**NICRF DEXA STUDIES procedures**

All DEXA studies at NICRF will go through the BHSCT procedure for research studies involving ionising radiation.

**At early stage the researcher must:**

* If NICRF are not supporting ethics approval for a study, the RRIP will be completed once the necessary documentation has been received by NICRF and reviewed by a local Practitioner/ and local MPE. The necessary documentation includes IRAS form, PIS, protocol.
* If NICRF are supporting ethics approval, the RRIP and IRAS can be completed/ submitted at the same time. Need to ensure no changes to key documentation such as PIS, study protocol.

Researcher must email the following documents to the NICRF (NICRF@qub.ac.uk):

* Draft IRAS form, PIS and study protocol.
* BHSCT Research Radiology and Imaging Proforma (RRIP) is submitted locally as part of the research governance process once the above documentation has been reviewed.
* Completed NICRF application form
* IRAS is part of the national IRAS/ethics committee approval process
* **RRIP** **Part A**: Completed & Signed only by PI
* NICRF will perform Quality checks and forward to IRMER Practitioner and MPE too complete sections
* **Part B**: Completed & Signed by IRMER Practitioner
* **Part C**: Completed & Signed by Local Medical Physics Expert
* **Researcher sends copies of the final documents as submitted to the REC to the NICRF**

A study specific DEXA Referral Form is completed by the NICRF, with the following details:

* Study Name
* IRAS Study ID and CI/ PI
* Referral criteria-**inclusion and exclusion** **criteria** and provided participants **have given informed consent**.
* Scan Type and Time Points
* NICRF will perform Quality Checks on all documents, and forward to the referrer with authorisation form.
* Participants will be referred for the following DEXA research scans in accordance with the study protocol. NICRF will attach a signed copy of both the referral and authorisation form for each participant to the confirmation form.

DEXA Guidelines for Authorisation Form is completed once per study by NICRF at the same time as the Referral form, and a signed copy appended to the referral form for each study participant.

Researchers can fill in the following details:

* Study Name
* IRAS Study ID and CI/ PI\_NICRF will send this IRAS ID
* List of the Operators that may authorise DEXA research scans for the study

Authorisation form - Signed by the operator or the IRMER Practitioner

The final stage in the NICRF procedures is when participants have been stratified is the DEXA Confirmation Form-completed and signed by the NICRF DEXA Operator for each participant.

**NICRF Quality Checks on**

* DEXA Referral form attached
* DEXA Guidelines for Authorisation form attached
* Pregnancy status

Operator authorisation: to confirm that authorisation guidelines for the study have been met and that the DEXA scan can proceed.

NICRF will only carry out DEXA scans once the IRMER study paperwork is complete and the final permission letter received from BHSCT Research Office or if the institution is a research contract organisation, written approval from NICRF.

All paperwork as above including the PIS, Study Protocol, IRAS form, and ethics approval letter will be kept in an IRMER folder for each DEXA study.

NICRF have a list of individuals or duty holders that have been entitled to act as referrer, practitioner, operator for DEXA research studies and Quality assurance.

Incident Reporting: If a participant has received an unintended or accidental exposure, the RPS and NICRF Director must be contacted immediately and a DEXA incident form completed. The incident will be reported in accordance with BHSCT Adverse Incident Policy. For further details consult the NICRF Employers Procedures and Local Rules documents.