Baystate Health | UMass Chan MEDICAL SCHOOL

Using External IRBs For Your Multi-site, Federally-Funded Study

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In this memo we want to provide some helpful information to facilitate approval of your multi-site study.

1. Be sure to schedule a consult with the single IRB analyst before agreeing to cede review to an external IRB. These consults are brief and can be very helpful to PIs and the study team to ensure efficient processing of your ceding request.

   Keep in mind that studies that are NOT federally-funded most likely will not be able to utilize an external IRB at this time and will need to be processed through the Baystate IRB.

   Additionally, remember we have two new manuals for single IRB: 1) manual for ceding to an external IRB; and 2) manual for single IRBs that utilize the Baystate IRB as the IRB of record. Both are located in IRBNet/Forms and Templates as well as the IRB website.

2. We utilize several large, commercial IRBs for many of our studies that have external IRB oversight.
   a. CIRB (for National Cancer Institute studies)
   b. WCG (formerly WIRB)
   c. Advarra

   Specifically, when utilizing WCG, it's important to remember that even though WCG is processed in IRBNet, as Baystate currently is, we cannot see submissions that you send directly to WCG. Any determinations you receive from WCG need to be submitted in a new package and sent to the Baystate IRB for documentation.

   In most cases, you will submit to WCG first, and then send determinations to Baystate. Exceptions include:
   a. **Staffing changes**—these can be submitted directly to Baystate, as we are responsible for the oversight of PIs and study team members (training and conflict of interest forms).
   b. **Initial submissions**—usually, you will not have a WCG determination for approval until after Baystate has reviewed and agreed to cede. Be sure to send us the WCG approval as an amendment after you receive it, so we can update the study, log the approval, and include the expiration date in IRBNet.

      WCG occasionally has provided global, project determinations for multi-site studies before you submit for approval at Baystate (usually large, multi-site studies that existed prior to Baystate PIs wanting to participate). However, you will still need to get specific site authorization from WCG after we agree to cede and send that to us at Baystate for documentation.