CONSENT TO TREATMENT POLICY

INTRODUCTION

The aim of this policy is to outline the principles and procedures that govern consent by patients receiving care and treatment via Heart Networks UK Ltd. It is not a detailed legal or procedural resource due to the nature and complexity of the issues surrounding consent.

Consent has three main elements:

- It must be voluntary – the decision to either consent or not to consent to treatment must be made by the person themselves, and must not be influenced by pressure from medical staff, friends or family
- It must be informed – the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment doesn't go ahead
- The patient must have capacity – the person must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision.

Where possible, a clinician must be satisfied that a patient understands and consents to a proposed treatment, immunisation or investigation, as well as the nature, purpose, benefits and risks of the procedure. Drawings, interpreters, videos or other means may be used to help ensure that the patient understands the situation, and has enough information to give 'Informed Consent'.

As a result of case law, consent must be clarified regarding not just the available options, but also the risks. The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks particular to them involved in proposed treatment, and of reasonable alternatives. A risk is "material" if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor is or should reasonably be aware that their patient would be likely to attach significance to it.

EQUALITY ANALYSIS

Heart Networks UK Limited is committed to promoting equality, diversity and human rights in all areas of its activities.

Heart Networks UK Limited undertakes equality analysis to ensure that its activities do not discriminate on the grounds of religion or belief, age, disability, race or ethnicity, sex or gender, sexual orientation, human rights and socio-economic status.

An equality analysis of the Consent to Treatment policy has been undertaken.

POLICY

The following principles will apply:

- All patients will be given a choice as to the services and treatments offered.
- Patients have a fundamental legal and ethical right to determine what happens to them.
- Full information about services and treatments will be provided prospectively, in order that any such consent is fully informed.
- Appropriate records will be kept concerning consent.
- Patients refusing to give consent should continue to receive the same high standards of care and respect as if such consent had not been refused.
- Patients deemed as unable to give informed consent will be reviewed by the clinician responsible, and as appropriate independent external review and assistance may be sought in order to decide how best to proceed.

PROVISION OF INFORMATION

i. The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example the removal of particular tissue. Once a decision to have a particular treatment/investigation has been made, patients need information about what will happen subsequently such as: where to go, how they will feel afterwards, and so on.

ii. Patients and those close to them will vary in how much information they want and in the form the patient understands. There will always be an element of professional judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

iii. A leaflet is attached at Appendix 1 for issue to patients regarding consent issues.

WHO IS RESPONSIBLE FOR SEEKING CONSENT?

i. The clinician carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done; it is they who will be held responsible in law if this is challenged later.

ii. Where oral or non-verbal consent is being sought at the point when the procedure will be carried out, this will naturally be done by the clinical professional responsible. However, team work is a crucial part of the way Heart Networks UK Ltd operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent. If the person cannot write or is physically unable to sign a form, a record that the person has given verbal or non –verbal consent should be made in their notes or on the consent form.

iii. Implied consent will be assumed for many routine physical contacts with patients. Where implied consent is to be assumed by the clinician, in all cases, the following will apply:

- An explanation will be given to the patient what he / she is about to do, and why.
- The explanation will be sufficient for the patient to understand the procedure.
- In all cases where the patient is under 18 years of age a verbal confirmation of consent will be obtained and briefly entered into the medical record.
- Where there is a significant risk to the patient, "Expressed Consent" is to be obtained in all cases.
- In case of any doubt, a full written Consent Form procedure will be used (see below).

iv. Expressed consent (written or verbal) will be obtained for any procedure which carries a risk that the patient is likely to consider as being substantial. A note will be made in the medical record detailing the discussion about the consent given and the risks of the procedure. A Consent Form may be used to express consent which should be attached to the clinical records.

COMPLETING CONSENT FORMS

i. Consent (Implied or Expressed) will be obtained prior to any procedure.

ii. The clinician will ensure that the patient is competent to provide a consent.

iii. Consent will include the provision of all information relevant to the treatment.

iv. The clinician providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

v. The clinician should explain the proposed treatment and any alternatives available to the patient, the risks and benefits of each option, and support the patient choice about which treatment best meets your needs.

vi. Questions posed by the patient will be answered honestly, and information necessary for all informed decision will be not be withheld unless there is a specific reason to withhold. In all cases where information is withheld then the decision will be recorded in the clinical record.

vii. The organisation acknowledges the right of a patient to refuse consent, delay the consent, seek further information, limit the consent or ask for a chaperone.

viii. If the patient signs the form in advance of a procedure (for example at a pre-assessment clinic), the clinician involved in their care on the day should sign the form to confirm that the patient still wishes to go ahead and has had any further questions answered.

ix. No alterations will be made to a Consent Form once it has been signed by a patient. Should consent be subsequently withdrawn, the patient should do so in writing and include in their note that withdrawal has been made after the implications have been explained to them.

x. Clinicians will ensure that consents are freely given and not under duress (e.g. under pressure from other present family members etc.)

xi. If a patient is mentally competent to give consent but is physically unable to sign the Consent Form, the clinician should complete the Form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

xii. A signed copy of the Consent Form should be retained in the patient's notes.

Other aspects which may be explained by the clinical include:

- Details of the diagnosis, prognosis, and implications if the condition is left untreated
- All options for treatment, including the option not to treat
- Details of any subsidiary treatments (e.g. pain relief)
- Patient experiences during and after the treatment, including any common or potential side effects and the recovery process.
- Probability of success and the possibility of the need for further treatments.
- The option of a second opinion.

REFUSAL OF TREATMENT

i. If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult person is entitled to refuse any treatment.

ii. Mental health legislation does provide the possibility of treatment for a person's mental disorder and its complications without their consent. This legislation does not give power to treat unrelated physical disorders without consent. If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, the clinician (and where possible the patient) should make a record of this.

iii. Where a patient has refused a particular intervention, the clinician must ensure that any other appropriate care to which they have consented continues to be provided. The clinician should also ensure that the patient realises 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.

iv. If a patient consents to a particular procedure but refuses certain aspects of the intervention, the doctor must explain to the patient the possible consequences of their partial refusal. If the doctor genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, he/she is not obliged to perform it. The clinician must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can

be safely carried out under the conditions specified by the patient, transferring the patient's' care to that health professional may be appropriate.

MENTAL CAPACITY ACT

The Mental Capacity Act (MCA) 2005 became fully effective on 1st October 2007 in England & Wales and provides a framework to empower and protect people who may lack capacity to make some decisions for themselves. 'A person who lacks capacity' is defined as a person who lacks capacity to make a particular decision or take a particular action for themselves at the time the decision or action needs to be taken. The lack of this capacity could be due to a mental health condition, a severe learning disability, a brain injury, a stroke or unconsciousness due to an anaesthetic or sudden accident and may be on either a temporary or a permanent basis.

The MCA makes clear who can take decisions in which situations, and how they should go about this. Heart Networks staff must always ensure that should any patient have a lasting Power of Attorney for their Health (as opposed to finance) a copy is obtained and scanned to the clinical file.

DEPRIVATION OF LIBERTY SAFEGUARDS

The Deprivation of Liberty Safeguards (DoLs) can only apply to people who are in a care home or hospital. This includes where there are plans to move a person to a care home or hospital where they may be deprived of their liberty. The care home or hospital will work with the Local Authority in authorising a DoLs and the organisation may be asked to contribute to the decision.

PHOTOGRAPHY, AUDIO AND VIDEO RECORDINGS

- Photographic, audio and video recordings made for treatment purposes form part of a patient's record. It should always be made clear in advance if any photographic, audio or video recording will result from that procedure.

- Photographic, audio and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. If the clinician wishes to use such a recording for education, publication or research purposes, consent in writing should be obtained ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the patient must be made aware that he/she may not be able to control future use of the material once it has been placed in the public domain.

- Photographic, audio and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

- If the clinician wishes to make a photographic, audio or video recording of a patient specifically for education, publication or research purposes, consent to make the recording - and then seek their consent to use it – should be obtained. Patients must know that they are free to stop the

recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

Appendix 1

Patient Information Leaflet – "Consent- it's up to you"

About the consent form

Before the doctor examines or treats you, they need your consent. Sometimes you can simply tell them whether you agree with their suggestions. However, sometimes a written record of your decision is helpful so you'll be asked to sign a consent form. If you later change your mind, you're entitled to withdraw consent – even after signing.

What should I know before deciding?

Health professionals must ensure you know enough to enable you to decide about treatment. They'll write information on the consent form and offer you a copy to keep as well as discussing the choices of treatment with you. Although they may well recommend a particular option, you're free to choose another. People's attitudes vary on things like the amount of risk or pain they're prepared to accept. That goes for the amount of information, too. If you'd rather not know about certain aspects, discuss your worries with whoever is treating you.

Should I ask questions?

Always ask anything you want. As a reminder, you can write your questions in the space over the page. The person you ask should do his or her best to answer, but if they don't know they should find some-one else who is able to discuss your concerns. To support you and prompt questions, you might like to bring a friend or relative. Ask if you'd like someone independent to speak up for you.

Is there anything I should tell people?

If there's any procedure you **don't** want to happen, you should tell the people treating you. It's also important for them to know about any illnesses or allergies which you may have or have suffered from in the past.

Who is treating me?

Amongst the health professionals treating you may be someone in training. They will only carry out procedures for which they have been appropriately trained. Someone senior will supervise – either in person accompanying a less experienced doctor or nurse in training or available to advise someone less experienced.

Photographs, audio and video tapes

As part of your treatment some kind of photographic record may be made – for example clinical photographs or sometimes an audio or video tape. You will always be told if this is going to happen. The photograph or recording will be kept with your notes and will be held in confidence as part of your medical record. This means that it will normally be seen only by those involved in providing you with care or those who need to check the quality of care you have received. The use of photographs and recordings is also extremely important for other work, such as teaching or medical research. However, we will not use yours in a way that might allow you to be identified or recognised without your express permission.

What are the key things to remember?

It's your decision! It's up to you to choose whether or not to consent to what's being proposed. Ask as many questions as you like, and remember to tell the team about anything that concerns you or about any medication, allergies or past history which might affect your health.

Questions to ask health professionals

As well as giving you information health professionals must listen and do their best to answer your questions. Before your next appointment, you can write some down in the space below.

Questions may be about the **treatment itself,** for example:

- What are the main treatment options?
- What are the benefits of each of the options?
- What are the risks, if any, of each option?
- What are the success rates for different options – for this unit or for you (the surgeon)?
- Why do you think an operation (if suggested) is necessary?
- What are the risks if I decide to do nothing for the time being?
- How can I expect to feel after the procedure?
- When am I likely to be able to get back to work?