Bournemouth University

Suggested Trial Master File Contents

SECTION	TITLE	CONTENT/COMMENTS	Sponsor File/ISF/Both
	Table of contents		Both
	Contact details of sponsor staff	Details of researcher Details of academic supervisors (if applicable) Details of sponsor representative (and Clinical Governance Advisor)	Both
1	Protocol / amendments	Current protocol Protocol amendments Historical protocols	Both
2	**Sample** CRF/ QLQ Diary Cards		Both
3	Regulatory approval documentation[1] IRAS form submitted for approval		Both
3	Amendment approvals and notifications Research site acceptance/non-acceptance of study amendments		Both
4	Site signature /responsibility log (of each participating site)	In addition to original being filed in site's investigator site file	Both
5	Curriculum Vitae and GCP certificates	CVs for all research personnel listed in the signature/responsibility log	Both
6	Patient Identification form Patient recruitment /screening form		ISF
7	Sample of current and all historical Patient Information / Informed Consent form and GP Letter Completed patient Information and Informed Consent Forms	 In ISF, not Sponsor file unless REC approved	Both ISF **only**
8	Correspondence inc. study set-up with regulatory bodies	File in chronological order all correspondence to/from the coordinating research body. File email communication Include a separate section here for newsletters	Both (set-up correspondence with REC/HRA/MHRA in Sponsor file only)
9	Minutes from Initiation meeting Monitoring logs Notes of telephone calls	If the study is not monitored state this in a file note in this section Document telephone call in relation to agreements or significant discussions regarding trial administration, trial conduct, adverse events or protocol violations	Both
10	Blank serious adverse event forms and guidelines for their completion		Both

[1] The regulatory approvals received will depend on your study – in most cases, HRA approval will be provided. If your study involves patients or midwives, then REC approval will be given. If your study is an investigation using medicinal products or devices (including apps and software), then you will receive MHRA Clinical Trial Authorisation.

	Completed SAE forms from participating sites		Sponsor file
11	Notification of serious adverse events and/or safety reports	By Investigator to co-ordinating research body By co-ordinating research body to Investigator By co-ordinating research body to regulatory authorities (if this will not be supplied place a file note stating this)	Both
12	Randomisation details	Instructions (if applicable)	Both
13	Instructions for handling trial medication and trial related materials Shipping records	This responsibility is normally that of the clinical trial pharmacist if this is the case place a file note in this section stating this	Both ISF
14	Clinical Laboratory	Laboratory normal reference ranges (including revisions) Laboratory certificate(s)	ISF
15	Contracts/Participating Site's Statement of Activities R&D 'confirmation of capacity and capability'	Investigator Commitment Statement/Study Acknowledgement Indemnity Confidentiality Clinical Trial Agreement including financial details. Completed and signed FDA 1572 form (if applicable) Financial disclosure letter (if applicable)	Both Both
16	Investigator's Brochure Safety alert letters/Updates		Both
17	Completed Data Queries		Both
18	Study Training Materials		Both
19	Miscellaneous (specify)…….		Both

Comment [SW1]: Commercial projects only

AFTER THE COMPLETION OF THE TRIAL THE FOLLOWING MUST BE ALSO FILED IN THE TRIAL MASTER FILE

20	Investigational product(s) accountability at site	This will be with the clinical trials pharmacist	Pharmacy Site File
21	Documentation of Investigational product destruction	If destroyed at site this will be with the clinical trials pharmacist	Pharmacy Site File
22	Final report	From Investigator to REC	Both
23	Clinical study report	To document results and interpretation of trial	Both