Edinburgh Imaging

www.ed.ac.uk/edinburgh-imaging

Study Application Process

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1: START HERE

Your study idea

2: Contact

Contact Edinburgh Imaging at imaging.trials@ed.ac.uk to discuss costs for grant application before submission

10: Meeting

Project meeting for formal approval

8: Discussion

Further discussion with Edinburgh Imaging team

7: Meeting

PI/study team invited to attend the project meeting to present study

11: Operational approval

Operational Management approval (CRF)

14: FINISH

The study will get the 'green tick'

12: SLA

is sent and returned



Service Level Agreement





9: Feasibility

Robust feasibility report produced

13: Regulatory approval

Regulatory approvals in place



3: Funding

If funding successful complete CRF application. REC/R&D forms from www.accord.scot

Discussion with Scientific



6: E number

Unique 'E' number is assigned to the



So why do all this?

- Completing essential documents in a timely manner assists in the successful management of the trial by the investigator, sponsor and Edinburgh Imaging and Clinical Research Facility (CRF).
 - **Essential documents** demonstrate the **compliance** of the investigator, sponsor, Edinburgh Imaging and CRF with the standards of **good clinical practice** and all applicable regulatory requirements.
- **Essential documents** are audited by the sponsors independent audit function and inspected by regulatory authorities as part of the process to **confirm the validity** of the trial conduct and the integrity of the data collected.

NB - studies involving radiation must have an ARSAC licence in place, IRMER regulations require confirmation by an appropriate Medical Physics Expert (MPE) that

the radiation doses used locally are

consistent with the Total Research

Protocol Dose approved by REC.

For studies involving more than one modality (for example, nuclear medicine and diagnostic x-ray), a Medical Physics Expert for each modality must be consulted.

4: Discussion

Contact to establish protocol and feasibility of study

5: Documents

Provide essential documents such as imaging protocol, study protocol, PIS etc