

Federal-wide Assurances (FWA)

The DCH IRB holds a Federal-wide Assurance with the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS). FWAs are required for every institution that is “engaged” in Federally supported human subject research. An FWA is an agreement with DHHS to review and approve research involving human subjects in accordance with the ethical principles outlined in the Belmont Report and the DHHS regulations at 45 CFR Part 46.

An institution that receives a direct DHHS award to support research is automatically considered to be “engaged”, even if all of the activities involving human subjects are carried out by a subcontractor or collaborator. In this case, the awardee institution is ultimately responsible for protecting human subjects under the award. There are many scenarios in which an institution might be considered to be “engaged” and determining this can be complicated. It is highly recommended that you contact the IRB for guidance when working with sites outside the DHS.

<ul style="list-style-type: none">• DHS - FWA0000582 (DCH-CC and clinics, Driscoll Health Plan (DHP), Children's Physician Services of South Texas (CPSST))• DCH-RGV - FWA00034573 (DCH-RGV and clinics)	IRB00001444 IORG0000879
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IRB Authorization Agreement (IAA)

An IRB Authorization Agreement (IAA) is required if an institution outside of is “engaged” in human subjects’ research and files a Federalwide Assurance with the Office for Human Research Protections designating DCH IRB as the IRB of Record. This is a written agreement between DCH IRB and the other institution to document the extent to which DCH IRB will act in this capacity.

The IAA can be written so that DCH IRB will review:

- all studies conducted at that institution;
- a particular study named in the IAA; or

- a subset of studies designated (e.g., “all studies conducted by DCH staff”). The IAA is signed by the Institutional Official for each institution.

Permission should be obtained before DCH IRB is designated on an FWA for an outside institution because there are occasions when this would not be appropriate. All inquiries related to an IAA should be directed to Juleros.Nazareno@dchstx.org cc: IRB.Office@dchstx.org.

Individual Investigator Agreement (IIA)

There are instances when an individual, who is not acting as an employee or agent of either DHS, is “engaged” in human subjects research in **collaboration** with a DHS researcher. In most cases, that individual will not have access to an IRB to provide approval and/or oversight for the research activities being performed. For these situations, an Individual Investigator Agreement (IIA) may be appropriate. An IIA is a formal agreement describing the expectations and responsibilities for the individual and is signed by the individual investigator as well as the DHS Institutional Official. All inquiries related to an IIA should be directed to Juleros.Nazareno@dchstx.org cc: IRB.Office@dchstx.org.