University Hospitals of Leicester NHS
NHS Trust

Policy for Delegated Consent

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CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

V1 - Approved June 2013

V2 - Approved October 2017

- Overall structure changes amended to reflect CMG's
- Section 5 Roles & Responsibilities: consultants added as separate section
- Section 10: Legal Liability updated

V3 – Policy transferred to new template
Policy updated to reflect current management arrangements

V4- Minor amendments and corrections. References to digital consent forms added. Consent training updated to reflect current modules.

KEY WORDS

List of words, phrases that may be used by staff searching for the Policy in PAGL

- Delegated
- Consent

1 INTRODUCTION AND OVERVIEW

1.1 It is a fundamental legal and ethical right of all patients where able to make informed decisions about their healthcare and treatment. As such taking written consent evidences the discussion between a healthcare professional and the patient regarding a specific proposed procedure/treatment.

1.2 If consent for the procedure is not valid, then the healthcare professional performing the procedure may be liable for criminal charges of assault or battery or face accusations of civil charges of trespass upon a person, or negligence. For consent to be valid, the patient must:

- Be competent to take the particular decision;
- Have received sufficient information to make the decision; and
- Not be acting under duress.

1.3 This policy addresses the procedures and responsibilities for obtaining delegated consent to examination or treatment.

1.4 The General Medical Council (GMC) states that the doctor providing treatment or undertaking an investigation is responsible for discussing it with the patient to obtain consent as he/she will have a comprehensive understanding of the procedure or treatment, how it is carried out and the risks attached to it. Where this is not practicable then this may be delegated provided the person to whom it is delegated:-

- Is suitably trained and qualified;
- Has sufficient knowledge of the proposed investigation or treatment

1.5 This policy will ensure that when consent is obtained by a healthcare professional that is not competent to perform the procedure, but is able to take consent for it, it is done appropriately and safely.

1.6 To support the appropriate delegation of consent, this policy will also detail the training requirements of the process and the monitoring arrangements for ensuring adherence to the process.

2 POLICY SCOPE – WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

2.1 This policy applies to all staff who are delegating consent and to whom consent is delegated.

2.2 This policy applies to procedures where informed consent is taken by a registered healthcare professional that is not competent to perform the procedure.

The following exclusions apply:

- Consent taking must never be delegated when it is determined that the patient is not mentally competent to give consent. Please refer to the guidance found in the Policy for Consent to Examination or Treatment (A16/2002) and also to the Mental Capacity Act

2.3 Policy for Consent to Examination or Treatment details the Trust's approach to consent and should be read in conjunction with this policy.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Definitions

3.1.1 The Trust recognises two mechanisms for taking valid informed consent, they are:

- Standard Consent - Consent for the procedure is taken by the healthcare professional who is competent to perform the procedure.

- Delegated Consent - Consent is taken by a healthcare professional who is **not** competent to perform the procedure, but has been trained to take consent for this procedure.

3.2 Abbreviations

CMG – Clinical Management group

4 ROLES – WHO DOES WHAT

4.1 Executive Lead / Medical Director

4.1.1 The Medical Director is responsible for ensuring that when consent taking is delegated it is done appropriately and in accordance with this policy. This includes ensuring there are appropriate systems in place to identify and train people to take delegated consent by overseeing the implementation and compliance with this Policy. The Medical Director is also responsible for ensuring there are appropriate systems in place for reporting compliance with this policy to the Board.

4.2 Consent Committee

4.2.1 The Consent Committee is responsible for monitoring compliance with this policy.

4.3 Consultants

4.3.1 The consultant should assure themselves that the person they are delegating the obtaining of consent to has received appropriate procedure based consent training. Services or Clinical Management Groups (CMG's) where obtaining consent is routinely delegated to individuals not capable of doing procedures themselves must hold an up-to-date register of suitably trained delegated consenters. This person on the list should be approved by the service / CMG.

4.4 Delegates

4.4.1 All Consultants that delegate consent must do so in accordance with this policy. All healthcare professionals that take consent for a procedure that they are not competent to perform must do so in accordance with this policy.

4.5 The CMG Directors/Heads of Nursing (for Nurses)

4.5.1 The CMG Directors have operational responsibility for ensuring that staff within their CMG adhere to this policy. These responsibilities are:

- Identifying appropriate procedures for delegated consent
- Completion and return of Appendix 1 - Identification of procedures for which consent can be delegated for submission to the Chair of the Consent Committee
- Development of training programmes for relevant procedures in accordance with this policy
- Ensuring that all clinical staff who take delegated consent have been trained and assessed as competent and that training records are accurately maintained
- It is the responsibility of relevant CMG Directors and Heads of Nursing to ensure there is a process to identify staff that can be trained to take consent for procedures which they are not capable of performing themselves. This may occur as result of clinical need within the department

4.5.2 In the event that concerns are raised via incidents, complaints, claims, audit or observation regarding the competence of a registered healthcare professional to take delegated consent, the CMG Director is responsible for ensuring that an investigation is undertaken and remedial action taken as appropriate, in line with relevant advice and guidance from the Patient Safety Team.

4.6 Service Leads

4.6.1 These duties will be the responsibility of the CMG Director who may choose to delegate this responsibility to Service Leads.

4.6.2 Under the direction of the CMG Director the Service Lead's responsibilities are as follows:

a) identifying appropriate staff who are not capable of performing the procedure but are authorised to obtain consent for that procedure

b) ensuring that relevant written patient information and training programmes for identified procedure(s) are available

c) completion and return of Appendix 2 - procedure specific training for delegated consent

d) delivering appropriate training and assessing competence in registered healthcare professionals who take delegated consent

e) maintaining local records of staff trained in taking delegated consent and providing copies of these records to the CMG Quality Board for monitoring purposes

f) completing the competency statement (appendix 3), including forwarding copies to the CMG Quality Board for monitoring and recording and forwarding a copy to the relevant staff to include in the trained healthcare professionals' personal file. Any concerns regarding the competence of any individual that has been identified in taking delegated consent should be reported to the CMG Clinical Director.

4.7 CMG Quality Board

4.7.1 The CMG Quality Board will:

a) Store all necessary information received from service leads centrally

b) Review any areas of concern identified by audit regarding compliance with this policy and implement actions as appropriate

c) Be responsible for monitoring compliance with this policy

d) Provide assurance reports to the Consent Committee including action that has been taken in relation to areas of non-compliance with this policy

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS – WHAT TO DO AND HOW TO DO IT

5.1 The Trust is committed to the use of a systematic process to ensure that when consent taking is delegated it is done in accordance with this policy. Appendix 1 needs to be completed by all CMG's irrespective of whether they undertake delegated consent or not. Consent must be delegated in line with the Procedure for Delegated Consent below.

5.2 Procedure for Taking Delegated Consent

5.2.1 Notwithstanding the procedure of delegated consent, it remains the responsibility of the person undertaking the procedure to ensure that the patient has given valid consent and that someone capable of performing the procedure has confirmed consent by the patient prior to the procedure / treatment.

5.2.2 This policy outlines the Trust's procedure for taking consent when the responsibility has been delegated to a healthcare professional that is not competent to perform the procedure themselves, but has received training to take consent.

5.2.3 Appendix 4 provides guidance on developing procedure specific training programmes.

5.3 General Exclusions

- Consent taking must never be delegated when it is determined that the patient lacks the mental capacity to consent to the particular procedure / treatment. Please refer to the guidance found in the Policy for Consent to Examination or Treatment and also the UHL Mental Capacity Act Policy

- Only well established procedures, with developed patient information leaflets (which comply with the Patient Information policy B18/2002 and are available on YourHealth) and training programmes can be delegated

- Delegated consent must not proceed if the patient has expressed concerns regarding giving consent to the delegated healthcare professional

- Delegated consent must not proceed if the consent taker has any queries regarding the appropriateness of the procedure for the patient. Where there are queries the consent taker must raise these with the referring clinician, the healthcare professional competent to undertake the procedure or the CMG lead or CMG Clinical Director

5.4 STEP 1: Initial consultation/consent discussion with a healthcare professional

5.4.1 When the decision is made to refer a patient for treatment or investigation where delegated consent is taken, a trained delegated consent healthcare professional will discuss the procedure and take consent in accordance with the Trust Policy for Consent to Examination or Treatment.

5.4.2 Patient information leaflets for the procedure should be used to aid discussion.

5.4.3 If the patient does not feel that they are able to make an informed decision on their treatment, based on the discussion with the trained healthcare professional they must be referred to a healthcare professional that is competent to perform the procedure.

5.4.4 The patient must be advised that it is their legal right to make an informed decision.

5.4.5 Alternatively, the patient may have their initial discussion with a member of staff that is competent to carry out the procedure and step 2 below is carried out by a trained delegated consent healthcare professional.

5.4.6 In some instances, a consent form may be sent with the patient information leaflet to the patient at home, or a link to a digital consent form (with associated patient information) may be sent to the patient's email address or mobile phone number.

5.5 STEP 2: Re-confirmation of consent

5.5.1 Consent must be re-confirmed by the healthcare professional undertaking the procedure prior to commencing treatment

5.5.2 Alternatively, if step 1 has been carried out by a member of staff that can perform the procedure, then the re-confirmation stage may be carried out by a registered healthcare professional

5.6 For consent to be delegated appropriately there must be:

a) A system for identifying appropriate patients and procedures

b) Development of patient information (in line with the Trust Patient Information policy B18/2002)

c) Training programmes for each identified procedure

d) Assessment of an individual's competency to take consent

5.7 Patient Information

a) Written patient information must provide the necessary details on the proposed treatment including risks, benefits and alternatives and the possible consequences of no treatment

b) Patient information leaflets should be produced on Trust templates following the Patient Information Policy (B18/2002) and approved by the Patient Information Librarian

c) Leaflets should be in Plain English, avoiding unnecessary medical terminology, aiming for a reading age of 11.

d) Wherever possible, patient information should be provided in a language or format appropriate to the patient's needs and requirements (e.g. a different language, larger font, Braille)

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 The training to take delegated consent will consist of a core module and a procedure specific module as identified in section 4.5. If the healthcare professional is identified to take delegated consent for any additional procedures they are not required to repeat the core module but must undertake the relevant specific module for each additional procedure.

6.2 The Clinician delegating the consent must complete and return the procedure specific training for delegated consent form (Appendix 2) and return to the CMG Quality Board. The form identifies the training requirements for the procedure, appropriate staff for training, patient exclusion criteria, methods of teaching and assessing

competency. This form must either be signed by the Clinician delegating and forwarded to the CMG Quality Board.

6.3 All consultants delegating consent and those having consent delegated to them are required to complete the core module every three years (as per the requirements detailed in the UHL Policy for Consent to Examination or Treatment, section 19 - training).

6.4 Core Modules

6.4.1 The four core modules will teach the healthcare professional:

a) the legal aspects of taking delegated consent in accordance with Trust policy

b) the skills necessary to ensure the patient makes an informed decision

c) These core modules are available on helm and are titled:

1. Consent in Context: The Legal and Ethical Framework
2. Consent in Practice
3. Consent and Capacity
4. Consent – End of Life Issues, other Legal and Ethical Challenges

6.5 Procedure Specific Modules

6.5.1 The Clinician delegating the procedure will be responsible for:

- developing the procedure specific training
- overseeing the delivery of the training
- assessing the competence of trained healthcare professionals

6.5.2 Please see Appendix 4 for guidelines on developing procedure specific training.

6.5.3 The format of the procedure specific module will be specified by the CMG. The clinician delegating consent must complete and return Appendix 2 to the CMG Clinical Director, to outline the methodology for training and competency assessment.

6.5.4 The information given to the healthcare professional that is to be trained must include:

- exclusion criteria for appropriate patients
- the serious or frequently occurring risks of the procedure
- where known, the Trust's own figures to quantify the risks
- benefits of the procedure

- alternatives to the procedure, and their risks including the option not to treat

6.5.5 The trainee must be aware of the limitations in their knowledge regarding the procedure and know how to access further information or support if required (including other experts and text based information).

6.6 Competence in Delegated Consent

6.6.1 Assessment of competency in the procedure specific module will depend on the requirements specified by the Clinician delegating. This may be in the form of a self-assessment statement or in the form of an assessed project. Appendix 3 must be completed and signed for each procedure the healthcare professional has been trained to take delegated consent.

6.6.2 The CMG Quality Board will store copies of the training records on the core training and procedure specific training sessions. It is the responsibility of the CMG lead(s) to provide the necessary information to the CMG Quality Board. Copies must be kept on staff member's personal files.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 Monitoring

7.1.1 The CMG management teams will maintain a central record of the following information:

- procedures that have been identified as appropriate for delegated consent
- the clinicians delegating identified to provide training and assessment
- individuals that that have been trained and assessed to take delegated consent
- individuals that have been suspended from taking delegated consent

7.1.2 This record will be used as a central data source of compliance with some aspects of this policy. The CMG Quality and Safety Team will monitor compliance with this policy against the elements shown in the table below.

7.1.3 All CMG's will be required to assess compliance with the policy following any related incident or complaint.

7.1.4 Implementation of the policy will be monitored across the Trust through the Consent Committee with an annual assurance process. Individual CMGs or specialities within CMG's may choose to do audit more frequently for specific purposes and this would form part of their local audit programme.

Element to be monitored	Lead	Method	Frequency	Reporting arrangements

Process for identifying staff that are not capable of performing the procedure but are authorised to obtain consent for that procedure	CMG Clinical Director	Review of CMG arrangements by using Appendix 2.	Annually	CMG Quality & Safety Committees or equivalent
Process for the delivery of procedure specific training on consent for staff whom the consent process is delegated and who are not capable of performing the procedure	CMG Clinical Director	Review of training arrangements and the number of staff trained carried out via audit	Annually	CMG Quality & Safety Committees or equivalent
Process for following up those who have obtained consent for a procedure without being authorised to do so	CMG Clinical Director	Review of the outcome of related incidents reported	Annually	CMG Quality & Safety Committees or equivalent

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- Policy for the Consent to Examination or Treatment
- Policy on the Development of Information for Patients, carers and the public
- The Code for Nurse and Midwives (NMC)

- Consent and Physiotherapy Practice, Chartered Society of Physiotherapy 2011
- Mental capacity Act Policy

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

The most up to date version of this policy is available through the Trust's Policies and Guidelines Library accessed via INSite.

APPENDIX 1: IDENTIFICATION OF PROCEDURES FOR DELEGATED CONSENT

Complete only section A or section B. PLEASE RETURN THE COMPLETED FORM TO THE CMG Quality and Safety Teams

SECTION A: THERE ARE NO PROCEDURES FOR DELEGATED CONSENT

There are no procedures undertaken within the ……..CMG for which consent taking is delegated.

Signed ……. (CMG Lead) Date……..
Print Name ……

SECTION B: TAKING CONSENT FOR THE FOLLOWING PROCEDURE WILL BE DELEGATED

Please complete one form per procedure and then proceed to Appendix 2 and 3, completing as required

Procedure	
Name of procedure to be delegated	
Name of nominated Clinician lead for training for this procedure	
Can the nominated lead perform the procedure for which delegated consent is being taken *(please tick)*	Yes ☐ No ☐
Types and grades of healthcare professionals who will be trained to take consent. Please include any exclusion criteria for example you may wish to specify the number of years experience or prior knowledge of the identified staff	(e.g. Nursing staff – Band 5 or above; Orthoptist)
Is there a Patient Information Leaflet for this procedure available on YourHealth?	Yes ☐ No ☐ Number: Expiry date: **Please contact your Governance Facilitator immediately**
Signed ……. (CMG lead) Date…….. Print Name ……	

APPENDIX 2: PROCEDURE SPECIFIC TRAINING FOR DELEGATED CONSENT

SECTION A: PROCEDURE TO BE DELEGATED

CMG	
Name of Procedure to be delegated	
Name of lead Clinician for this Procedure	
Job Title of Lead Clinician	

SECTION B: HEALTHCARE PROFESSIONALS TO BE TRAINED

	Staff type	**Grade**
Which Healthcare professionals will be trained to take delegated consent for this procedure?	1.	
	2.	
	3.	
	4.	
Will all healthcare professionals receive the same training?	Yes ☐ No ☐	
If the answer is No, please complete one Section C for each healthcare professional.		

SECTION C: PROCEDURE SPECIFIC TRAINING PROGRAMME

1. How will the training be delivered? *(Please tick all that apply)*

1.	Attendance at a specific course, lecture or presentation (external)	
2.	Attendance at a specific course, lecture or presentation (internal)	
3.	1-1 Tuition	
4.	Facilitated Group Discussion	
5.	Self-study	
6.	Reading and understanding specified documents	
7.	Observation of practice	
8.	Development of specific skills	

2a. Is the delegate aware of the risks of the procedure?
2b. Does the delegate know (if appropriate) what the unit's average recorded risk rates for the procedure are?
3. Describe the benefits of the procedure
4. Can the delegate describe alternatives to the procedure and their risks (including no treatment)?
5. Can the delegate describe how the healthcare professional will be assessed as competent?

SECTION D: RESTRICTIONS ON DELEGATING CONSENT

Please describe if there are any patients or circumstances which will require consent to be taken by a healthcare professional competent to perform the procedure. *(E.g. children, adults who are not able to retain information, when complications are suspected….)*

Signed …… (CMG lead) Date……..

PRINT name …….

PRINT job title …….

APPENDIX 3: DELEGATED CONSENT PROCEDURE-SPECIFIC MODULE - COMPETENCY STATEMENT

(Please PRINT name)……..confirms that they have received the procedure-specific training in the following procedure(s)

PROCEDURE NAME	CMG & speciality	NAME OF TRAINER (please PRINT)	SIGNATURE OF TRAINER	DATE OF TRAINING

- I have the knowledge and skills required to discuss the above procedure(s) with a patient, with a view to obtaining consent for this treatment / investigation
- I acknowledge that I can only take consent for the above named procedures
- I am aware of my limitations and will refer patients to …… (name of agreed expert) for further information if required

Signed …….. Print name…….

Job title……..Grade……..

Registration number * ……(GMC/NMC – where appropriate)

Appendix 4: Guidelines for developing Procedure Specific training

1. Ascertain the healthcare professional's current knowledge regarding consent to inform your training plan.

2. The healthcare professional must read the Policy for Consent to Examination or Treatment and the Policy for Delegated Consent.

3. The trained healthcare professional must know of the risks, benefits and alternatives of the proposed procedure. They must be able to discuss these in detail, and where possible quantify risks in terms of the units own figures. The trained healthcare professional must also know what the consequences of not having any treatment will be.

4. The trained healthcare professional must know the details of the procedure, as it would normally be explained to the patient, i.e. why the procedure is done, how the procedure is done, what to expect during / following the procedure and likely outcomes.

5. The trained healthcare professional must know the limits of when they can consent, therefore it must be clear that they can only consent for the specific procedure covered in the training. Additionally include warning indicators for any kind of patients for whom the procedure is not appropriate due to the complexity of their care.

6. The healthcare professional must know how to access the person who is delegating consent, or other experts and other sources for more information.

7. Information in the form of audio visual aids that the healthcare profession can review at any time may be helpful. This must compliment at least one teaching method detailed below.

8. Possible methods for teaching include:
    a. Attendance at a specific course, lecture or presentation (external / internal)
    b. Tuition
    c. Facilitated group discussion
    d. Self-study
    e. Reading and understanding specified documents
    f. Observation of practice
    g. Development of specific skills

9. Active learning which requires the healthcare professionals to investigate information or participate in the learning should be encouraged.

10. Small assignments may be helpful to ascertain if the trainee has learned all relevant information.

11. Various staff groups may need a variety of training?

12. Training programmes must contain all relevant information and should be updated following changes in national guidance, or any significant developments or changes to the procedure.

APPENDIX 5: DELEGATED CONSENT PROCEDURE FLOWCHART