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We use this protocol and it's working

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LEGACY01: REGULATORY ISSUES

In 1 collection

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DISCLAIMER

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ABSTRACT

This protocol details regulatory issues in an experimental medicine study of seasonal influenza vaccination responses in Lymph nodE single-cell Genomics in AnCestrY (LEGACY01).

ATTACHMENTS

602-1266.docx

ETHICS APPROVAL

The Study Coordination Centre will obtain approval from an NHS Research Ethics Committee (REC) and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from Imperial College Healthcare NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered, and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study, the clinician remains free to give alternative treatment to that specified in the protocol or to withdraw participant from lymph node sample donation at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases, the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

CONFIDENTIALITY

Definition of terms

Pseudonymised data can be linked to an individual e.g., through a coded study key kept at the NHS study site.

Anonymised data cannot be linked directly back to an individual e.g., aggregated data for publication.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Individuals will receive a single non-transferable study code when attending screening for the study and keep the same code upon enrolment to the study. Data collected for the study will be pseudonymised by means of a coded study key kept at the NHS study site (Imperial College Healthcare NHS Trust. Pseudonymised data will be transferred from the study site to Imperial College London and University of Oxford for analysis without the study key. Anonymised data will be published.