FAQs About IRB AUPO Altus Pilot Study 2022

What is the Western IRB (WIRB)?

WIRB is a central IRB which can be and often is used for multicentered sites for various types of research.

Do local IRBs work with WIRB?

A majority of institutional IRBs have agreements with WIRB through reliance agreements. Some local IRBs will abide by all WIRB decisions. Others may limit their work with IRB to certain circumstances, eg., federally funded research, research with minimal risk, etc. You will need to check with your local IRB to determine their relationship with WIRB.

What did the WIRB say about the Altus study?

The WIRB approved the protocol and stated that the project is exempt from continuing review by the Board. WIRB stated only administrative and regulatory oversight was necessary for this project. They also indicated that the research qualified for a waiver of consent from participants.

What do I need to do with my local IRB?

You should present the protocol and the WIRB letter for their review. They may ask for additional material, eg., the data fields in the redcap site, more information on how you will store date locally at your site, or security processes. (Please see <u>WIRB Approval Letter</u>, <u>Study Protocol</u>, <u>Data Entry, Protection</u> and <u>Management Protocols</u> documents.)

What are the possible responses that my local IRB could give to the WIRB response?

Your IRB is likely to answer in one of the following ways:

- a. They have a reliance agreement with WIRB and accept their ruling.
- b. They do not have a reliance agreement with WIRB but would be willing to obtain one for this study. If WIRB or the institution states that there is a cost for this, AUPO will officially request waiver.
- c. They do not accept outside IRB rulings and require you to submit the project for their local review.

How should I submit to my local IRB if they request it?

You should ask for the project to be exempt with waiver of consent (mirroring the determination of WIRB). The PI should be the program director (PD), and associated personnel who will assist with data entry and management would be co-investigators. Remember that review of applications to determine the top 100 applicants is NOT part of the research, nor is the interview process. Thus, all faculty who review files or who serve as interviewers need not be investigators. Although faculty may contribute opinions on applications and applicants, in the end it is the PD and/or Chair who make(s) the final interview decisions and rank list.