All other Chief Investigators

Who/what are your study subjects?

Study type

What approvals do UWWBIC need to see?

Participants identified via NHS

- All research except CTIMP or non-CE marked device research → **Pathway F**
  - HRA approval (through IRAS)
  - Sponsorship
  - Insurance/indemnity arrangements
  - Terms and Conditions of User Agreement
- CTIMP** and/or non-CE marked device* → **Pathway G**
  - MHRA device letter of no objection
  - HRA approval (through *new part* of IRAS)
  - Sponsorship
  - Insurance/indemnity arrangements
  - Terms and Conditions of User Agreement

DO I NEED HRA APPROVAL?
http://www.hra-decisiontools.org.uk/ethics/

Participant not identified via NHS

- CTIMP** and/or non-CE marked device* → **Pathway H**
  - MHRA device letter of no objection
  - HRA approval (through *new part* of IRAS)
  - Sponsorship
  - Insurance/indemnity arrangements
  - Terms and Conditions of User Agreement
- Human Tissue only → **Pathway J**
  - HRA approval (through IRAS)
  - Sponsorship
  - Insurance/indemnity arrangements
  - Terms and Conditions of User Agreement
- All other research (i.e. not CTIMP, human tissue only or non-CE marked device) → **Pathway K**
  - A University or equivalent ethics approval
  - Terms and Conditions of User Agreement
  - Sponsorship
  - Insurance/indemnity arrangements

Key:
HRA: Health Research Authority
MHRA: Medicines and Healthcare products Regulatory Agency
•*Safety/efficacy of a medicine, foodstuff or placebo

*For advice on non-CE marked device trials and CTIMPs** (Clinical Trial of an Investigational Medicinal Product, please see:
https://www.hra.nhs.uk/documents/2663/UK_SW_Criteria_updated_19.11.2021.pdf

All studies will require a UWWBIC/UEA Risk Assessment