UEA Chief Investigators

Who/what are your study subjects?

Study type

What approvals do UWWBIC need to see?

Participants identified via NHS

Participant not identified via NHS

All research except CTIMP or non-CE marked device research

CTIMP** and/or non-CE marked device*

CTIMP** and/or non-CE marked device*

Human Tissue only

All other research (i.e. not CTIMP, human tissue only or non-CE marked device)

Pathway A

- HRA approval (through IRAS)
- Sponsorship
- Insurance/indemnity arrangements

Pathway B

- MHRA device letter of no objection
- HRA approval (through *new part* of IRAS)
- Sponsorship
- Insurance/indemnity arrangements

Pathway C

- MHRA device letter of no objection
- HRA approval (through *new part* of IRAS)
- Sponsorship
- Insurance/indemnity arrangements

Pathway D

- HRA approval (through IRAS)
- Sponsorship
- Insurance/indemnity arrangements

Pathway E

- UEA Ethics Approval

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

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