Children's Healthcare of Atlanta

Institutional Review Board

irb@choa.org
http://www.choa.org/clinicalresearch

Research, Not Research, or Not Human Subject Research?
Guidance to determine what type of oversight your project requires

Before submitting a project to the IRB- the first question that should be answered is:

Step 1: Is this project "research"? **Research is defined as "A systematic investigation designed to contribute to generalizable knowledge".** 45 CFR 46.102(d)

When evaluating a project, it is best to think of this definition as a requirement for 2 key elements-

1. The project involves a "systematic investigation"- this can be a characteristic of both research and non-research activities, including quality assessment and improvement. A general collection of information that has no general applicability is not research. A study should be conducted with the intention of drawing conclusions, using a commonly accepted scientific method. Research should answer a question and have a hypothesis.

2. The design, goal, intent or purpose- is to develop or contribute to generalizable knowledge. "Generalizable knowledge" can be tricky. Intent to publish does NOT make a project research, if the knowledge applies only to a specific institution or group. Generalizable knowledge is knowledge/data or conclusions that can be applied to larger groups and that information should apply to individuals or settings *beyond* those individuals and settings that were the focus of the inquiry.

If you answer "no" to either of these questions, your project is not research and does not require IRB oversight. You can still publish but cannot call it research. If you answer "yes" to both of these questions, your project is indeed research, but is it Human Subjects Research?

Step 2: Does research involve Human Subjects?
The next step is determining if your research meets the definition of "human subject research".

1. Human Subjects are defined as - a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual 45 CFR 46.102(f)(1),(2) or (2) identifiable private information. 45 CFR 46.102(f)(2)

2. In many cases, the project involves collected of existing data/specimens (NOT interaction or intervention). If the data is completely de-identified, meaning there is no identifiable data being obtained/recorded, then the research is not "human subject research" and will not require IRB oversight. However, if any identifiable data is collected, even if coded, it is still considered human subject research and will require IRB oversight.

If you have a question regarding a specific project, or when planning a project, please contact the IRB at 404-785-7555 or 404-785-9376. Non-Human Subject Research does NOT require an official determination by the IRB, but the IRB can provide an official determination letter as needed.

Please reference the NHSR Determination Form.

Human Subject Decision Chart

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46.