Do I need NHS Ethics Review, NHS Trust Management Approval, or Health Research Authority (HRA) Approval?

Does the research proposal involve:
- Clinical Trial of an Investigative Medicinal Product (CTIMP) in the EU
- Administration of an unlicensed drug within the EU
- Ionising radiation
- Adults lacking capacity to consent
- Use of a non-CE marked Medical Device or CE marked Medical device for a new purpose

Participants recruited by virtue of being UK National Health Service (NHS) patients?

Clinical Trials & Research Governance (CTRG) for University Sponsorship

Cellular components used in research >12 hours after sampling OR Storage for >7 days before transportation or rendering acellular

NHS National Research Ethics Service Review

Concurrent HRA Approval

Local NHS Trust Confirmation

Taking/Processing/Storing of Human Tissue (including blood, urine, saliva)

Clinical Trials & Research Governance (CTRG) for University Sponsorship

NHS staff¹, facilities², premises³ or data⁴?

Central University Research Ethics Committee (CUREC) Review (via either OxTREC, the MS IDREC or the SSH IDREC (or one of its Departmental Research Ethics Committees (DRECs)))

Additional HRA Approval (following ethics approval)

Local NHS Trust Management Approval

1. Staff - people recruited to research by virtue of their status as current or former employees of the NHS
2. Facilities includes equipment owned by the NHS, clinical services run or subcontracted by the NHS
3. Premises includes NHS Hospitals, individual departments / centres run by NHS, mobile clinical units etc.
4. Data means data generated by an NHS clinical service, or held in NHS databases or behind NHS firewalls, or owned by the NHS in any other capacity. It does not matter whether the data hold identifying personal information or whether they are anonymised.

Latest revision January 2017