



**PREMISE Authorization is the responsibility of the Covered Entity.** The HIPAA Privacy Rule is centered on the responsibilities and duties of the Covered Entity. Researchers working in Covered Entities have duties that are broader than those related to their research data involvement

**BASIC POLICY** IRB/Privacy Board review is required for (a) review for a waiver of authorization and (b) review of authorizations embedded as a part of a consent form needing IRB review. This will be the extent of involvement of the IRB as a part of the review process.

IRC staff can and will comment on other aspects of our clients' compliance with the privacy rules. Such comment must be considered informational only; it should lead to better focusing a client's questions directed to its own HIPAA advisor.

### **CHARGES**

- \$250 Modification of a current consent form to add HIPAA language
- \$ 50 Review a separate authorization form - for elements only
- \$250 Review a separate authorization form - for approval, if specifically requested
- \$400 Waiver of authorization approval by the Privacy Board/IRB

### **REVIEW INFORMATION**

#### **We want to see HIPAA information from sites.**

This is an effort to assure that sites are aware of the rules. If, for instance, they are a CE and they don't know what a privacy notice is or whether authorization is required, it is evidence of a need to get them to a place where they can get practice related information. IRC will have a separate HIPAA form to accompany every application.

#### **We will not review or approve separate authorization forms unless asked.**

IRC's IRB will not "approve" authorization forms unless specifically asked to do so.

IRC staff can review to determine presence of elements and can complete an evaluation form. If there are issues, we will inform the site/sponsor. This is advisory only.

IRC has a HIPAA form (4-40A) to accompany every application. This is to assure that the local site is aware of their responsibilities and have local means of compliance.

When a separate Authorization form is used, the consent form should refer to the Authorization. A good place for this is at the end of the paragraph on privacy.

#### **We must review integrated consent and authorization forms:**

- The IRB will be required to review the information integrated in the consent document.
- All authorization elements will be necessary and must be in plain language.
- Ideally, the authorization information should be set aside graphically to distinguish it from the usual information.

