PHS INSIGHT/eIRB
IMPORTANT REMINDERS

1. Insight/eIRB can only be accessed by individuals who have an active Partners username and password. If you have a Partners username and password and cannot access Insight, contact the PHS Insight Helpdesk at Insighthelpdesk@partners.org.

2. Insight/eIRB may be accessed remotely using VPN access or through the secure website https://insight.partners.org.

3. Insight/eIRB works best when using the following internet browsers: Internet Explorer 6.0 and higher (PC) or Firefox or Safari (MAC).

4. Each individual must use his/her own Partners username and password to authenticate the electronic sign-off processes. This "electronic signature" is considered equivalent to a handwritten signature. **Sharing of passwords is prohibited.**

5. Individuals listed on the protocol record in the Staff & Access page have access to the protocol record. Others may be given access on a need-to-know basis to fulfill their institutional responsibilities. **The names of study staff submitted via amendment for IRB approval appear in the non-study staff grid until the amendment is approved.**

6. Insight/eIRB may contain information that is confidential and proprietary to the participating Hospitals and/or the study sponsor. **Distribution of confidential and proprietary documents beyond the Hospital research team and others within Hospital/Partners with a need to know is prohibited without prior written approval by Hospital and the third party involved.**

7. Submissions received by the IRB and IRB actions are displayed in Insight/eIRB the next day. **Each pending submission (new protocol, amendment, continuing review, adverse event) is listed as a separate transaction on the Pending Applications page.**

8. IRB Review Notification Letters and the IRB-approved consent form(s) will be emailed to the PI and contact person(s) and will be available as pdf documents on the Active Protocols and Protocol Details pages the next day.

9. When submitting a response to the IRB's request for modifications, all changes to forms and documents must be made to the actual submission (form, staff, attachments) on the Pending Applications page. The submission will be unlocked by the IRB staff so the investigator can attach a point-by-point response, make the required modifications, and resubmit. **Modifications must be made in eIRB/Insight to keep the protocol documents up-to-date.**

10. Revised/updated versions of documents that are already in the Attachments page should be versioned. **Do not attach revised/updated versions of documents as a new document.** This is important for record keeping purposes. Marked or highlighted versions should always be attached as a new version prior to attaching the unmarked version.

11. The Insight/eIRB electronic protocol record is not a substitute for your regulatory binder/files. **It is important to maintain complete records of submissions, documents and IRB correspondence in your regulatory binder/files.**

12. When applicable, Investigator Disclosure Forms should be sent under separate cover to the Human Research Office (email as pdf or fax to 617-424-4199). **Investigator Disclosure Forms should not be included in the Attachments page in Insight/eIRB.**

13. Only new Insight/eIRB protocol records created as of March 1, 2009 will contain the application form and protocol-related documents submitted to the IRB for initial review and approval, as well as all subsequent IRB submissions, such as amendments, continuing reviews, and adverse event reports. **Some protocol records from the first phase of eIRB rollout will contain protocol documents.**

14. For active protocols received prior to March 1, 2009, protocol documents will need to be added to the Insight/eIRB record at continuing review when the current approved version of the protocol documents are submitted for re-approval.

15. For technical assistance, contact the PHS Insight Help Desk at Insighthelpdesk@partners.org. For business questions, contact Daniel Connor at dconnor@partners.org.