



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.

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.