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LEGACY01: PARTICIPANT ENTRY

In 1 collection

Katrina M Pollock[1], Calliope Dendrou[2]

[1]NIHR Imperial Clinical Research Facility, ICTEM Building, Hammersmith Hospital Campus, Du Cane Road, London W12 0HS, UK;
[2]Wellcome Centre for Human Genetics, University of Oxford, Oxford OX3 7BN

Katrina M Pollock: Chief Investigator;
Calliope Dendrou: Scientific Lead

Human Cell Atlas Method Development Community

Katrina M Pollock
University of Oxford , Imperial College London

ABSTRACT

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

ATTACHMENTS

602-1266.docx

GUIDELINES

PRE-REGISTRATION EVALUATIONS

Participants will attend a screening visit and provide written informed consent to enrol onto the study.

PARTICIPANT INCLUSION CRITERIA

- Healthy adults aged 18 years to 55 years on the day of screening
- Willing and able to provide written informed consent
- Identifies as having African or Asian ancestry[i]
- Usually resident in the UK for at least 5 years prior to screening
- If female and of childbearing potential[ii] not pregnant on the day of screening and willing to use a highly effective form of contraception until 12 weeks after the study immunisation[iii].
- Willing to avoid all other vaccines within 4 weeks either side of the study injection and fine needle aspiration[iv].
- Willing and able to comply with the visit schedule and provide samples.
- Willing to grant authorised persons access to his/her trial related medical record

and GP records either directly or indirectly.

Note

[i] A list of ethnic groups in the UK is available at List of ethnic groups - GOV.UK (ethnicity-facts-figures.service.gov.uk).

[ii] A woman will be considered of childbearing potential following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A post-menopausal state is defined as no menses for 12 months without an alternative medical cause.

[iii] Highly effective forms of contraception include medical sterilisation of a women or her partner, hormonal methods of contraception that prevent ovulation and intrauterine devices or systems. Barrier methods of contraception are not considered highly effective. Abstinence should be the preferred and usual lifestyle of the participant.

[iv] An exception is made for authorised or licensed COVID-19 vaccination according to national clinical directives. A gap of at least 28 days either side of an FNA is preferred but where there is clinical imperative a shorter gap is acceptable. Where a COVID-19 vaccine is scheduled near to an FNA, the FNA should occur before the vaccination where possible.

PARTICIPANT EXCLUSION CRITERIA

- Pregnant or lactating
- Has a significant clinical history, physical finding on clinical examination or laboratory finding during screening, or presence of a disease that is active or requires treatment to control it, including cardiac, respiratory, endocrine, metabolic, autoimmune, liver, neurological, oncological, psychiatric, immunosuppressive/immunodeficient or other disorders which in the opinion of the investigator is not compatible with healthy status, may compromise the volunteer's safety, preclude vaccination or tissue sampling or compromise interpretation of the immune response to vaccine. Individuals with mild/moderate, well-controlled comorbidities are allowed.
- Body mass index of 30 or greater
- History of anaphylaxis or angioedema
- History of severe or multiple allergies to drugs or pharmaceutical agents or contraindicated from receiving influenza vaccine or local anaesthetic including lidocaine.
- History of severe local or general reaction to vaccination defined as:

local: extensive, indurated redness and swelling involving most of the arm, not resolving within 72:00:00

general: fever ≥ 39.5 °C within 48:00:00; bronchospasm; laryngeal oedema; collapse; convulsions or encephalopathy within 72:00:00 .

- Receipt of any immunosuppressive agents within 18 weeks of screening by any route other than topical
- Prescribed regular blood thinning medication likely to induce bruising or bleeding on fine needle aspiration
- Detection of antibodies to hepatitis C
- Detection of antibodies to HIV
- Detection of anti-hepatitis B core antibodies
- Participating in a clinical trial with an investigational drug or device or treated with an investigational drug within 28 days of screening.

WITHDRAWAL CRITERIA

Participants are free to withdraw from the study at any time and for any reason without prejudicing their usual medical care.

Discontinuing sample donation: those participants who choose to discontinue lymph node tissue donation can be followed up to donate blood samples. Those participants where the investigator chooses to discontinue tissue donation can be followed up to donate blood samples.

Participants who choose to discontinue all (blood and lymph node) sample donation will be withdrawn from the study once the investigator deems it safe to do so.

Withdrawing from vaccination: Those participants who choose not to, or are unable to, have an influenza vaccine as part of the study schedule can continue to provide lymph node and blood samples.

Additional volunteers may be enrolled to replace withdrawn participants or those who are unable to complete the study schedule of visits per protocol for any reason.

COENROLMENT GUIDELINES

Participants will be entered into the TOPS database to prevent over-volunteering. Co-enrolment into another study is discouraged but can be allowed at the discretion of the investigator where neither the safety of the participant nor the integrity of the data is at risk. An example would be co-enrolment into an observational study with either no sampling or a low volume blood draw.