# THE ROYAL BOURNEMOUTH AND CHRISTCHURCH HOSPITALS NHS FOUNDATION TRUST

## Responsibilities of Investigators Conducting Research Approved by The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust

The Chief or Principal Investigator (Investigator) on a research study is responsible for the conduct of their research at their local site. This document outlines the expectations of The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (Trust) of investigators running research projects in the Trust.

### Investigator Responsibilities when Conducting Research in the Trust

- The Investigator is responsible for the daily management of their research at their site.
- It is the Investigator's responsibly to ensure Trust-wide Policies and Standard Operating Procedures (SOPs) and/or study-specific SOPs are followed.
- The Investigator must ensure that the necessary approvals for their research are in place prior to the research commencing.
- For Clinical Trials of Investigational Medicinal Products (CTIMPs) the Investigator must ensure that the study is performed in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031) & Amendment Regulations 2006 (SI 1928) and the principles of GCP based on Article 2 to 5 of the GCP Directive1.
- The Investigator must ensure all essential documents are maintained for their research in the form of an Investigator Site File (ISF).
- The Investigator must ensure research is conducted in accordance with the approved protocol and that appropriate systems are in place to guarantee version control of the protocol.
- The Investigator must ensure that each member of their research team is qualified by education, training and experience for their role in the study.
- The Investigator will ensure supervision of the study by attending regular meetings with the research team & study monitors to review documentation and ensure timely resolution of medical, ethical or GCP issues.
- For all research conducted in the Trust (with the exception of those studies involving staff only), it is a requirement that the research team be trained in the principles of GCP.
- The Investigator must ensure that, as applicable, informed consent is obtained from research participants before any research activity is undertaken.
- The Investigator must ensure that amendments to the protocol or other study documentation are submitted to Trust R&D for review to confirm that there are no changes to the approval status of the research. Amendments must also be submitted to the REC and Regulatory Authorities for approval as applicable.
- The Investigator must protect the integrity and confidentiality of research data.
- The Investigator must ensure where appropriate that relevant healthcare professionals (e.g. GPs) are informed of their patients' participation in research.
- The Investigator must take responsibility for the monitoring, recording and reporting of Adverse Events (AEs) Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse (Drug) Reactions (SUSARs) which occur during the conduct of a CTIMP. It is the Investigators responsibility to inform the Sponsor immediately (within 24 hours) of becoming aware of a serious event.
- Investigators must provide access to all study documents, devices and equipment as required for monitoring, auditing and inspection purposes.
- Investigators must ensure appropriate archiving of study documents at the end of a study.
- Investigators must notify Trust R&D, REC and Regulatory Authorities as appropriate of changing timelines on a study and of the end of a study.

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**Declaration**

By signing this document you agree to assume the responsibilities outlined above for the conduct of research in the Royal Bournemouth and Christchurch Hospitals NHS FT for the following study:

**Study Title**:

**IRAS Project ID:**

*(delete as appropriate)*:

I agree to act as Chief Investigator/Principal Investigator/Local Contact for the above named study and have read and understood the obligations I have as the Chief Investigator/Principal Investigator/Local Contact for this study.

**SIGNATURE:**

**DATE:**

**PLEASE PRINT NAME:**

Please return signed forms electronically to the R&D department, keeping the wet copy for your records.