequences of their participation in the research. Competence to understand will be heavily influenced by how the information is presented to the child or young person, and the language used. The study information must firstly be given to the minor by staff with experience of working with minors. Gaining a child's views and desires can require the use of creative ways of providing information and alternative means for them to express their thoughts.

CTIMPs

Under the Clinical Trials Regulations, a 'minor' is a person under the age of 16 years. There is no provision for Gillick Competence within CTIMPs.

The Regulations prescribe a hierarchy for determining who should be approached to give informed consent on behalf of a minor, prior to their inclusion in the trial.

Parent: A parent or person with parental responsibility. It may be unclear who has parental responsibility for a minor. A mother automatically has parental responsibility for her child from birth, though this may not be the case for the father. This can be a complex area which should be handled with sensitivity. It can also be further complicated when a parent has lost parental responsibility or when a mother is under the age of 16 years. The person taking consent must be satisfied that the issue of parental responsibility has been addressed and is clear, before taking consent. More information can be found via the Gov.uk guidance on Parental Responsibility

Personal legal representative: A person not connected with the conduct of the trial who is suitable to act as a legal representatives by virtue of their relationship with the minor, and is both available and willing to do so.

Professional legal representative: A person nominated by the relevant healthcare provider who is not connected with the conduct of the trial.

The provisions for informed consent by a legal representative only apply if by reason of the emergency nature of the treatment provided as part of the trial

no person with parental responsibility can be contacted prior to the proposed inclusion of the minor.

Children and Young People's wishes and Assent

In situations where a child or young person is competent, it is still normally good practice to involve the family in the decision-making process, provided the child or young person does not object

Even when a child or young person is deemed not competent to consent, or in situations where they are not legally empowered to do so, (e.g. in a CTIMP), it is important that:

- The child / young person receives information about the study from staff with experience of working with children / young people. The information should be appropriate for them, explain what is involved and the potential risks and benefits
- if the child or young person is capable of assessing the information provided you must consider their explicit wishes. This includes their refusal to take part, or desire to withdraw from the study
- it is usually inappropriate to ask very young children (e.g. under fives) to sign an assent form, however their views should be considered.

Appropriate information sheets and assent forms should be provided by the study Sponsor and the consent/assent process approved in the REC application should be followed. The assent process alongside the consent process should be documented in the medical notes.
Where assent forms are provided but the investigator judges that it is not appropriate to use them, the reasons for this should be documented in the medical notes.

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment) Regulations 2008 made additional provision relating to trials involving minors in emergency situations. 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. The amendment allows minors to be entered into a trial prior to informed consent being obtained provided that:

- With 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 participant, and
- 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.

The Consent and Participation Guidance pages of the HRA website contains information on consenting minors in research, and includes example and template documentation.
A Consent-Capacity Guidance Table which includes consent in adults and minors in research is provided in Appendix 03

7.0 Distribution

This SOP will be distributed via the CVUHB intranet and internet, CVUHB R&D intranet pages.

Appendix 01 – Hyperlink addresses

Hyperlinks are valid at the time of publication. Where superseded, it is the reader's responsibility to ensure they are accessing the most up to date information. Please liaise with the R&D Office where required.

GMC Guidance - Decision Making and Consent
https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA

ICH-GCP E6 (R2)
https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf

Health and Care Research Wales Valid Informed Consent training
https://healthandcareresearchwales.org/valid-informed-consent-research

NIHR Learn Portal
https://id.nihr.ac.uk/authenticationendpoint/login.do?RelayState=ss%3Amem%3A2195eb72c453f32cf344254e8b8495b27b5c3e804e1fba38282abcc8d737a0cb&commonAuthCallerPath=%2Fsamlsso&forceAuth=false&passiveAuth=false&tenantDomain=carbon.super&sessionDataKey=c52adfdb-2fb0-42df-ae39-6dcc2c94c3ef&relyingParty=learn.nihr.ac.uk&type=samlsso&sp=NIHR+Learn&isSaaSApp=false&authenticators=SAMLSSOAuthenticator%3ANIHR%3BAttributeBasedAuthenticator%3ALOCAL

Medicines for Human Use (Clinical Trials) regulations (2004)
https://www.legislation.gov.uk/uksi/2004/1031/contents/made

Mental Capacity Act 2005
https://www.legislation.gov.uk/ukpga/2005/9/contents

HRA Guidance on informed consent, including templates
http://www.hra-decisiontools.org.uk/consent/index.html#main-content

HRA and MHRA joint statement on seeking consent by electronic methods
https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhra-econsent-statement-sept-18.pdf

MCA code of practice
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf

Principles of Consent pages of the HRA website
http://www.hra-decisiontools.org.uk/consent/principles-ALC.html

The Clinical Trials Amendment Regulations (2) 2006
https://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf

Principles of consent: Children and Young People (Scotland)
Principles of consent: Children and Young People (Scotland) - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)

Gov.uk guidance on Parental Responsibility
Parental rights and responsibilities: What is parental responsibility? - GOV.UK (www.gov.uk)

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment) Regulations 2008
https://www.legislation.gov.uk/uksi/2008/941/contents/made

Consent and Participant Information Guidance pages of the HRA Website
http://www.hra-decisiontools.org.uk/consent/principles.html

Appendix 02 – Delegation of Informed Consent Template – EXAMPLE ONLY

A Word version of this example template: ***TPL/003/05 Template for Delegation of Informed Consent Responsibilities for Research*** which can be adapted as required for use, should be downloaded from the R&D pages of the Cardiff and Vale UHB (CVUHB) Intranet, or requested from R&D.

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

Signature _____ Date _____

Acceptance of delegated responsibility

Name (PRINT) _____

Signature _____ Date _____

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

Appendix 03 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