All other Chief Investigators

Who/what are your study subjects?

Participants identified via NHS

Participants not identified via NHS

Study type

All research except CTIMP or non-CE marked device research

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)

What approvals do CRIC need to see?

Pathway F

• NHS REC approval
• NHS permission (R&D approval)
• Sponsorship
• Terms and Conditions of Use Agreement

Pathway G

• MHRA CTA (IMP) or device letter of no objection
• NHS REC approval
• NHS permission (R&D approval)
• Sponsorship
• Insurance/indemnity arrangements
• ARSAC (if applicable)
• Terms and Conditions of Use Agreement

Pathway H

• MHRA CTA (IMP) or device letter of no objection
• NHS REC approval
• Sponsorship
• Insurance/indemnity arrangements
• ARSAC (if applicable)
• Terms and Conditions of Use Agreement

Pathway J

• NHS REC approval
• Sponsorship
• Insurance/indemnity arrangements
• Terms and Conditions of Use Agreement

Pathway K

• A University or equivalent ethics approval
• Terms and Conditions of Use Agreement
• Sponsorship
• Insurance/indemnity arrangements

Key:
ARSAC: Administration of Radioactive Substances Advisory Committee
REC: Research Ethics Committee
MHRA: Medicines and Healthcare products Regulatory Agency
*Safety/efficacy of a medicine, foodstuff or placebo
• CTA: Clinical Trial Authorisation

*For advice on non-CE marked device trials see http://www.mhra.gov.uk/Howweregulate/Devices/ClinicalTrials/index.htm
**CTIMP: Clinical Trial of an Investigational Medicinal Product, see http://www.mhra.gov.uk/home/groups/l- unit1/documents/websitesources/con009394.pdf

All studies will require a CRIC Bristol Risk Assessment

For advice on non-CE marked device trials see http://www.mhra.gov.uk/Howweregulate/Devices/ClinicalTrials/index.htm

*CTIMP: Clinical Trial of an Investigational Medicinal Product, see http://www.mhra.gov.uk/home/groups/l-unit1/documents/websitesources/con009394.pdf

Participants not identified via NHS

Human Tissue only

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