Wrightington, Wigan and Leigh NHS Foundation Trust

STANDARD OPERATING PROCEDURE:	**Consent to Examination or Treatment Procedure**
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CONSULTED WITH	

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Manager responsible for review (Job title**)** *N.B. This should be the Author's line manager*	**Director of Governance**	

The WWL Way

AT ALL TIMES, STAFF MUST TREAT EVERY INDIVIDUAL WITH RESPECT AND UPHOLD THEIR RIGHT TO PRIVACY AND DIGNITY

1 VALID CONSENT

1.1 Consent to treatment must be given by anyone before they receive any type of medical treatment, test or examination. This must be done on the basis of an explanation by a healthcare professional.

1.2 Consent should also be obtained for any visual or audio recording, including photographs or other visual images – please see supporting documentation (Appendix 2).

1.3 For consent to be valid, it must be **voluntarily** given by an appropriately **informed** person who has the **capacity** to consent to the intervention in question (See below: Who can give consent).

1.4 For consent to be voluntary, the decision to consent to treatment must be made by the person and not influenced by pressure from medical staff, friends or family.

1.5 For consent to be informed, the person must be given all of the information about what the treatment involves, including all the benefits and risks, whether there are reasonable alternative treatments (including the decision to do nothing), and what will happen if treatment does not go ahead.

1.6 To have capacity, the person must be capable of giving consent, which means they understand the information given to them, are able to retain it long enough to make the decision and can use as part of the decision-making process. They should also be able to communicate their decision (this can be by talking, using sign language or even using simple muscle movements such as blinking an eye or squeezing a hand).

1.7 Acquiescence where the person does not know what the intervention entails is not valid consent.

1.8 Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves, no-one else can give consent on their behalf. However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance decision or where a Lasting Power of Attorney has been appointed.

2 WHO CAN GIVE CONSENT?

2.1 Adults with capacity – please see supporting documentation (Appendix 2).

2.2 Young people aged 16 and over with capacity - please see supporting documentation: Consent Guidance Young Children (age under 16) and Young Persons (age 16 to 17).

2.3 A person who has parental responsibility for a young person under the age of 18 - please see supporting documentation: Consent Guidance Young Children (age under 16) and Young Persons (age 16 to 17).

2.4 Children under 16 years of age who are assessed as being Gillick competent - please see supporting documentation Consent Guidance Young Children (age under 16) and Young Persons (age 16 to 17).

2.5 A person authorised to make treatment decisions under a valid Lasting Power of Attorney for Health and Welfare.

2.6 A patient detained under the Mental Health Act 1983 may still have the capacity to be able to consent to care, and so their consent will be required before any treatment or procedure.

2.7 A person who has the authority to make treatment decisions as a Court Appointed Deputy (this must be in the patient's best interests and can never include the power to make a decision about life-sustaining treatment).

3 OBTAINING CONSENT

3.1 Consent must be obtained before any clinical intervention is carried out.

3.2 Patients may indicate consent orally, in writing, or non-verbally (for example by presenting their arm for their pulse to be taken).

3.2 Healthcare professionals must document clearly both a patient's agreement to the intervention and the discussions which led up to that agreement.

3.3 Healthcare professionals should ensure that the patient is clearly informed that they can withdraw their consent at any time and should verbally state this during the consent process (See below: Lifetime, Refusal or Withdrawal of consent).

3.4 It is the responsibility of the healthcare professional to ensure that communication with the patient is effective. Any issues in understanding caused by language, understanding, and/or special requirements must be addressed. Extra time will be needed; explanations should be in plain language, without the use of jargon. Assistance may be necessary in the form of an accompanying family member, friend or advocate. However, this should only be arranged with the consent of the individual and consideration of the likely impartiality of the family member. Where English is a second language an interpreting or translation service must be used; not a family member. It is critical to check understanding by asking the patient to describe what they understand the information means. Only then is it possible to ensure that informed consent to any assessment, care or treatment is being given.

4 DOCUMENTING CONSENT

4.1 Written consent must be sought in all circumstances when:-

- 4.1.1 The treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some healthcare professionals would describe as side-effects or 'complications');
- 4.1.2 The procedure involves general/regional an anaesthesia or sedation;
- 4.1.3 Providing clinical care is not the primary purpose of the procedure;
- 4.1.4 There may be significant consequences for the patient's employment, social or personal life;
- 4.1.5 In circumstances when written consent for operative/invasive procedures and treatments is required and recorded using a Consent form;
- 3.1.6 Details of the process and information provided must be recorded on the consent form and backed up with further necessary detail in the patient's notes;
- 3.1.7 A copy of the completed consent form should be kept with the patient's medical notes;
- 3.1.8 A further copy of the completed consent form should be handed to the patient/guardian etc;
- 4.1.9 Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

4.2 When verbal consent has been given:-

- 4.2.1 It must be documented in the patient's notes that they have given oral consent;
- 4.2.2 All documentation must include full details of the planned intervention that has been explained and agreed to;
- 4.2.3 It is not always necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However,

staff should use the following to assist decisions as to what and how much to document;

4.2.4 The risks and consequences associated with the proposed examination/treatment to the particular patient.

4.2.5 When the patient is refusing care/examination/treatment.

4.2.6 This is particularly important where there is the likelihood of the decision being disputed; and/or

4.2.7 There is the likelihood that staff will need to defend a decision in situations including an informal discussion, incident, complaint and/or claim.

4.2.8 NB: An adult who has capacity is allowed to refuse treatment even where refusal leads to their death, or the death of their unborn child.

5 DELEGATION OF RESPONSIBILITY FOR THE CONSENT PROCESS

5.1 The healthcare professional providing treatment or undertaking an investigation will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. It is the healthcare professional's responsibility to discuss the procedure or treatment with the patient and ensure that they have made an informed decision to consent.

5.2 Where it is not practical for the treating healthcare professional to complete the consent process themselves, they may delegate these tasks providing they make sure that the person to this is delegated to:

5.3 Suitably trained and qualified:-

5.3.1 Has sufficient knowledge of the proposed investigation or treatment, and

5.3.2 Understands the risks involved; and

5.3.3 Will act in accordance with the guidance in this policy and supporting documents.

5.4 The healthcare professional will remain responsible for making sure that the patient has been given sufficient time and information to make an informed decision, and has given their consent, before any investigation or treatment is started. The amount of time and information given to the patient is determined by the healthcare professional's own clinical judgement.

6 WHEN CONSENT IS NOT REQUIRED

6.1 There are a few exceptions where treatment can be given without the person's consent, even if they are capable of giving their permission. It may not be necessary to obtain consent if a person:-

6.1.1 Needs emergency treatment to save their life but they are incapacitated (e.g unconscious). However, the reasons why treatment was necessary should be fully explained once they have recovered.

6.1.2 They immediately require an additional emergency procedure during an operation. There should be a clear medical reason why it would be unsafe to wait to obtain consent.

6.1.3 They are a risk to public health as a result of rabies, cholera or tuberculosis.

6.1.4 They have a severe mental health condition such as schizophrenia, bipolar disorder or dementia and they lack the capacity to consent to the treatment of their mental health (under the Mental Health Act 1983 – please see supporting documentation **Appendix 2**). In these cases, treatment for unrelated physical conditions still requires consent which the patient may provide despite their mental illness.

6.1.5 They require hospital treatment for a severe mental health condition but had self-harmed or attempted suicide while competent and are refusing treatment (under the Mental Health Act 1983 – please see supporting documentation **Appendix 2**). The person's nearest relative or approved social worker must make an application for the

person to be forcibly kept in hospital and 2 doctors are required to assess the person's condition.

7 TRAINING

7.1 Wrightington, Wigan and Leigh NHS Foundation Trust is committed to ensuring that all staff receive appropriate training, education and supervision to enable them to carry out their duties safely and competently and this applies to the patient consent process and policy.

7.2 CQC, GMC and DoH guidance recognise (see Appendix 2) that:-

7.2.1 The healthcare professional carrying out the treatment or procedure will have the appropriate knowledge and experience of the risks, benefits, and alternatives to that treatment, to ensure that informed and valid consent is obtained.

7.2.2 That healthcare professional is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done and could be held to account in law if this is challenged at a later date, even if the task is delegated or shared between other members of the healthcare team.

7.3 Delegating the consent process

If the task of information giving and obtaining written consent is delegated to another member of the healthcare team (who will not be carrying out the procedure) they should have:

7.3.1 Received specific training beforehand and been formally assessed by a senior colleague, educational supervisor or consultants competent and as having the appropriate knowledge and skills to do so.

7.3.2 The results of this assessment documented:

7.3.2.1 on the proforma at Appendix 1; or

7.3.2.2 in the doctor's portfolio; or

7.3.2.3 in the case of nursing, midwifery or allied health professionals the individual's staff Performance and Development Plan (PDP) and Performance Development Record (PDR)

7.4 Medical and nursing students, FY1 and FY2 doctors should never be asked to obtain written consent, but they may be involved in the information giving and consent process under the direct supervision of qualified staff and as part of the training and educational curriculum.

7.5 Service/Specialty Induction

7.5.1 The Trust's Consent to Examination and Treatment Policy and DoH forms are available on the intranet.

7.5.2 Services' induction policies and programmes should also include and specify any instances were obtaining written consent may be delegated to other persons other than the person conducting the procedure itself and how any specialist training and supervision will be provided.

7.6 Formal teaching and education

7.6.1 General training issues, including the provision of training sessions for new and updates for existing staff, should be agreed at service level.

7.6.2 Services should be aware of, and utilise courses which can be provided through the organisation which incorporating issues of consent, e.g. Record keeping, Consent and Clinical Negligence.

7.6.3 Consent training is also available on request via the Governance Department.

7.6.4 Consent training for FY1 doctors is delivered as part of the FY1 teaching programme. Further information is available from the Medical Education Manager.

7.6.5 Training on the Mental Capacity Act is available through the Trust's Adult Safeguarding Lead.

8 LIFETIME, REFUSAL OR WITHDRAWAL OF CONSENT

8.1 Consent is valid for as long as the patient/parent/guardian (if a child)/ substitute decision-maker:-

8.1.1 Is able to recall the comprehensive information required for an informed consent; and

8.1.2 As long as there has been no significant change in health status.

8.2 To address the possibility of long waiting times and/ or risks that may have changed over time:-

8.2.1 The consent should be gained as close to the treatment as possible.

8.2.2. The consent is only considered valid for a period of twelve months.

8.2.3 A new consent must be obtained if the patient/parent/guardian (if a child)/ substitute decision-maker is unable to recall the information.

8.2.4 Capacity to consent should always be re-considered - see the Consent Guidance documents at Appendix 2.

8.3 A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983.

8.3.1 If, after discussion of possible treatment options, an adult with capacity refuses all treatment, this should be documented in their medical notes.

8.3.2 Where a patient with capacity has refused a particular intervention, the healthcare professional must ensure that they continue to provide any other appropriate care to which the patient has consented and that this is documented in their medical notes.

8.3.3 If a patient with capacity consents to a particular procedure but refuses certain aspects of the intervention, the healthcare professional should explain to the patient the possible consequences of their partial refusal and document this in their medical notes.

8.3.4 If the healthcare professional genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, the healthcare professional is not obliged to perform it. The healthcare professional should, however, continue to provide any other appropriate care and document details of their decision making and discussion with the patient in the medical notes.

8.3.5 If the patient has already signed a consent form, but then changes their mind, the healthcare professional (and where possible the patient) should note this on the form. The healthcare professional must also ensure that the patient knows that they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

8.3.6 For detailed guidance around **refusal of children's consent** staff should refer to the Department of Health's 'seeking consent: working with children'.

8.4 A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure**.**

8.4.1 Where a patient does object during treatment, the healthcare professional must, if possible, stop the procedure, establish the patient's concerns and explain the consequences of not completing the procedure.

8.4.2 If stopping the procedure at that point would genuinely put the life of the patient at risk, the healthcare professional is entitled to continue until the risk no longer applies.

8.4.3 Assessing capacity during a procedure may be difficult and, as noted above, factors such as pain, panic and shock may diminish capacity to consent. The practitioner should try to establish whether at that time the patient has the capacity to withdraw a previously given consent.

8.4.4 If capacity is lacking, it may sometimes be justified to continue in the patient's best interests, although this must not be used as an excuse to ignore distress and details of the decision making must be documented in the medical notes.

9 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this policy and they have, where appropriate, been fully reflected in its wording.

10 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g. large print, Braille and audio cd.

For more details, please contact the HR Department on 01942 77(3766) or email equalityanddiversity@wwl.nhs.uk

Appendix 1

Consent to Treatment
Delegated Consent Training Competency Pro forma

Name ……..**GMC/Pin Number**……..…….....

Procedure…….....

		Tick	Date Achieved
1.	**Has read the explanatory notes for the procedure**		
2.	**Consent basics:** Introduces self to patient Confirms patient's identity Confirms intended procedure Uses correct consent form Completed all required sections Confirms patient's right to withdraw consent Has demonstrated knowledge of the Trust's Consent Policy Has completed a generic training programme		
3.	**Consent dialogue included:** Satisfactory explanation Use of sedation/LA if appropriate All Risks/benefits Alternative investigations which could be considered if appropriate (including the option to do nothing). Aftercare Making the patient aware of other sources of information e.g. Patient Information Sheets		
4.	**Can answer general questions e.g.** Who will be performing the procedure? How long will it take? Will it hurt? Where to find additional information about the procedure What do you think might be wrong? What treatment might help? Who would be involved in the treatment and how would it help? Can I drive afterwards? How soon can I return to work? Will I be able to look after my family?		
5.	**Specific situations:** Understand options if consent is withheld **or** If the patient is unable to give consent Knows to seek senior help before completing consent if unable to answer a specific question		

…….. **(Print title, name and grade)**

Confirm that the above named doctor is able to perform delegated consent for the above procedure

Signed……..**Date**…….

Appendix 2

REFERENCES AND FURTHER INFORMATION:

- **Department of Health Guidance**
  https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

- **GMC Consent Guidance**
  http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_other_sources_of_information.asp

- **NHS: Consent to Treatment – Children & Young People**
  http://www.nhs.uk/Conditions/Consent-to-treatment/Pages/Children-under-16.aspx

- **Department of Health's 'seeking consent: working with children'**
  http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4067204.pdf

- **Code of Practice to The Mental Health Act 1983**, Department of Health 2008 Code of Practice to the Mental Capacity Act 2005, Department of Constitutional Affairs 2007
  Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11 Need for Consenthttp://www.cqc.org.uk/content/regulation-11-need-consent

- **Consent: Supported Decision-Making, A guide to good practice, Royal College of Surgeons November 2016**
- **NHS: Emergencies and Consent to treatment under the Mental Health Act 1983**
  https://www.nhs.uk/using-the-nhs/nhs-services/mental-health-services/mental-health-act/

Further information can be sought from the **Head of Legal Services** regarding legal principles set by relevant case law in this area.

Please contact the Legal Services Department for a copy of the in-house training presentation entitled **Montgomery: the last word on consent?**

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