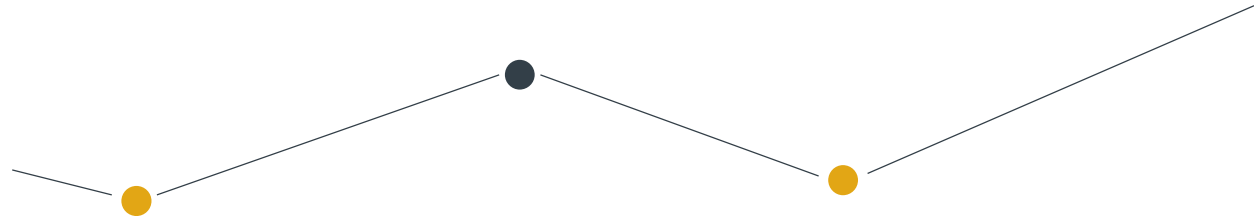


The Framework Agreement

- The legal agreement underpinning research & development activities at the University of Edinburgh & Lothian Health Board
- Current version dated 2010, a revised version is near finalisation
- Covers arrangements and responsibilities between LHB and UoE in connection with clinical research
 - includes ethics and other governance, employment (honorary status), intellectual property, publication, funding applications & high level material and data sharing



Contracts for investigator-led clinical research – an overview



Clare Whittaker

Head of Research Contracts, Governance & Integrity

Clare.Whittaker@ed.ac.uk

When Lothian Health Board and University of Edinburgh co-sponsor ...

Funder is a commercial entity, but research is investigator led:

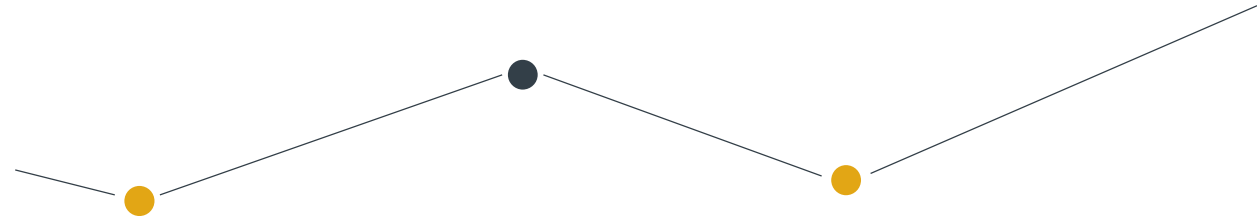
- Funding agreement
- Collaboration Agreement

... supported by Edinburgh Innovations (Business Development) in conjunction with UoE's Legal Services

Funder is non-commercial, charity, research council:

- Funding Agreement
- Collaboration Agreement

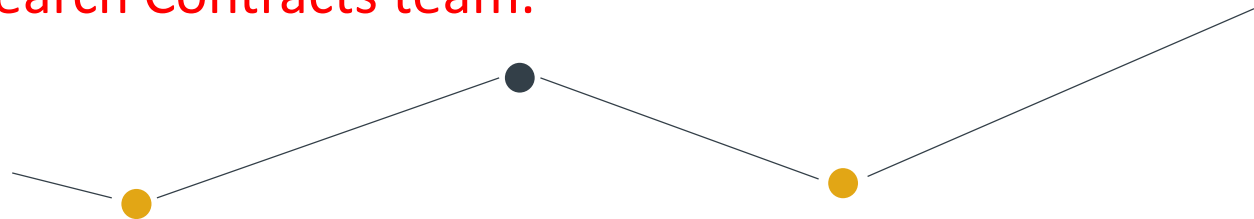
... supported by Edinburgh Research Office (Research Funding Team) in conjunction with ERO's Research Contracts team



When Lothian Health Board and University of Edinburgh co-sponsor ...

Agreements for regulated studies such as

- Drug supply agreements, technical agreements, device supply agreements
 - Co-Sponsorship & Site Agreement
 - Site agreements (we use HRA templates for UK sites)
 - mNCA (the “model site agreement”)
 - OID (“Organisation Information Document”) used ‘as a contract’
- ... are supported by ERO’s Research Contracts team.



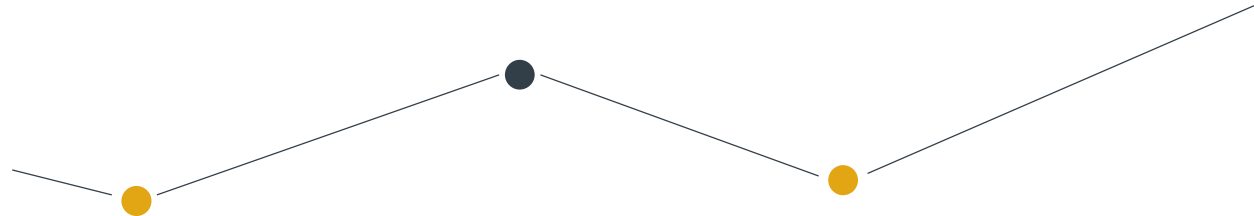
When Lothian Health Board and University of Edinburgh co-sponsor ...

Other contracts required may include:

- License agreements
- Data sharing agreements
- Service agreements
- Other academic and non-commercial research contracts connected with clinical research

... supported by ERO's Research Contracts team

NB Site agreements to recruit patients into an externally-sponsored clinical study are always handled by Lothian Health Board.

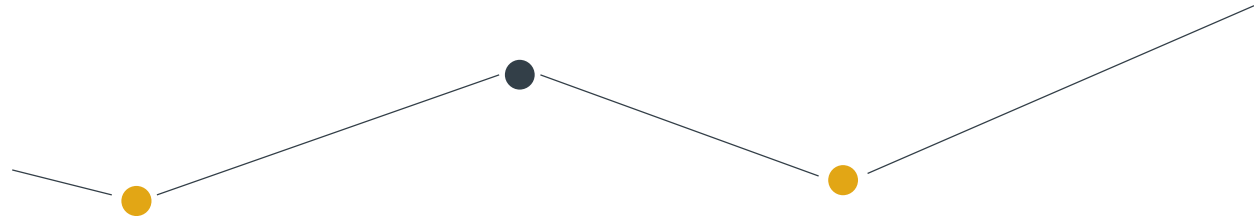


Contacting the ERO Research Contracts team

ERO Research Contracts: ERO.Contracts@ed.ac.uk

Please ensure:

- The appropriate [Request Form](#) is completed as fully as possible with each new request. (This gives a contract its best start to move as quickly through the system as possible.)
- Once a contract is set up on Worktribe, the requester will be issued with a c-reference – **please quote this in all future correspondence.**



Confidentiality agreements may be required at the start of investigator-led research

With a commercial entity:

... supported by Edinburgh
Innovations Contracts Team
EI.Contracts@ed.ac.uk

With a non-commercial entity:

... supported by Edinburgh
Research Office Research
Contracts team
ERO.Contracts@ed.ac.uk

NB Lothian Health Board will almost always need to be party to such confidentiality agreements

Summary of support for investigator-led clinical contracts at the University of Edinburgh

Edinburgh Research Office

- Research Funding Team
 - On award, kick-off meeting for clinical trials
 - Funding Agreements for research grants
 - Collaboration Agreements
- Research Contracts (RCGI)
 - Confidentiality Agreements with non-commercial entities
 - Collaboration Agreements
 - Drug /Device Supply, Technical Agreements
 - Co-sponsorship & Site Agreements
 - Data and Material Sharing Agreements
 - ... and more

Edinburgh Innovations

- EI Contracts Team
 - Confidentiality Agreements with commercial entities
 - Consultancy Agreements
- Business Development
 - Funding and Collaboration Agreements with commercial partners
 - Link to Legal Services

