

## **IRB AUTHORIZATION** **AGREEMENT TIP SHEET**

### **What is a Reliance or IRB Authorization Agreement?**

When a MD Anderson (MDACC) Investigator is involved in a collaborative research project with a non-MDACC employee or Institution, an agreement is needed. Because an IRB's purview to review and oversee research involving human subjects under a Federal Wide Assurance (FWA) is limited to the actions of the employees or agents of its institution, such collaborative research requires IRB review by each site engaged in the research. Alternatively, and with the agreement of both IRBs, a Reliance or IRB Authorization Agreement (IAA) may be implemented. A reliance agreement is a document signed by two or more institutions engaged in human subjects research that permits the IRB of one institution to rely on the IRB of another institution for the review of human subjects research. The signed agreement permits a single IRB to review human subject research activities for more than one site.

### **What is the purpose of a reliance or authorization agreement?**

A reliance agreement helps reduce duplicative IRB initial review, amendment review, continued oversight, and reporting responsibilities when multiple IRBs have jurisdiction for the same multi-site research protocol.

### **When should I submit a request for use of a Reliance Agreement?**

A request can be submitted at any time.

### **What documentation is needed when submitting the Reliance Agreement Request?**

This would depend on the type of submission and request (cede/rely) needed for the study. In order to process a request for the MDACC IRB to serve as the IRB of record, we would first need to determine if the individual and/or site is engaged in research. The protocol must accurately describe the role and responsibilities of the outside person or site involved. The external site would also need to have a Federal Wide Assurance (FWA) in place prior to executing the agreement. For studies requesting the MDACC IRB cede review to an external IRB, we would need to review the protocol, consent template and any other relevant study documentation.

### **How is a decision made whether MDACC is willing to cede review to an external IRB?**

The MDACC IRB first collects preliminary information from MDACC Principal Investigator to determine our willingness to cede or accept IRB review for a particular protocol.

The first step is to submit a generic memo to PDOL indicating that you would like to implement an Authorization or Reliance agreement. Complete and attach the "IRB Oversight Request Form" to the memo.

Your information will be reviewed by an IRB Chair (or designee) to determine if the MDACC IRB is willing to cede/accept oversight based upon the details provided. When a determination has been made regarding oversight, you will receive an IRB memo. Our Institutional Official, and Institutional Compliance will be involved in the decision making process and in drafting the agreement.

### **Who can I contact for further detail or guidance?**

Wanda Quezada, Office of Human Subjects Protection Director; [wquezada@mdanderson.org](mailto:wquezada@mdanderson.org); 713-563-5445 or Leola Griffin, Quality Assurance Specialist; [lgriffin@mdanderson.org](mailto:lgriffin@mdanderson.org); 713-563-5450