

Governance of research at the Royal Free London following the acquisition of Barnet Hospital and Chase Farm Hospital

Information for investigators and research teams

This information sheet provides an outline of the general conditions and principles that will apply to the management of research studies following the acquisition of Barnet Hospital and Chase Farm Hospital by the Royal Free London NHS Foundation Trust. This information is relevant to all investigators and research teams at any site and all staff setting up, or planning to set-up, new studies within the new trust.

General conditions and principles that apply following the merger

- All active studies will remain open in their current locations.
- Standard operating procedures (SOPs) for the management of research are [available on our website](#). These SOPs apply to all research hosted and sponsored by the trust. A further set of additional day 100 SOPs is currently in development and will be published by 1 October 2014.
- All studies will be registered on the ReDA research management system which is currently in operation at the Royal Free London.
- All study agreements and contracts issued by Barnet and Chase Farm Hospitals NHS Trust are taken over by Royal Free London as the new contract party.
- CRN (clinical research network): North Thames divisions and permission centres have been notified of the merger. The study set-up and approval process for studies progressing via the North Thames CRN harmonised process remains in operation as previously.

The role of principal investigators (PIs) and co-investigators

Under the principles of research governance, principal investigators assume responsibility for the proper conduct of the research study or trial, including:

- The submission and authorisation of the site specific information sheet (SSI).
- Taking responsibility for ensuring that staff involved in the research at the site hold appropriate contract for the duration of the research, are familiar with the research SOPs and are appropriately trained and experienced and informed about their trial-related duties and functions.
- Ensuring all regulatory and ethical approvals including NHS research permission (research and development approval) is in place before recruitment commences on a research study.
- Regular recruitment reporting.
- Completion of any progress and/or final reports.
- Maintaining a project file in accordance with the trust policy.
- Ensuring that all serious adverse events are handled according to the trust policy.

The role of co-investigators is to carry out study tasks as recorded in the 'delegation of authority' log.

Studies currently active across the trust

- The research and development office, together with research teams, will support the PIs and co-investigators in ensuring that high standards of GCP compliance are maintained following the merger. The research and development team will provide advice on the appropriate measures for maintaining PI oversight and the delegation of tasks across the different locations.
- All active studies will remain open in their current locations under existing study management and under the current PIs oversight.
- In some situations, existing studies can be integrated into one site, for example if there is sponsor agreement and sufficient evidence that PI oversight can be exercised across all locations.
- All investigators must inform the research and development department prior to integrating any study sites. The research and development office will advise if any additional documents are required, for example contract amendments and localised patient information sheets.

Extending study activity to new trust locations

Investigators wishing to extend their study activity to the new trust locations (for example Royal Free Hospital studies wishing to extend patient recruitment to the Barnet Hospital) will not require any additional research governance approval and letters of access.

- All investigators must inform the research and development office prior to activating their studies in any additional hospital locations of the trust.
- The research and development office will review the study documents and advise if any additional documents are required, for example contract amendments and localised patient information sheets.

Contact for the research and development office

Royal Free London NHS Foundation Trust
Admin Corridor Medical School Building
Pond Street
London
NW3 2QG
T: 0207 794 0500 Ext: 33211
rf.randd@nhs.net

Research and development processes will be integrated to ensure that researchers receive consistent standards of service across the new organisation. Please contact us with any queries regarding the upcoming and changes and their implications for

your studies. The research and development team at the Royal Free London will be happy to help.

Liba Stones

Research and development manager
Royal Free London