From: OC GCP Questions
To: [redacted]
Subject: RE: IRB waiving jurisdiction
Date: Wednesday, June 03, 2015 9:43:00 AM

Dear [redacted],

21 CFR 56.114 permits cooperative review with the intent of avoiding duplication of effort http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.114

As you note in the guidance, *Using a Centralized IRB Review Process in Multicenter Clinical Trials*, if an institution, its IRB, and a central IRB agree (under 21 CFR 56.114) to participate in a centralized IRB review process, they should document that action in an agreement signed by the parties and both IRBs must have written procedures in place to implement the centralized IRB review process (21 CFR 56.108, 56.114). Also, as noted on page 3 of the guidance, because the goal of the centralized process is to increase efficiency and decrease duplicative efforts that do not contribute to meaningful human subject protection, it will usually be preferable that a central IRB take responsibility for all aspects of IRB review at each site participating in the centralized review process. Other approaches may be appropriate as well.

The answer to your question about how to implement the process of waiver of jurisdiction of IRB oversight and the agreement depends on a lot of details that are specific to your institution (e.g., institutional policies, procedures, and written agreements/contracts your institution may have with external IRBs). How your institution decides to handle waiver of jurisdiction of IRB oversight is an institutional process question that you will need to discuss with the appropriate institutional officials at your institution. As you stated, it is mainly up to your institution and your IRB on how to address these issues.

FDA may audit FDA-regulated studies for a number of reasons. For example, if there was misconduct on the part of an investigator, FDA would look to see which IRB was responsible for the review of the study or studies in which the investigator was involved. FDA would look at the written agreement between the local and central IRBs and at each IRB's written procedures to determine which IRB was responsible. If the central IRB was totally responsible for the review of all studies involving the investigator, then FDA would only look at the central IRB's role in the review of those studies. If the central IRB was relying upon the local IRB for some aspects of the review, than FDA would look at the review by both the central IRB and the local IRB. If the investigator conducted some studies under the central IRB and others under the local IRB, then FDA would consider the IRBs' roles in the studies for which each had review responsibility. If FDA's investigation of the investigator determined that an IRB was not fulfilling its review responsibilities, FDA could cite the IRB for noncompliance with the regulations. The criteria used by FDA for an IRB site inspection is publicly available and can be found at http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf

OHRP may be contacted directly for questions at OHRP@hhs.gov .

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Tuesday, June 02, 2015 9:29 AM
To: OC GCP Questions
Subject: IRB waiving jurisdiction

I work for an IRB in a large medical center. All studies that fall within the jurisdiction of this hospital or studies conducted by staff members are subject to review by this institutions IRB. We went into an authorization agreement with the [redacted] CIRB a few years ago as we have had a relationship with them for over 10 years. This institution is now looking at working with central IRBs for some new rapid enrolling trials. Our IRB has policies and procedures in place for the CIRB studies and will need to revise them for central IRBs. Our IRB understands that in order to waive jurisdiction and rely on another IRB to review certain studies, we must have an authorization agreement in place defining what each institutions roles and responsbilities are and also this must be written in our P&P. (as noted in the Guidance for Industry Using Centralized Process-2006)

What our concern is and would like some guidance on, is if our institution waives jurisdiction, where does the line of responsiblity get drawn? If we allow another IRB to take full review responsbility, is our institution still liable for certain things and would the FDA still aduit us on these studies? Are there any recommendations are to whether or not our IRB still needs to review every protocol amendment, continuing review, Investigator brochure, patient materials, memos, etc? Our institution still reviews informed consents to make sure our local boiler plate language is inserted, we monitor noncompliance issues and serious adverse events and we also monitor investigators qualifications.

We are not sure if there are any FDA regulations on this or if it is mainly up to our institution and our IRB. Thanks for any guidance you can provide.

[redacted]