INVESTIGATOR STUDY FILE MAINTENANCE

- Please review the study file and familiarise yourself with the contents of all sections so that you know where to find the information when needed.
- It is important that the study file is available to the trial team and kept in a safe place at the hospital.
- Please ensure the study file is kept up-to-date.
- Please note that the study file will also need to be available at monitoring visits by the coordinating centre or any relevant regulatory authorities.

THE FOLLOWING LOGS MUST BE KEPT UP TO DATE AT ALL TIMES – THIS IS A LEGAL REQUIREMENT AND THE LOGS WILL BE REQUIRED FOR MONITORING:

- Site responsibility signature log – list all team members who have trial related responsibilities. Remember to mark if they leave the trial and to add new team members. Also please file CVs for each sub-investigator in this section.
- Patient Screening log – enter details of patients who were screened but are not eligible for the trial
- Patient Randomisation Log – enter patients as they are randomised.
- Drug Accountability Log – Please enter details each time a pack is used for randomisation.
- Site visit log – to be completed when a representative of the coordinating centre visits your hospital for any purpose.

THE FOLLOWING COMPLETED FORMS MUST BE KEPT IN THE STUDY FILE – THEY WILL BE REQUIRED FOR MONITORING:

- Consent Forms: All original signed consent forms must be kept in the study file
- Case Report Forms: All original data collection forms must be kept in the study file which should remain on site at all times.