Baystate Health | UMass Chan Medical School

What is "Local Context" in single IRB?

By: Linnea Rademaker, PhD, CIP IRB Reliance Analyst

The federal regulations for single IRB are well-detailed on the OHRP website. Research teams often ask why the NON-reviewing IRB needs to spend so much time reviewing and documenting things. One perception is that these things are outside our purview as the relying IRB.

To be clear, the OHRP is very specific about what the federal regulations require, and that these items must be reviewed and documented/approved by the reviewing IRB. However, OHRP leaves space for local, institutional, and state requirements. These latter are called "local context."

For example, the state of Massachusetts has statutes about the "age of majority" for research participants, and the collection of specific permission for gathering and storing genomic sequencing data, which may be different from other sites in other state that are part of the same, large, multi-site trial. Researchers from Baystate need to follow the Massachusetts state regulations. These differences will be noted in the informed consent form, or in other documents needed for initial local review.

Regarding institutional policies, we have requirements that must appear in IRB submission, such as specific language regarding HIPAA that must appear in our informed consent form, and specific information about injuries, or payments to participants (just as some examples).

Understanding the local context, and how the IRB reviews for both federal regulations and local context can help research teams understand the complexity of applying to the IRB for ceding to an external IRB and why so much is required.

For any questions about single IRB, please be sure to contact Linnea Rademaker, our sIRB reliance analyst. Be sure to check out the sIRB manuals, located on our website, as well as other single IRB forms and resources: sIRB at Baystate.