

Wolfson Resource Allocation Committee

Terms of Reference

1. Purpose

The purpose of the Wolfson Resource Allocation Committee (WRAC) is to review all applications from investigators wishing to undertake research studies using the WBIC facilities:

- To ensure appropriate ethical approvals have been granted.
- To ensure protocols accurately describe the proposed activities in the WBIC.
- To ensure Research Governance procedures are/will be met.
- To consider resource implications and approve their use.
- To offer advice to researchers where appropriate.
- To provide oversight of the usage of the WBIC and report to the WBIC Executive Committee.

Access to WBIC facilities is subject to WRAC approval. The WRAC meets monthly. All meetings are minuted.

2. Membership

The WRAC membership is comprised of the Directors of the WBIC (MRI, PET, PET Chemistry, Computing), the Superintendent radiographer of the WBIC, PET Imaging Technologist, Radiochemistry Laboratory Manager, the WBIC Business Manager, and a representative from each of CUHNHSFTD R&D and the CRF as deemed appropriate.

3. Review Process

3.1 All WRAC members receive a summary of each application submitted for review. The application includes:

- Study protocol
- Addenbrooke's Hospital Research & Development department (R&D) approval, or University approval as appropriate.
- Research Ethics Committee (REC) approval
- NRES/IRAS application documentation (where relevant)
- ARSAC (where relevant)
- Information Sheet
- Consent Form
- UoC Insurance Confirmation
- UoC/CUHNHSFT Sponsorship confirmation
- MRI User Terms for UoC Researchers
- WRAC Application form

3.2 A WRAC member is nominated to summarise the application, and any salient issues that are raised by the requested resources and the accompanying documentation.

4. Quorum requirements

A quorum shall consist of a minimum of three members. Where a study involves patients, approval is contingent on the assent of a clinically qualified member (which can be received either

at the meeting, or sought by circulation if such a member is not present). However, if CUHNHSFT is a joint sponsor with the University, then Clinician member approval will not be required.

5. Confidentiality

WRAC meetings are held in private to allow free discussion of all applications. A summary of each application, any issues arising and approval status is recorded in the minutes. All members are bound to maintain confidentiality concerning protocols submitted.

6. Declaration of interest

A committee member involved in an application that is submitted to the WRAC should declare this. The Chair may ask the member to leave the room whilst the application is being discussed.

7. WRAC decision options

7.1 *Full Approval*

Approval granted for the study, scanner specified, WBIC study number allocated.

7.2 *Conditional Approval*

Study is approved subject to amendments, additional information, pending REC or R&D approvals, financial agreements. WBIC study number allocated, location agreed. Issues raised are brought forward to the next WRAC as 'matter arising' for reconsideration for full approval.

7.3 *Deferred*

Committee is unable to make a decision from the information submitted. Additional information is requested and / or investigator invited to attend the next WRAC meeting to discuss the project. Study allocated WBIC number and location agreed.

7.4 *Rejected*

The study is not agreed. The reason(s) for rejection will be recorded in the minutes.

8. Protocol Amendments

Investigators are requested to provide copies of protocol amendments to the WBIC. This must include evidence of REC approval. Protocol amendments will be reviewed by the committee when considered necessary i.e. if changes to the protocol are likely to impact significantly on the patient or the WBIC.

9. Serious Adverse Events

The Superintendent Radiographer will report all serious adverse events to the committee as near to the event as possible.

Date March 2014
Version 1