Waiver of Documentation of Informed Consent

Section 1. PROTOCOL INFORMATION

Primary Investigator: Dr Rajpreet Sahemey
Project Title: ANTHROPOMETRIC METHOD FOR ESTIMATING COMPONENT SIZES IN TOTAL HIP ARTHROPLASTY

Section 2. WAIVER OF INFORMED CONSENT

A consent procedure which does not document obtained consent through a physical signature may be approved by the IRB under certain conditions. To request IRB approval of a consent procedure which does not document consent through a physical signature, provide a response to **only one** of the following. Note that the IRB may require the investigator to provide subjects with a written statement regarding the research, even though the documentation requirement may be waived.
2A. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations.)
2B. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the consent. YES
2C. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

2B: This retrospective study involves no more than minimal risk to the participants.

Institutional Review Board (IRB) approval was not required in accordance with National Research Ethics Service (United Kingdom) guidance on the use of anonymised data collected retrospectively as part of routine clinical care.
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