NHS
Great Ormond Street Hospital for Children
Research and Innovation

DIRECTORATE OF RESEARCH AND INNOVATION (R&I)

Principal Investigator (PI) Code of Practice

Study R&D Number:	
Short Study Title:	

The R&I Directorate can assist those who want to carry out research or develop their research career by providing research infrastructure and expertise. The R&I team can give you advice and support to facilitate your research. However, you are responsible for the delivery of the research and the success of the research will depend on your leadership, commitment and engagement.

This Code of Practice will support effective and transparent working between you and R&I. It is not intended to be a comprehensive list of PI responsibilities, these are listed in separate guidance (such as ICH E6 and the MHRA Grey Guide) as well as in local Standard Operating Procedures (SOPs). If you have any questions or concerns either now or during the study, you should contact the R&I team.

Declaration: By signing this Code of Practice, I'm confirming that:

- I understand that I am responsible for the conduct of the study (and all study activity) at this site.
- I will inform R&D of any changes to PI, Co-PI or Sub-Investigators in a timely manner.
- I have completed the appropriate training (e.g. Good Clinical Practice (GCP), informed consent) and have read and understood the relevant SOPs (as sent to me by R&D).
- I will have sufficient time, facilities, resources and staff available to properly conduct and deliver the study within the agreed period and according to the approved study protocol (and if this changes I will let R&D know).
- I understand that if the study is interventional, I need to delegate a Co-PI or Sub-Investigator before the study starts to ensure there is appropriate cover if I'm temporarily unavailable.
- The site recruitment target is justifiable and feasible (and if this changes I will let R&D know).
- I will ensure that any participants recruited to the study are recorded as such on their EPR.
- I understand that I must not implement any changes to the study without agreement by the Sponsor and documented approval from the relevant authorities, except where this is necessary to eliminate an immediate hazard(s) to study participants.
- I understand that I am responsible for the maintenance and appropriate retention of the site section of the Trial Master File (TMF) and that if I become unable to do this (e.g. due to relocation or retirement), I must notify the Sponsor, CI and GOSH/ICH Named Archivist in writing.
- I will ensure each study team member is appropriately trained, qualified and experienced and has the necessary employment contracts/agreements in place to perform their duties for the study before delegating them and that they have adequate supervision, support and training for these duties. I will ensure the delegation log is maintained, signed, and up to date throughout the study.
- I will ensure that the practice of me and my study team meets the requirements of the approved study protocol and study application (including any approval conditions), any risk assessments, GCP and any applicable legislation, policies, procedures or guidelines.
- I will permit monitoring and auditing by the Sponsor and or relevant contracted partners, and inspection by the appropriate regulatory authority(ies) and must respond to queries and/or reports in a timely manner.
- I will acknowledge the NIHR in any future publications.
- If the study is using the digital research environment (DRE) I will also comply with the DRE User Terms and Conditions.

PI Name:	PI Signature:	Date of Signature:
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Signed copy to be scanned and sent to R&D office (Research.Governance@gosh.nhs.uk), original to be filed in the site file.