




APR 19, 2023

## LEGACY01: QUALITY ASSURANCE AND CONTROL

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**Protocol Citation:** Katrina M Pollock, Calliope Dendrou 2023. LEGACY01: QUALITY ASSURANCE AND CONTROL. **protocols.io** <https://protocols.io/view/legacy01-quality-assurance-and-control-cmj6u4re>

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**Protocol status:** Working**Created:** Jan 11, 2023**Last Modified:** Apr 19, 2023**PROTOCOL integer ID:**  
75102**Keywords:** Single-cell sequencing, lymph node, influenza vaccine, ancestry

Human Cell Atlas Method Development Community



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### ABSTRACT

This protocol details quality assurance and control in an experimental medicine study of seasonal influenza vaccination responses in Lymph node single-cell Genomics in AnCestrY (LEGACY01).

### ATTACHMENTS

[602-1266.docx](#)

## GUIDELINES

### **QUALITY ASSURANCE AND CONTROL**

Quality assurance (QA) includes all the planned and systematic actions established to ensure the study is performed and data generated, recorded and reported in compliance with the principles of GCP and any regulatory requirements. Quality control (QC) includes the operations to ensure that requirements for the study activities are fulfilled.

### **SAFETY AND RIGHTS OF PARTICIPANTS**

Participants will be donating tissue and undergoing immunisation using procedures that are commonly undertaken for patients in the NHS. Confidential information will be kept allowing safety assessments to be made throughout the study.

### **PROJECT DESIGN AND RELIABILITY**

A feasibility study is already underway lead by the Chief Investigator (EAVI2020\_01 FNA sub study). This study has indicated that lymph node sampling is feasible, safe and with ample yields to be undertaken as part of human vaccine research.

### **CLINICAL DATA RECORDING AND MONITORING**

Worksheets for the study will be created for each study visit. Completed worksheets will undergo regular QC assessments by the study clinical team. Data will be stored by means of an electronic database using REDCap or similar software system.

### **AUDITS**

The study may be subject to audit by Imperial College London, under its remit as sponsor, and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

### **REFERENCE**

Day S, Kaur C, Cheeseman HM, de Groot E, McFarlane LR, Tanaka M, Coelho S, Cole T, Lemm N-M, Lim A, Sanders RW, Asquith B, Shattock RJ and Pollock KM (2022) Comparison of blood and lymph node cells after intramuscular injection with HIV envelope immunogens. *Front. Immunol.* 13:991509. doi: 10.3389/fimmu.2022.991509