Research Guidance Sheet No.10b
Safety – Investigator Responsibilities
Annual & End of Study Reports

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1. Annual safety reports

1.1 For IMP studies, one year following the granting of a Clinical Trials Authorisation Certificate, and thereafter annually, the Chief Investigator (CI) with assistance from the Research Management Office will send an annual safety report to the Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC). Appendix 6 and 7 of the UH Bristol Research Related Adverse Event Reporting provides templates and detailed guidance for annual reports available at: *http://www.uhbristol.nhs.uk/research/information-for-researchers/post-approval/adverse-events.html*. For clinical trials which started before 1 May 2004, the reporting period starts with the issue date of the CTX (Clinical Trial Exemption) letter or first DDX (Doctor and Dentist Exemption) letter by the MHRA (or previously by the Medicines Control Agency).

1.2 Each submission of an annual safety report to the REC must be accompanied by the Safety Report form for CTIMPs (Clinical Trial of an Investigational Medicinal Product) available at: *http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/safetyreports/safety-reports-for-ctimps/*

1.3 All report forms should be copied to the sponsor and the R&D offices of the host organisations (Research Management Office at UH Bristol).

2. Annual progress reports

2.1 Annual progress reports should be submitted thereafter until the end of the study.

2.2 For all non-IMP studies, one year following the granting of a favourable ethical opinion and thereafter annually, the CI will submit progress reports to the Research Ethics Committee. These reports will include information on the safety of participants. The form for providing these reports is available at: *http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/progress-reports/#Annualprogress*

2.3 For IMP studies, one year following the granting of a favourable ethical opinion and thereafter annually, the CI will submit progress reports to the Research Ethics Committee. These reports will include information on the safety of participants and are required in addition to the annual safety report. The form for providing these reports is available at: *http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/progress-reports/#Annualprogress*

2.4 For blinded studies where UH Bristol is sponsor, in compiling these reports, at the request of the CI the Research Management Office will provide any additional information required relating to the Sponsor's assessment of Serious Adverse Events (SAEs). The Research Management Office will take all reasonable efforts to ensure that no information that could unblind and therefore compromise the study is provided direct to the CI.

2.5 All report forms should be copied to the sponsor and the R&D offices of the host organisations and the Research Management Office at UH Bristol.

3. End of study reports

3.1 For non-IMP trials, at the end of the study the CI will submit an end of study report to the Sponsor (where UH Bristol is the sponsor this will be the Research Management Office) and the REC. This report will be submitted on the form available at: *http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofstudy/*

3.2 For IMP trials, at the end of the study the CI will submit an end of study report* to the Sponsor (where UH Bristol is the sponsor this will be the Research Management Office), the MHRA and the REC. This report will be submitted on the form available at: *https://eudract.emea.europa.eu/docs/forms/Declaration_Of_The_End_Of_Trial.doc*

3.3 For blinded studies where UH Bristol is sponsor, in compiling these reports, at the request of the CI the Research Management Office will provide any additional information required relating to the Sponsor's assessment of SAEs.

3.4 All end of study reports should be copied to the Sponsor and the R&D offices of host organisations (Research Management Office at UH Bristol).

* As limited information was required at the time of application for Clinical Trials Exemption (CTX) and Doctor and Dentist Exemption (DDX) studies, the MHRA has been unable to process amendments or end of trial notifications to such studies electronically, resulting in delays to assessment and responses to sponsors. To remedy this the MHRA are asking applicants to fill out a CT Form UK 1 available at: *http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=724*

Note: Where UH Bristol is sponsor, at the request of the CI the Research Management Office will assist the CI in compiling the annual safety, annual progress and end of study reports. In meeting such requests the Research Management Office will take all reasonable efforts to ensure that no information that could unblind and therefore compromise the study is provided directly to the CI, unless the CI is already unblinded.