Serving as the Reviewing IRB for University of Chicago Affiliate Sites: Advent Health and Ingalls.

The following document provides instructions for requesting the University of Chicago to serve as the IRB for affiliate sites through a master agreement. Below are instructions for adding Advent Health and Ingalls either at the time of new submission or through an amendment. For questions about the reliance process please contact the IRB Reliance team at: irbreliance@bsd.uchicago.edu .

These instructions do not apply when the University of Chicago is not the IRB of record. If you have a study that relies on an external IRB and wish to expand research to Advent Health or Ingalls, please contact the University of Chicago BSD Reliance team for further information.

When submitting a request to add Advent or Ingalls, the BSD IRB will determine whether a waiver of authorization for screening is required. If necessary, the IRB will grant the authorization at the time the affiliate site is added to the study protocol in AURA IRB.

Advent Health:

Step 1: Research Activities Occurring at Advent at the time of new submission

- In View 1.0 General Information Questions 5 and 6, please list the staff members at Advent that will be engaged in the research.
- In View 1.5 question 1, please check the option for the affiliate sites where research will occur.
    - Advent (select the locations where research activities will occur)
- In View 1.5 question 2 of the AURA-IRB submission form, please indicate this is a multisite study.
- In view 1.5 question 5 of the AURA-IRB submission form, please indicate that another site is requesting UChicago IRB to serve as the IRB of record.
    - In View 1.5 question 5a indicate what sites (Advent) are requesting UChicago serve as the IRB of record.
    - In View 1.5 question 5b, state what research activities are occurring at the

affiliate site.

- In View 1.5 question 5c, upload a copy of the Master Reliance agreement with Advent.

- In the consent form header (on page 1), please add University of Chicago Medicine Advent Health to reflect this site's participation in the research.
- If you are planning to utilize the Clinical Research Data Warehouse for prescreening patients, please ensure that "CRI/CRDW" is selected as a data collection source.

Step 2: Submitting an Amendment to add Advent Health

- If the study is already approved, an amendment will need to be submitted to include the affiliate site. When submitting the amendment, under view 1.2 Nature of the Amendment question 1, please be sure to select all changes that are applicable to the reliance request:
  - Change to study sites
  - In the brief summary of changes please include the following: *The purpose of this amendment is to request the University of Chicago BSD IRB serve as the IRB of record for Advent Health. The Master Reliance agreement has been provided.*
- If individuals from Advent will be engaged in the research, a personnel amendment should be submitted to add these individuals to the study team.
- In View 1.5 question 1, please check the option for the affiliate sites where research will occur.
  - Advent (select the locations where research activities will occur)
- In View 1.5 question 2 of the AURA-IRB submission form, please indicate this is a multisite study.
- In view 1.5 question 5, please indicate that another site is requesting UChicago IRB to serve as the IRB of record in the AURA-IRB submission form.
  - In View 1.5 question 5a indicate what sites (Advent) are requesting UChicago serve as the IRB of record.
  - In View 1.5 question 5b, state what research activities are occurring at the affiliate site.
  - In View 1.5 question 5c, upload a copy of the Master Reliance agreement with Advent.

- In the consent form header (on page 1), please add University of Chicago Medicine Advent Health to reflect this site's participation in the research.
- If you are planning to utilize the Clinical Research Data Warehouse for prescreening patients, please ensure that "CRI/CRDW" is selected as a data collection source.

Ingalls

Step 1: Research Activities Occurring at Ingalls at the time of new submission

- In View 1.0 General Information Questions 5 and 6, please list the staff members at Ingalls that will be engaged in the research.
- In View 1.5 question 1, please check the option for the affiliate sites where research will occur.
    - Ingalls (select the locations where research activities will occur)
- In View 1.5 question 2 of the AURA-IRB submission form, please indicate this is a multisite study.
- In view 1.5 question 5, please indicate that another site is requesting UChicago IRB to serve as the IRB of record in the AURA-IRB submission form.
    - In View 1.5 question 5a indicate what sites (Ingalls) are requesting UChicago serve as the IRB of record.
    - In View 1.5 question 5b, state what research activities are occurring at the affiliate site.
    - In View 1.5 question 5c, upload a copy of the Master Reliance agreement with Ingalls.
    - In addition, when adding Ingalls to a **non-cancer center study**, the IRB Chair at Ingalls and the Assistant Dean for Clinical Research at University of Chicago should be consulted.
        - Study teams should contact Melissa Byrn, Assistant Dean for Clinical Research and provide the completed form: Clinical Research Protocols and Ingalls Hospital. This form can be accessed on the BSD IRB Reliance page.
        - Study teams should also contact Al Fisher and provide the details of the study, what activities are happening at Ingalls and whether any

Ingalls staff or resources will be utilized.

- The email confirmation from the University of Chicago Assistant Dean for Clinical Research should be uploaded to View 1.5 question 5c.
- The email confirmation from the Ingalls IRB Chair should be uploaded to View 1.5 question 5c.

Step 2: Submitting an Amendment to add Ingalls

- If the study is already approved, an amendment will need to be submitted to include the affiliate site. When submitting the amendment, under view 1.2 Nature of the Amendment question 1, please be sure to select all changes that are applicable to the reliance request:
  - Change to study sites
  - In the brief summary of changes please include the following: *The purpose of this amendment is to request the University of Chicago BSD IRB serve as the IRB of record for Advent Health. The Master Reliance agreement has been provided.*
- If individuals from Ingalls will be engaged in the research, a personnel amendment should be submitted to list this individuals as study staff.
- In View 1.5 question 1, please check the option for the affiliate sites where research will occur.
  - Ingalls (select the locations where research activities will occur)
- In View 1.5 question 2 of the AURA-IRB submission form, please indicate this is a multisite study.
- In view 1.5 question 5, please indicate that another site is requesting UChicago IRB to serve as the IRB of record in the AURA-IRB submission form.
  - In View 1.5 question 5a indicate what sites (Ingalls) are requesting UChicago serve as the IRB of record.
  - In View 1.5 question 5b, state what research activities are occurring at the affiliate site.
  - In View 1.5 question 5c, upload a copy of the Master Reliance agreement with Ingalls.
  - In addition, when adding Ingalls to a **non-cancer center study**, the IRB Chair at Ingalls and the Assistant Dean for Clinical Research at University of Chicago

should be consulted.

- Study teams should contact Melissa Byrn, Assistant Dean for Clinical Research and provide the completed form: Clinical Research Protocols and Ingalls Hospital. This form can be accessed on the BSD IRB Reliance page.
- Study teams should contact Al Fisher and provide the details of the study, what activities are happening at Ingalls and whether any Ingalls staff or resources will be utilized.
- The email confirmation from the University of Chicago Assistant Dean for Clinical Research should be uploaded to View 1.5 question 5c.
- The email confirmation from the Ingalls IRB Chair should be uploaded to View 1.5 question 5c.

When submitting a request to add Advent or Ingalls, the BSD IRB will determine whether a waiver of authorization for screening is required. If necessary, the IRB will grant the authorization at the time the affiliate site is added to the study protocol in AURA IRB.