



PATIENT CONSENT POLICY

(Version 1.2)

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1. **AIM:** This policy aims to outline what constitutes informed patient consent to ultrasound examination.
2. **INTRODUCTION:** It is our duty performing diagnostic imaging to ensure that our patients arrive for their appointments fully aware of what the procedure entails and that they are ready to give their consent to the examination. This policy sets out the variables of informed consent, this is for our clinicians and clinic staff to refer to ensure they are getting informed consent from patients, be it verbal or written.
3. **ROLES AND RESPONSIBILITIES:** It is the responsibility of the company directors and clerical staff appointing, to ensure that there is a valid patient booklet/information letter to accompany all patient appointment letters. This information should be explicit in the details of the ultrasound scan the patient is being booked for, to enable them to make an informed decision regarding giving their consent. Clerical staff should also have clear knowledge of what each scan entails, should they be asked to reiterate this to a patient verbally. There should also be patient information booklets available on reception for patients to read (this is especially needed should they have had their appointment booked by telephone).

It is foremost, however, the responsibility of the clinician performing the scan to check that the patient has read the information booklet and understands the procedure. It is their responsibility to assess the patient's *capacity* to make the decision. It is also their responsibility to ensure written consent has been obtained from the patient to perform the procedure prior to the patient getting on the bed.

4. **EQUIPMENT:** It is important that the patient is made aware of all the equipment, i.e. Probes, scan gel and pelvic wedge etc... That are there to facilitate their scan and ensure their comfort during the examination. It is important clinicians annotate their reports to state ***Written consent obtained from patient prior to appointment***

5. **HAZARDS and SAFETY:**

There are potential hazards when undertaking any physical examination of this kind if consent is not clearly given and this policy and procedural document is not upheld. These hazards are:

- **Implied consent**, it is not binding if a patient implies consent by just climbing onto the examination couch and exposing the body part for the scan. As the clinician needs to have first established that the patient has the *capacity* to understand what the procedure entails and that they have given verbal consent.
- **Patient consents to scan but does not understand it:** It is reasonable that a patient could consent to a scan without fully understanding the details of the examination. It is a risk for this patient as they may abort the scan midway through as they did not understand enough to give consent, this would make their offer of consent to treatment invalid, as it was not 'informed' consent. It is important that clinicians assess the patient's *capacity* to understand the procedure and that they are informed of the details.
- **Consent not obtained in writing:** if consent is not obtained in writing and by the conversation between patient and clinician to establish and confirm patient's *capacity* to understand the examination, therein lies a legal issue. It is reasonable if a patient has not been told (via the consent form and prior information) of the details of their examination and they are not asked to give written consent, they can then, during or after the examination raise the issue that their consent was not obtained in writing and they were unaware of the details of the examination. If this has caused distress to the patient then they would be able to take legal action against the company and clinician as they did not give informed consent and the clinician did not seek it.
- **Lack of mental *capacity*:** it is reasonable that some patients may arrive for scans who lack the capacity to understand the procedure or to give verbal consent. It is important for the clinician to observe the following

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advice from the NHS *Consent to treatment*:

'If the health professional feels you don't currently have the capacity to give consent, and you have not made an advance decision or formally appointed anyone to make decisions for you, they will need to carefully consider what is in your best interests before making a decision'

It is the responsibility of the clinician to decide on whether to proceed with the examination and if it is in the patients best interests to do so if they lack the capacity to understand and give written consent. However, if the patient has appointed a friend or family member to take legal responsibility it is their role to give consent to treatment in writing.

- **Persons under 16 years:** Persons aged 16 years and over have the right to consent to treatment, should the have the *capacity* to do so.

However, if patients under the age of 16 are thought to have the capacity to understand and consent to the examination this is allowed and taken as consent, providing the patients parent or guardian be in agreement. If a parent consents to a scan and the child does not, then it is the clinicians duty to assess if it reasonable for the child not to consent to the scan i.e. the age and mental *capacity* of the child and proceed with or abandon the examination.

If the clinician believes it is reasonable that the child does not consent to the scan they can refuse to scan the patient until the dispute is settled. In some extreme cases this may need to be settled by the Court of Protection who will assess if the treatment is in the patients best interests. If a parent does not consent to an examination and the child's long term health will be affected or there is a danger of death then this decision can be overruled by the courts.

- If any consent issues are called into dispute and are litigious in nature this is detrimental to the reputation of the company in the community, which also makes it VERY important that the procedures in this document are upheld.

6. PROCEDURE / SYSTEMS: These are the complete details of our company procedure for patient consent and should be followed out verbatim:

Upon receiving referral:

- Whether it is a GP, Nurse practitioner, Midwife, consultant or self-referral it is the company's responsibility to ensure that the patient is well informed of the procedure prior to their appointment this is done by the following:
 - Appointment letter contains scan name and preparation (See Appendix A)
 - Accompanying the appointment letter is an information sheet on the service. (See Appendix B)
 - When making a telephone appointment, (when the appointment is soon and there is no time to send a letter) the clerical staff member must inform the patient of the details of the examination and preparation.

When the patient has booked in for their appointment at reception:

- Clinic staff must ask patients to complete a consent form detailing the examination and what to expect (See Appendix C, D, E and F)

In the scan room with the clinician:

- The clinician must establish if the patient has read the details, understands the procedure and has completed and consent form.
- If the patient has not read the details or been told, the clinician needs to inform the patient of the details of the examination and ensure they complete a consent form.
- The clinician needs to assess if the patient has capacity to make informed consent, if they agree they are able to

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consent then they can proceed. If the clinician does not think the patient has the mental capacity to make informed consent then the clinician needs to decide if the examination is in the patient's best interests to proceed.

- After assessing the patient's capacity the clinician MUST establish there has been written consent for the examination, or if the patient lacks capacity agree with nominated persons, parents, guardians, persons with power of attorney to proceed if it is in the patient's best interests.
- If there is no person immediately available to obtain consent clinicians must refer to NHS *Consent To Treatment* guidance (under subheading: *Lack of mental capacity* in this policy document).
- Consent MUST be documented on the patients report and the written consent form uploaded on to patient profile. Likewise if the patient lacks the capacity for consent the reasoning of the clinician performing the scan must be documented on the report.

7 QUALITY CONTROL and AUDIT

This policy is subject to review every six months by the company directors and practice manager. If any incidents of consent disputes arise these must be documented and reviewed during the meeting.

If there are any incidents in which the policy needs immediate alteration then this is documented the policy changes agreed by the directors and carried out. It is essential that all clinic staff are informed of these changes and read and sign the new policy document to confirm their understanding and commitment to carry out policy changes.

8. REFERENCES & APPENDICES / RELATED DOCUMENTS

- <http://www.nhs.uk/Conditions/Consent-to-treatment/Pages/Introduction.aspx>
- Mental Capacity Act (2005)
- Deprivation of Liberty Safeguards. (Part of the Mental Capacity Act 2005)

Appendix A: Patient Appointment Letter (Example Male – Abdomen and Pelvis)

PRIVATE AND CONFIDENTIAL

<<Patient_Forename>> <<Patient_Surname>>
<<Patient_Address>>

Patient ID: <<Patient_ID>>
DOB: <<Patient_DOB>>
NHS Number: <<Patient_NHS_Number>>

ULTRASOUND APPOINTMENT

Letter Date: <<Letter Date>>

Dear <<Patient_Forename>>

We are contacting you on behalf of your GP/Consultant, they have requested an appointment for an **ABDOMEN AND MALE PELVIS** ultrasound scan on <<Appointment_Date>> at <<Appointment_Time>> at **HEM Clinical Ultrasound Service Limited, Unit 5, Conqueror Court, Vellum Drive, Sittingbourne, ME10 5BH – PLEASE SEE SERVICE INFORMATION ATTACHED.**

There will be a chaperone present (*please be aware the chaperone could be a male or female member of staff*), if you want to bring someone along with you, they can come too. You will be asked to sign a consent form at reception prior to your scan.

WHAT IS AN ULTRASOUND SCAN?

An ultrasound scan is a medical test that uses high-frequency sound waves, emitted from a small hand-held probe, to capture live images from the inside of your body. It's also known as sonography. Ultrasound examinations require a water based gel to be used between the probe and the skin, this helps obtain a clear image.

PREPARATION IS REQUIRED: Fast for four hours and drink 1-2 pints of water - see further information below.

ABDOMEN PREPARATION

Please fast for 4 hours prior to your scan, this means, no sugary drinks, only water or black tea/coffee (No sweeteners) and please avoid smoking or chewing gum during the fasting period. If you are taking medication please continue to do so as usual, and if you are diabetic please contact your GP/Nurse if you have concerns regarding fasting, and always ensure you bring a snack to eat after your scan, should you need it.

MALE PELVIS PREPARATION

A full bladder is required to undertake the scan, so please drink 1-2 pints of water 1 hour prior to your scan. You will need to expose your pelvis as the ultrasound requires skin contact with the probe, so please wear loose fitting clothing.

If you have any further enquiries please give us a call on 01795 436465, to speak to a member of our team.

<<Sent_By_Full>>

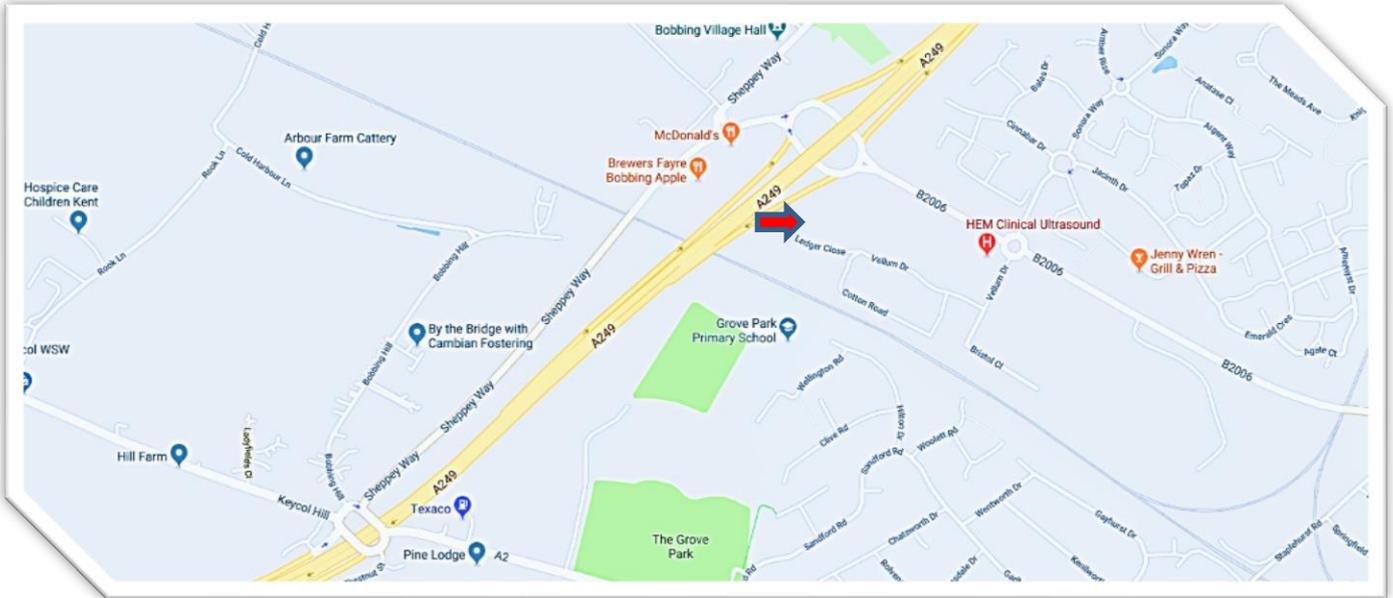
Booking team - HEM Clinical Ultrasound Service Limited

Appendix B: Service Information Sheet:

SERVICE INFORMATION – HEM SITTINGBOURNE

We are HEM CLINICAL ULTRASOUND SERVICE LIMITED a private provider of diagnostic ultrasound services on behalf of the NHS.

WHERE IS THE CLINIC LOCATED? (Address at top of page)



We are based in Sittingbourne. If approaching from the A249 – take the exit at the Bobbing roundabout and follow the B2006 Staplehurst Road to the first roundabout take the third exit onto Vellum Drive and follow to Conqueror Court. If approaching via Sittingbourne, follow signs for Bobbing and the B2006 Staplehurst Road look for Vellum Drive first exit at the roundabout prior to the Bobbing roundabout. If approaching from the A2 via Newington take the second exit at the Keycol roundabout – Sheppey Way, then take the second exit at the Bobbing roundabout onto Staplehurst Road, then take the third exit on the next roundabout onto Vellum Drive, you will see signs for Conqueror Court.

PRIVACY NOTICE

What is a Privacy Notice? A Privacy Notice is an important tool for any company who processes personal and confidential information. It is the way a company informs service users (Patients) and staff of how they use their information. With the new data protection regulations being introduced on 25th May 2018 it is now extremely important that individuals are aware of how their information is used and that they have:

- **The right to be informed...**
... of what information we hold and how we process it
- **the right of access;**
... to request copies of their patient/personnel file and be informed of who has had access to it
- **the right to rectification...**
... to request any errors in information found by patients or personnel are rectified
- **the right to erasure...**
... to request information held about themselves is deleted
- **the right to restrict processing...**
... to restrict overall data processing to certain aspects
- **the right to data portability ...**
... to ensure information is available across organisations at the individuals request
- **the right to object ...**

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... to object to processing of personal data for marketing or research purposes

- ***the right not to be subject to automated decision-making including profiling...***

... individuals personal and confidential information is held and processed under careful consideration by staff within organizations and not automatically passed for profiling or automatic decision making.

We are a UK based Ultrasound service provider, we will **ONLY** process your information for healthcare purposes as part of our any qualified provider contract with West Kent CCG. **WE WILL NEVER** release any patient sensitive data or staff data to third party organisations for marketing purposes. If there is a possibility, at a future date, of collaboration with a third party to disclose patient personal or sensitive data for research purposes, we will always ask for written consent from patients or staff to do so.

Your personal data lifecycle:

1. Referral for a scan (from GP/Midwife/Nurse Practitioner or e-referral) printed and filed securely.
2. Your details are entered on to a secure patient management system.
3. Referral read and scan carried out (by sonographer or radiologist).
4. Report e-mailed or faxed securely to the referring practitioner.
5. Referral, report, images and communications securely stored for patient continuity.
6. 5%-10% of all patients scanned each month have their information sent to *Medica Reporting Group limited*, they are our clinical auditing company. *Medica* have a team of radiologists on hand to review our images and reports to ensure they find them clinically accurate.
7. Patient records securely deleted after 10 years inactivity for general scan appointments. Obstetric records securely deleted after 25th birthday of unborn child and paediatric records child securely deleted after 25th birthday of the child.

CONTACTS

e-clinic offices are located Kirkgate House, 30 Kirkgate, Shipley, West Yorkshire, BD18 3QN.

Copies of referrals and reports and images will be routinely saved securely off site with our patient management system *e-clinic* to ensure them against accidental loss or damage should the clinic be subject to a natural disaster/human error or malicious damage in and ISO 27001 compliant data centre.

Medica Reporting Group LTD offices are located:

Fifth Floor, Havelock Place, Havelock Road, Hastings, East Sussex, TN34 1BG

HEM Clinical Ultrasound Service Limited, Unit 5, Conqueror Court, Vellum Drive, Sittingbourne, Kent, ME10 5BH.

If you would like more information regarding our policies please e-mail: igteam.hemultrasound@nhs.net

Alternatively, all our information Governance Policies and procedures are located on the company website – www.hem-ultrasound.co.uk

DO YOU HAVE A CONCERN ABOUT YOUR PERSONAL INFORMATION?

If you have a concern about the way in which your information is held and processed by HEM Clinical Ultrasound Service Limited or by our supporting companies *e-clinic* and *Medica Reporting Group* please contact the information commissioners office- The UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

Information Commissioners Office: Online: <https://ico.org.uk/concerns/> Or by Phone: 0303 123 1113.

Requesting access to your records:

You are welcome to request a copy of your patient file. You need to do this in writing, this can be letter or e-mail. to referrals.hemultrasound@nhs.net. Or Send a letter to: The Operations Manager, HEM Clinical Ultrasound Service

LTD, Unit 5, Conqueror Court, Vellum Drive, Sittingbourne, Kent, ME10 5BH

Company Policies:

If you would like to have a copy of any patient care policy held by the company please do not hesitate to

Appendix C: NHS Consent Form



NHS PATIENT CONSENT FORM



<input type="checkbox"/> RENAL TRACT ULTRASOUND	<input type="checkbox"/> MUSCULOSKELETAL ULTRASOUND	<input type="checkbox"/> VASCULAR ULTRASOUND (SUSPECTED DVT)
<input type="checkbox"/> ABDOMINAL ULTRASOUND	<input type="checkbox"/> TESTES ULTRASOUND	<input type="checkbox"/> MALE PELVIC ULTRASOUND
<input type="checkbox"/> FEMALE PELVIC ULTRASOUND Scans can be carried out trans-abdominally (moving the probe over the exterior pelvis) or transvaginal which would involve a specialised probe being placed a small way into the vagina. <i>*Please note*</i> We would never perform a Transvaginal scan on a patient whom had never been sexually active, or without written consent.		

WHAT IS AN ULTRASOUND SCAN?

An ultrasound scan is a medical test that uses high-frequency sound waves, emitted from a small hand-held probe, to capture live images from the inside of your body. It's also known as sonography. Ultrasound examinations require a water-based gel to be used between the probe and the skin, this helps obtain a clear image.

IN THE EXAMINATION ROOM:

There will be a sonographer and a chaperone present, if you want to bring someone along with you, they can come too. We use chaperones in all our appointments to safeguard the wellbeing of the patient and the sonographer.

PLEASE FILL IN BELOW:

I confirm that I understand the nature of my appointment and consent to undergoing an ultrasound examination and I have read and understood the information above.

Name: **Date of Birth:**

Gender: Male/Female (*please circle*)

Signature of Patient:..... **DATE:**.....

*****I confirm I have seen or been supplied with a copy of the Service Privacy Notice Yes/No (Please Circle)*****

Appendix D: Private General Consent Form



PRIVATE PATIENT CONSENT FORM

Your Ultrasound Scan: This consent form is to give you a clear idea of the appointment you are booked for and what to expect, in order for you to give your informed consent to the examination.

<input type="checkbox"/> RENAL TRACT ULTRASOUND	<input type="checkbox"/> MUSCULOSKELETAL ULTRASOUND	<input type="checkbox"/> VASCULAR ULTRASOUND (SUSPECTED DVT)
<input type="checkbox"/> ABDOMINAL ULTRASOUND	<input type="checkbox"/> TESTES ULTRASOUND	<input type="checkbox"/> MALE PELVIC ULTRASOUND
<input type="checkbox"/> FEMALE PELVIC ULTRASOUND Scans can be carried out trans-abdominally (moving the probe over the exterior pelvis) or transvaginally which would involve a specialised probe being placed a small way into the vagina. *Please note* We would never perform a Transvaginal scan on a patient whom had never been sexually active, or without written consent.		

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IN THE EXAMINATION ROOM:

There will be a sonographer and a chaperone present, if you want to bring someone along with you, they can come too. We use chaperones in all our appointments to safeguard the wellbeing of the patient and the sonographer.

PLEASE FILL IN BELOW:

Name: **Date of Birth:**

Gender: Male/Female (*please circle*)

I consent to HEM Ultrasound sharing my care information with my GP and/or consultant, and to the possible sharing of my report and images for clinical auditing purposes **YES/NO** (*please circle*)

I confirm that I understand the nature of my appointment and consent to undergoing an ultrasound examination and I have read and understood the information above.

Signature of Patient:..... **DATE:**.....

***I confirm I have seen or been supplied with a copy of the Service Privacy Notice Yes/No (Please Circle)

Appendix E: Private Obstetric Form – Viability



PRIVATE PATIENT CONSENT FORM

Your Ultrasound Scan: This consent form is to give you a clear idea of the appointment you are booked for and what to expect, in order for you to give your informed consent to the examination.

Early viability/reassurance scans 6- 15 Weeks		£70.00
TERMS AND CONDITIONS		
<p><i>The early viability and reassurance scan can be Transabdominal (on top of tummy) or Transvaginal (an internal scan) if pregnancy is not visible via abdominal route. You will be required to pay a 20% non-refundable deposit upon booking the appointment. The quality of the images can be dependent on patient BMI (Body Mass Index).</i></p> <p><i>Full Bladder is required for this scan. Please note the accuracy of scan findings is reliant on correct dates of last menstrual period supplied by the patient. Patient will receive written report and a CD with the images. You will be required to pay a 20% non-refundable deposit upon booking the appointment.</i></p>		
<p>Please note the accuracy of scan findings is reliant on correct dates of last menstrual period supplied by the patient</p>	<p>YES / NO</p>	

WHAT IS AN ULTRASOUND SCAN?

An ultrasound scan is a medical test that uses high-frequency sound waves, emitted from a small hand-held probe, to capture live images from the inside of your body. It's also known as sonography. Ultrasound examinations require a water-based gel to be used between the probe and the skin, this helps obtain a clear image.

IN THE EXAMINATION ROOM:

There will be a sonographer and a chaperone present, if you want to bring someone along with you, they can come too. We use chaperones in all our appointments to safeguard the wellbeing of the patient and the sonographer.

PLEASE FILL IN BELOW:

Name: **Date of Birth:**

I consent to HEM Ultrasound sharing my care information with my GP and/or consultant, and to the possible sharing of my report and images for clinical auditing purposes YES/NO (please circle)

I confirm that I understand the nature of my appointment and consent to undergoing an ultrasound examination and I have read and understood the information above.

Signature of Patient:..... **DATE:**.....

***I confirm I have seen or been supplied with a copy of the Service Privacy Notice Yes/No (Please Circle)

Appendix F: Private Obstetric Form – Wellbeing



PRIVATE PATIENT CONSENT FORM

Your Ultrasound Scan: This consent form is to give you a clear idea of the appointment you are booked for and what to expect, in order for you to give your informed consent to the examination.

Wellbeing scans 6- 34 weeks £70.00	
TERMS AND CONDITIONS	
<i>The wellbeing scan will be Transabdominal (on top of tummy) You will be required to pay a 20% non-refundable deposit upon booking the appointment. The quality of the images can be dependent on patient BMI (Body Mass Index).</i>	
<i>Full Bladder is required for this scan. Please note the accuracy of scan findings is reliant on correct dates of last menstrual period supplied by the patient. Patient will receive written report and a CD with the images. You will be required to pay a 20% non-refundable deposit upon booking the appointment.</i>	

Please note the accuracy of scan findings is reliant on correct dates of last menstrual period supplied by the patient	YES / NO
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WHAT IS AN ULTRASOUND SCAN?

An ultrasound scan is a medical test that uses high-frequency sound waves, emitted from a small hand-held probe, to capture live images from the inside of your body. It's also known as sonography. Ultrasound examinations require a water-based gel to be used between the probe and the skin, this helps obtain a clear image.

IN THE EXAMINATION ROOM:

There will be a sonographer and a chaperone present, if you want to bring someone along with you, they can come too. We use chaperones in all our appointments to safeguard the wellbeing of the patient and the sonographer.

PLEASE FILL IN BELOW:	
Name: Date of Birth:	
I consent to HEM Ultrasound sharing my care information with my GP and/or consultant, and to the possible sharing of my report and images for clinical auditing purposes YES/NO (please circle)	
I confirm that I understand the nature of my appointment and consent to undergoing an ultrasound examination and I have read and understood the information above.	
Signature of Patient: DATE:	

*****I confirm I have seen or been supplied with a copy of the Service Privacy Notice Yes/No (Please Circle)**
END OF DOCUMENT