**Sponsor Communications**

NOTE: Throughout the templates the word ‘sponsor’ does not mean simply the funder (sponsor in section 2 of eResearch) but means the creator/originator of the protocol as the word sponsor means in FDA regulations (21 CFR 312.3 & 812.3).

Keep originals or photocopies of all study-related communications, including e-mails, faxes, and a written summary of any phone conversation with the Sponsor. These items should be kept in the Regulatory Binder, or as directed by the Sponsor. It is recommended that PHI included in communication is not kept in the regulatory binder. Therefore one option is to redact any PHI that appears in such communications. However, if PHI remains in the regulatory binder then ensure that the binder is kept in a secure location in accordance with IRB approval.