What is required for "explicit consent"[1]?

Please note that the requirement for explicit consent is an additional safeguard which is required in order to be compliant with the Health Research Regulations. You will also need a lawful basis for the processing of personal data under Article 6 and Article 9 of the GDPR.

Lawful Basis - Ordinary Personal Data

If processing 'Ordinary' personal data[2] then you must satisfy at least one of the lawful bases as set out under Article 6 GDPR

Lawful Basis - Special Category Data (Sensitive Personal Data)

If processing sensitive personal data[3] then, in addition to the Article 6 lawful basis, you must also satisfy one of the conditions as set out under Article 9 GDPR

Health Research Regulations - Explicit Consent required for Health Research

In addition to satisfying Articles 6 & 9 GDPR requirements you must also obtain explicit consent for processing personal data for health research purposes. This mandatory requirement is set out under Regulation 3(1)(e) of the 2018 Health Research Regulations.

Explicit consent is informed consent which is recorded/documented

In order for consent to be valid, it must be:

- Freely given;
- Specific;
- Informed;
- Unambiguous; and
- Such consent must be recorded by a statement or by a clear affirmative action.

Please see table below for guidance on each of these aspects of informed consent.

Checklist to determine whether consent in is line with the GDPR and Health Research Regulations

[1] Article 4 (11) of GDPR and in accordance with guidelines on consent issued by the Article 29 Working Party – include link.
[2]Please see Article 4(1) for a definition of Personal Data: https://gdpr-info.eu/art-4-gdpr/
[3] Please see Article 9(1) of GDPR for a definition of special categories of personal data/sensitive personal data. https://gdpr-info.eu/art-9-gdpr/

GDPR Explicit Consent Requirements – Processing of Personal Data	Yes/No
1. Has the consent been freely given? Have you informed the data subject that they have the option to withdraw their consent at any time if they so wish? - The element "free" implies real choice and control for data subjects. - If the data subject has no real choice, feels compelled or coerced to consent in any way or if the data subject feels that if they do not consent their medical care or treatment may be affected in some way, then their consent will not be valid. - We understand that given the relationship between a data subject and the medical/research team, this can be a difficult balance. If your data subject is fully informed (see item 3), it will be easier to assess whether their consent is freely given. - The data subject must be informed that they can withdraw their consent at any time without detriment. This should be highlighted from the outset so that the data subject does not feel under any obligation to continue against their wishes.	Yes
2. Is the consent specific? - The data subject should not be surprised by any use of their personal data, health data or any other sensitive data by the research team. - Have all of the data controllers been clearly identified?	Yes
3. Is the consent informed? - In order to be informed, the data subject should have enough information to be able to make their decision to consent or not. - Have you clearly stated what (type of) personal data will be collected and used? (e.g. names, addresses, blood type, medical condition, etc.).	Yes
4. The consent must be unambiguous - Consent requires a statement from the data subject or a clear affirmative act, which means that the data subject must have taken a deliberate action to specifically consent to the particular processing of the personal data. Is it obvious that the data subject has consented to the particular processing?	Yes

- You must demonstrate that consent has been given to a particular processing activity. Have you maintained a written record of the consent? - The consent form should be signed by the data subject in order to remove all possible doubt.	
5. Automated decision-making *If applicable* Have you included information about the use of the data for automated decision-making in accordance with Article 22 (2)(c) GDPR? Processing is 'automated' where it is carried out without human intervention, and where it produces legal effects or significantly affects a data subject. Automated processing includes profiling.	N/A
6. International data transfers *If applicable* Have you included information on the possible risks of data transfers outside the EEA due to absence of an adequacy decision and of appropriate safeguards as described in Article 46? See: https://gdpr-info.eu/art-46-gdpr/	N/A

STUDY NAME: The Efficacy of Peri-Articular Injection for Pain Relief Post Total Hip Arthroplasty. A Single-Centre, Double-Blinded Randomised Control Trial

Identification Number for study:

Consent Form

General	**Tick box**
I confirm I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason. I understand that deciding not to take part will not affect my future medical care.	
I understand that my medical notes and records may be looked at by my [Study Doctor and his/her study team] at [hospital] where it is relevant to the research. I agree that these individuals can access my records. I understand that all information will be kept private and confidential and that my name will not be disclosed.	
I understand that I will not be paid for taking part in this study[4].	
I know how to contact the research team if I need to.	
I agree to take part in this research study having been fully informed of the risks, benefits and alternatives which are set out in full in the information leaflet which I have been provided with.	
[I agree to being contacted by researchers by [email/phone[5]] as part of this research study][6].	
Data processing	**Tick box**
I agree to allow personal information about me to be shared with third parties including; national and international hospitals, and academic research institutions for the purpose of orthopaedic research, as described in the Information leaflet[7].	
I agree to allow personal information about me to be shared with for-profit commercial research or biopharmaceutical companies	

[4] Amend as appropriate.
[5] Please include the appropriate relevant details.
[6] Please delete as appropriate.
[7] This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with.

for the purpose of orthopaedic research, as described in the Information leaflet[8].	
I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.	
I understand that there are no direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me.	
I understand that I can stop taking part in this study at any time without giving a reason and this will not affect my future medical care.	

[8] This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with.

Patient Name (Block Capitals) Patient Signature Date

Witness Name (Block Capitals) Witness Signature Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name _____

Title and qualifications _____

Signature _____

Date _____

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.