AAH RSPP GUIDANCE
Human Subject Research Determination

PURPOSE

To provide guidance on Advocate Aurora Health (AAH) Research Subject Protection Program's (RSPP) position on what does or does not constitute human subject research.

Definitions of *Italicized words* can be found in the AAH RSPP Glossary.

GUIDANCE

How to determine if a project is human subject research?

The IRB of Advocate Aurora Health (AAH IRB) is responsible for protecting the rights and welfare of *human subjects* in *research*. The first question an individual should ask him/herself is whether their project fits the definition of *research*. Under the federal Common Rule, "*research*" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*." In addition, the FDA has separate definitions for what constitutes research and therefore, if your project includes use of a *drug*, *device* or *biologic*, it may be subject to FDA regulations and require IRB review.

While some activities are typically outside the realm of research (e.g. operational activities such as defined practice activities in public health and medicine, or internal management activities such as quality improvement, quality assessment and program evaluation), some of these activities may constitute research in circumstances where there is a clear intent to contribute to *generalizable knowledge*. Often, determining whether a project constitutes research under federal and institutional regulations can be a complex process that involves assessing the project intent, design, mandates, expected outcomes, and dissemination of results.

Some projects may be research but may not involve human subjects as defined by the Common Rule. According to 45 CFR 46.102(f):

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- *Interaction* includes communication or interpersonal contact between investigator and subject.
- *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the

subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

An IRB's obligation is to oversee Human Subject Research. As a result, studies that do not involve human subjects likely do not require IRB oversight. It is often difficult to determine whether a study involves human subjects or not. The NIH has published a decision tree that may help.

Are Case Reports Considered Human Subject Research?
As stated above, research, as defined by the federal Common Rule, is "a *systematic investigation*".

Case reports generally involve the following:

- a retrospective review of medical records detailing a medical treatment in one or several patients with a unique treatment, disease course, or outcome;
- a description of a unique diagnostic finding or uncommon presentation;
- a report prepared by the clinicians who have personally provided care to the patients.

Case reports generally do not involve the following:

- a predetermined hypothesis or research question;
- plans for publication of the information about the patients' medical care prior to or during the patients' treatment.

It is the position of the AAH RSPP and the IRB that **case reports/case studies involving three (3) or fewer patients** generally do not meet the definition of research under the Common Rule or *HIPAA* Privacy Rule. That is, the activity does not normally meet the standards of 'systematic' or 'generalizability'. As such, reporting on 3 or few case reports does not require review/oversight by an IRB because they are not viewed as Human Subject Research.

Case reports involving more than three (3) patients are more likely to meet the criteria of human subject research, and typically do require IRB oversight.

Anyone who is unsure whether the use of a case report/case study requires IRB oversight should submit a Human Subject Research Determination form to the AAH RSPP office (see below).

Does publishing/presenting my findings make my project Human Subject Research?
The fact that you wish to publish/present the findings of your project does not automatically make the activity Human Subject Research. However, many journals or conferences want a letter or acknowledgement from an IRB to document that someone other than the publisher/presenter has made the decision that the project is not Human Subject Research. To address these needs, the RSPP has created a simple form, the Human Subject Research Determination form, that can be submitted to the AAH RSPP office. This form will ask questions about your proposed project. The RSPP office will review the provided responses and decide if the activity meets the threshold of Human Subject Research. NOTE: the determination should be made by the AAH RSPP prior to you conducting the activity. The RSPP reserves the right not to make retroactive determinations.

Does my project deemed 'Not Human Subject Research' require HIPAA oversight?
If you are using patient medical records or *protected health information* as part of your project, HIPAA oversight will be needed. However, the IRB of Advocate Aurora Health will not make HIPAA determinations for projects that are not Human Subject Research. Questions regarding HIPAA Privacy Rule requirements can for projects that are not human subject research be directed to AAH's Chief Privacy Officer at 414.299.1713 or the Privacy Officer at your hospital/region.

What is the Human Subject Research Determination Process?
The determination as to whether a project is deemed to be human subject research is made by AAH's *RSPP*. A Human Subject Research Determination form must be submitted to AAH's RSPP office to begin this consideration. See the Human Subject Research Determination form for instructions on how to submit.

If the AAH RSPP determines that your project does not constitute Human Subject Research, the submitter will receive a letter explaining the decision and your further obligations.

If the AAH RSPP determines that your project does constitute Human Subject Research and requires IRB oversight, you will receive a letter with information on submitting your request to the Advocate Aurora RSPP for IRB review or ceding to an external IRB. Any project deemed to be Human Subject Research **must** have IRB oversight before it is initiated at the institution.

Even if not determined to be human subject research, Advocate Aurora Research Institute (AARI) wishes to be notified of any project that is research. Some examples of this type of research are straightforward and easy to determine, e.g. analyzing de-identified tissue samples obtained from a commercial source or analyzing data from deceased individuals. It is your obligation to notify AARI of any research project conducted at AAH. For details contact research.preauthorization@aah.org.