Aurora Health Care’s Research Subject Protection Program (RSPP)

Guidance for protocols that include a health economic component

Protocols that include a health economic component require additional considerations by the IRB to ensure regulatory criteria for approval have been met. This document outlines the information that the IRB needs in order to make the appropriate determination.

Information in this document may also be applied to other types of sub-studies, such as blood or tissue banking.

What is a health economic component?

A protocol has a health economic component when a sponsor requests access to a patient’s billing information for research purposes. The purpose of the data collection is to study the costs (long-term and short-term) associated with healthcare and health outcomes. Often, billing records are requested from any sites where the research subject was treated (which could be outside Aurora).

Examples of health economic data frequently collected include:
- Cost of the procedure
- Length of the hospital stay
- Hospital re-admittance
- Cost of follow-up visits

The health economic component should be discussed in the sponsor’s main protocol objectives or in a stand-alone sub-study protocol. If the health economic component is only mentioned in the informed consent document and nowhere else, this is not acceptable. The IRB does not have enough information to approve the component.

Most health economic activities fit one of the following scenarios:

A. Health Economic component included in main protocol objectives and being performed by the sponsor
B. Health Economic component as a separate sub-study, but being performed by the sponsor
C. Health Economic component as a separate sub-study and being performed by a third party

What information does the IRB need?

The specific data collected in a health economic component can vary, and IRB review will depend on the individual protocol. The following is a list of requirements for most cases.

For scenario A (part of main study protocol):

1. The protocol should include:
   a. A clear explanation of the health economic component
   b. A list of the specific health economic data that will be collected and sent outside Aurora. Data collection sheets are required.
   c. Confirmation that the sponsor will be analyzing collected data.
d. Identification of the person(s) who will be collecting the data.

e. Statement about whether the health economic component is mandatory or optional for research participants.

f. The length of time the data will be maintained.

2. The submission application should include:
   a. Details about the health economic component of the protocol
   b. Description of how the data will be collected locally, and by whom.

3. The informed consent document should include:
   a. The purpose of the health economic data.
   b. The specific data that will be collected.
   c. Whether the data will be de-identified or coded.
   d. To whom the data will be sent.
   e. The length of time the data will be maintained.
   f. Statement about whether participation is mandatory or optional.
      i. If subject participation is optional, either include a 'yes'/’no’ checkbox or write a separate consent.
   g. Whether subjects will be able to withdraw their health economic data, and when.

4. If the billing department is responsible for any part in the health economic component, administrative acknowledgment from their department is required.

For Scenario B (sub-study conducted by the sponsor):

The submission should include the requirements for scenario A, plus:

1. Information about the IRB overseeing the database once the data has been collected. If the sponsor is requesting that the Aurora IRB fulfill this role, that should be clearly stated.

For Scenario C (sub-study involving a third party):

The submission should include the requirements for scenarios A and B, plus:

1. A description of who the third party is and why they are involved in the health economic component.

2. Information about the institution and/or IRB overseeing the data analysis component by the third party. If the sponsor is requesting that the Aurora IRB fulfill this role, that should be clearly stated.

3. Information about whether there is some type of agreement or contract between Aurora and the third party to cover this data collection.