Kinetiq

Developing a Written Reliance Agreement with a Central IRB

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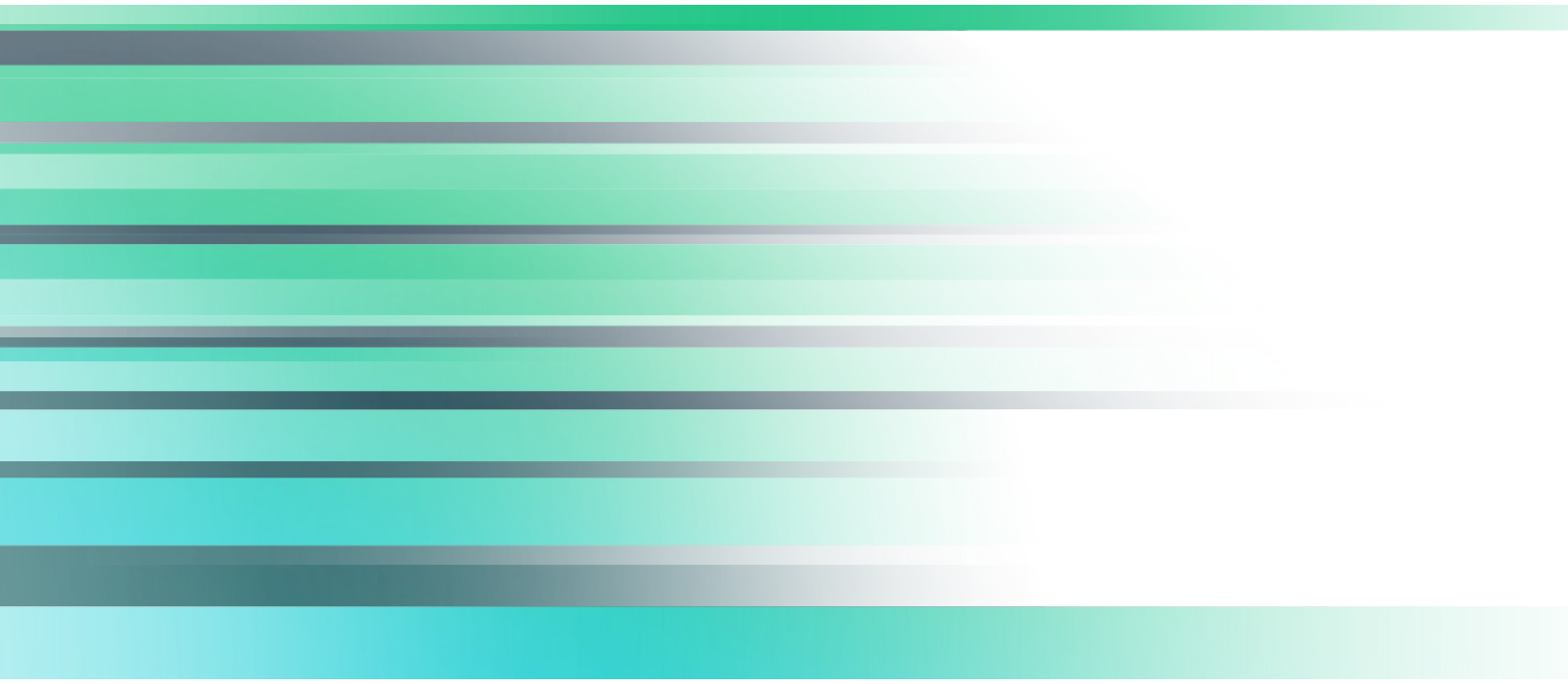


DESCRIPTION

One of the first steps for an institution that will defer IRB jurisdiction to another is to execute a reliance agreement. Fortunately, a number of tools are available to help with this process, including a template from the Clinical Trials Transformation Initiative (CTTI).

TOPICS

- CENTRAL IRB
- IRB AGREEMENTS
- CTTI TOOLS

Developing a Written Reliance Agreement with a Central IRB

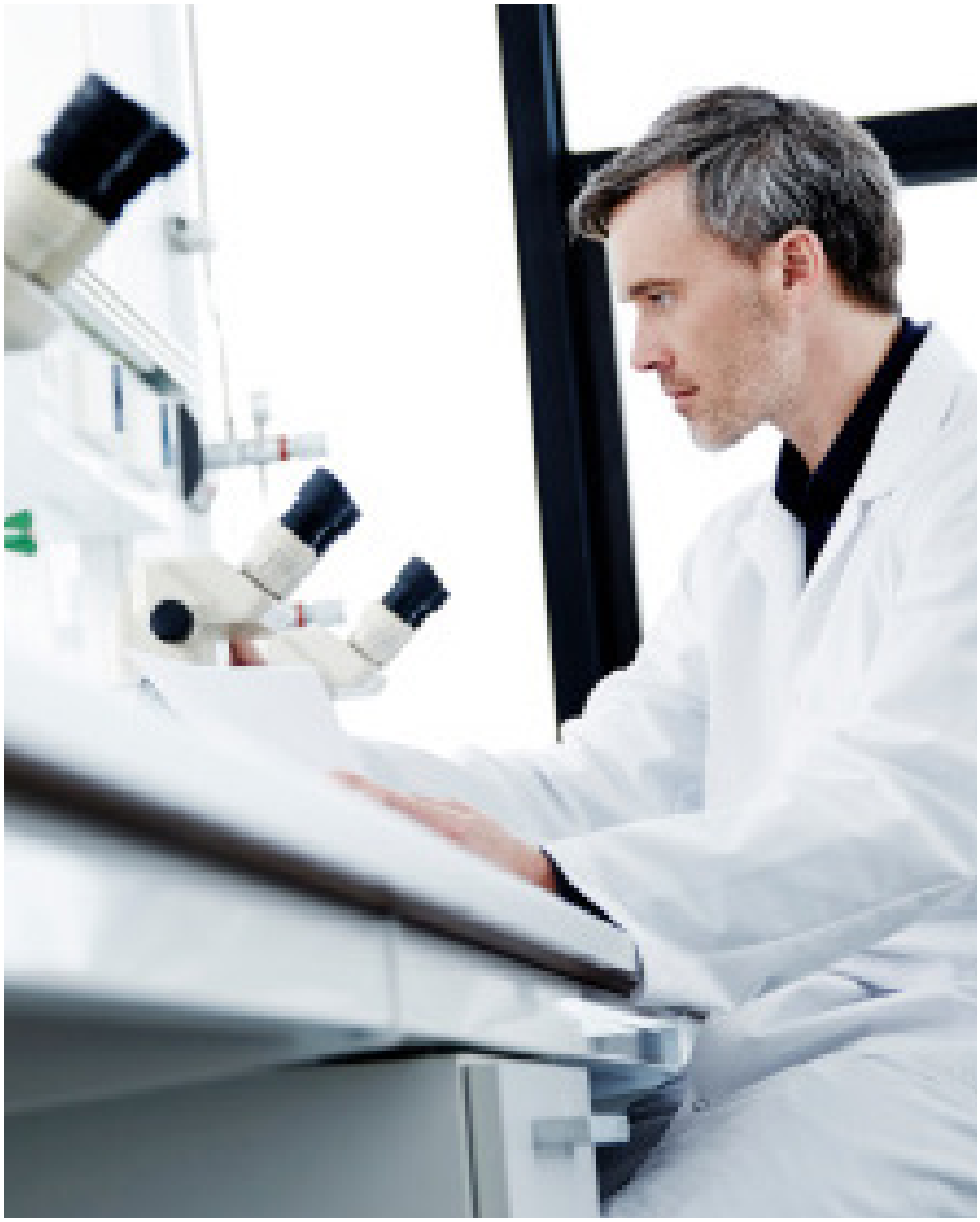
More and more frequently, institutions are asked to outsource their IRB review to an external IRB. One of the first steps for an institution that will defer IRB jurisdiction to another is to execute a reliance agreement. Fortunately, a number of tools are available to help with this process, including a template from the Clinical Trials Transformation Initiative (CTTI).

Momentum is building to require institutions involved in multi-site studies to agree to use a "single IRB of record" (or "central IRB"). Dr. Jerry Menikoff, the Director of the Office for Human Research Protections (OHRP), published an opinion piece in 2010 encouraging the use of a single IRB of record for multi-site studies.[1] In July of 2011, an advanced notice of proposed rule-making (ANPRM) published by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) proposed requiring a single IRB of record for multi-site studies by regulation. In 2014, the National Institutes of Health (NIH) published a draft guidance promoting the use of a single IRB of record for multi-site trials, and, in 2015, a notice of proposed rulemaking (NPRM) carried forward the proposal from the ANPRM.

Over the years, independent (commercial) IRBs have developed the ability to serve as central IRBs. OHRP and NIH have made it clear that an institutional IRB also can serve as the single IRB of record. Institutions across the country now are taking steps to develop the necessary arrangements among themselves and with independent IRBs to support centralized IRB review of multi-site studies.

Under U.S. federal regulations, institutions involved in multi-site research can rely on the review and oversight provided by an independent IRB or the IRB of another institution – if a written agreement is in place.[2] If an institution holds a Federalwide Assurance (FWA) pursuant to 45 CFR 46.103(a), the institution is required by the Terms of Assurance for the FWA to execute an agreement "outlining their relationship and include a commitment that the designated IRB will adhere to the requirements of this Assurance." FDA guidance and the Association for the Accreditation of Human Research Protection Programs (AAHRPP) also strongly encourage a "formal written agreement."

Organizations use a variety of terms to refer to agreements deferring IRB jurisdiction, including "reliance agreement," "cooperative agreement," "IRB authorization agreement" (IAA), "Master Services Agreement" (MSA), "Master Jurisdiction Agreement" (MJA) or "Memorandum of Understanding" (MOU).



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A reliance agreement can cover a single study, a category of studies, or all human subjects research under an organization's FWA.

In many situations a simple one-page agreement can suffice. OHRP has a sample "Institutional Authorization Agreement" (IAA) posted on its website, and this agreement can be used for one specific study or for all studies that might be deferred.

In many situations, however, it makes sense to develop more detailed agreements for the deferral of jurisdiction. Institutions typically have a number of concerns about delegating jurisdiction, including 1) ensuring quality and thoroughness of external review, as well as lack of precise metrics to measure IRB quality; 2) local context issues; 3) institutional liability; 4) complexity of shared control and accountability; and 5) costs of delegating review and/or loss of revenue for the relying institution. Detailed agreements delineating roles and responsibilities of all parties can be very helpful for facilitating collaboration and trust. OHRP has considered regulatory revisions to address some liability concerns; more information may be found at Request for Information and Comments on IRB Accountability (also referenced in the 2011 ANPRM and 2015 NPRM) and OHRP Correspondence—Use of a Centralized Institutional Review Board (IRB) (April 30, 2010).

Earlier this year, CTTI released guidance and templates for institutions to use in negotiating reliance agreements. CTTI is a public-private partnership co-founded by the FDA and Duke University to identify and promote practices that will increase the quality and efficiency of clinical trials. CTTI has published a "Considerations Document" that outlines how responsibilities should be allocated between an institution and a central IRB when executing a reliance agreement.

CTTI also published a Template IRB Authorization Agreement that can be used by contracting organizations. The CTTI template is the work product of a two-day expert meeting held in 2014 and is based on information and template agreements collected from twenty institutions and organizations. Of the IRBs that contributed template agreements for review, 56% were institutional IRBs, 31% were independent/commercial IRBs, 30% were IRBs associated with a federal sponsor, and 30% were IRBs associated with a clinical trial network. The CTTI project team created a proposed draft template that was then reviewed at an expert meeting and later validated by attendees. The agreement covers a wide range of topics, including allocation of responsibilities, consistency with the clinical trial agreement, and notification requirements.

The CTTI tools and the guidance published by AAHRPP, OHRP and the FDA all provide useful support for negotiating the reliance agreements that will be needed as multi-site studies move towards using a single IRB of record.

REFERENCES

1. Jerry Menikoff, The Paradoxical Problem with Multiple-IRB Review, 363 N. ENGL. J. MED. 1591 (2010).

2. 21 C.F.R. § 56.114 (2015); 45 C.F.R. § 46.114 (2015).

About Kinetiq

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