Research Study Activation Process

Upon receipt of the R&D approval email the following must have occurred before the study is officially activated by the Research team.

- Cross checking of all regulatory approvals (HRA, Ethics opinion letters, R&D and MHRA if applicable) to ensure there are no errors and all approvals are in the Investigator Site File. Contact sponsor to request any missing documentation.
- Cross checking of regulatory approvals (HRA, Ethics Opinion letters, R&D and MHRA if applicable) against study documentation to ensure up to date versions are in use and no documentation is missing. Contact sponsor to request any missing documentation.
- Supersede any study documentation in both the shared drive and Investigator Site File, found to have been updated following the above actions.
- Ensure all applicable patient documentation has been localised as per study and site requirements. If required send documentation to sponsor Clinical Research Associate (CRA) for review.
- File current approved patient documentation in Investigator Site File and into patient information and consent form folder on shared drive for use by study team
- If applicable contact pharmacy to ensure they are prepared for study activation to take place.
- Ensure green light email or letter has been received from the Sponsor/CRA.
- Send email to the Principle Investigator copying in the Research team include all applicable support departments and CRA to confirm activation of study at site. Template email below.

Study Activation Email

Dear [Principle Investigator]

Study Title:

Protocol No:

R&D No:

I am pleased to inform you that we now have all approvals in place for the above study and sponsor have activated us as a site. You may therefore begin working on this study.

All patient documents are on letterhead and filed in the shared drive and site file ready for use.

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On receipt of the R&D approval email the following **MUST** occur before the study is officially activated by the Research team**.**

Study Title:

Cross check all regulatory approvals (HRA, Ethics opinion letters, R&D and MHRA if applicable) to ensure there are no errors and all approvals are in the Investigator Site File. Contact sponsor to request any missing documentation.	Tick √ when done
Cross check regulatory approvals (HRA, Ethics Opinion letters, R&D and MHRA if applicable) against study documentation to ensure up to date versions are in use and no documentation is missing. Contact sponsor to request any missing documentation.	
Supersede any study documentation in both the shared drive and Investigator Site File, found to have been updated following the above actions.	
Ensure all applicable patient documentation has been localised as per study and site requirements. If required send documentation to CRA for review.	
File current approved patient documentation in Investigator Site File and into patient information and consent form folder on shared drive for use by study team	
If applicable contact pharmacy to ensure they are prepared for study activation to take place.	
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Completed by:

Signed:

Date: