Advocate Health HSR/IRB and Project Summary Instructions

Adapted from research/IRB Team 8.31.2020

Target Audience: Nursing student projects (all student projects must submit a determination form and project summary)

Note:

**HSR Determination Form** (submitted to the Advocate Aurora Health (AAH) IRB via IRBNet.org when there is uncertainty whether your project is human subject research. This form must be submitted, and a decision received from the AAH RSPP before you begin your project)

- The form must be completed in its entirety
- The study information should be thorough and complete
- Study information that does not include specific details on how you will obtain your goal will be returned for more information. This will cause delays if the application must be returned.
- Study information topics include but are not limited to:
  - Implementation of a tool that has been validated or an evidence-based practice change and doing a chart review pre- and post-implementation to see if it improves outcomes
  - Testing an algorithm using de-identified data
  - Providing a survey to employees or patients
  - Develop and provide education to nursing staff or patients
- Any supplemental documents must be attached (e.g., surveys, tools, abstracts, etc.)
- The form must be typed and e-signed, and submitted to IRBNet

All documents referenced in these Guidelines are available within the IRBNet *Forms and Templates* library.

1. Creating an Account

All submissions to the Advocate Health IRB will be made through a cloud-based system titled *IRBNet*. You must register within the system and click on a confirming email to establish an account. No emailed or hard copy submissions will be accepted by the IRB.

**Register in IRBNet**

Go to the website [www.IRBNet.org](http://www.IRBNet.org). Click New User Registration, and create an IRBNet account using *firstname.lastname* as the user ID and your email address. Use your Advocate Health email address if you are also an employee. You must **click the link in your confirming email**, or the account will not be activated.
• Select the Research Institution or Organization as shown below: Ensure you select Advocate Aurora Health, Downers Grove, IL (do not select the other Advocate option).

• Review and Accept Individual User Terms of Use.
• You will receive an automated email. Click the link within the email.
• Create Account Recovery Information.
• Create a New Project.

• IRBNet self-training resources are available at: http://training.irbnet.org
• using the ID & pw:
  o AdvocateResearch2 or AdvocateResearch6
  o training
• Key terms within the system are Project and Package. Each protocol from inception to completion is termed a single Project within IRBNet. When requesting a determination as to whether a study requires IRB review, you will create a new Project to contain the materials submitted to the IRB. Once the IRB provides determination, that Project ends.

• The named primary investigator (PI) must sign off on the project before it is submitted. The student may be the principal investigator for quality/process or evidence-based practice projects. If you are conducting research, the principal investigator must be an employee. If someone else
creates the IRBNet project file, then the prepared submission should be “Shared” with the PI who must sign it before submission.

- Current versions of primary AHC IRB forms and documentation will be maintained in the IRBNet Researcher Library – see under Forms and Templates.

2. Requesting a Determination

Once AAH IRB has reviewed your completed HSR Determination form and if it is determined that your project involves Human subject Research, you will be informed that you must complete the entire Human Subject Research application along with the additional documents and you must obtain preauthorization from AARI using their RAPR process/submission system before resubmitting your project in IRBNet. You may email RAPR at aah-research-authorization-and-protocol-review@aah.org. Once they have approved your project you will receive authorization via email. A copy of this email must be included with the submission in IRBNet. Only Human Subjects research requires IRB review. Accordingly, some projects, for example, those specifically tied to hospital operations as are some QA/QI projects, may receive a determination by the IRB establishing that review is not necessary.

To submit a request for a determination

- Log into your account and select “Create New Project.”

- Complete the HSR Determination form. This form can be found in the IRBNet Library. If you are unable to locate Forms and Templates (as pictured below), please check the Research Institution or Organization you selected upon registration: Ensure you selected Advocate Aurora Health, Downers Grove, IL (not the other Advocate option).
3. Project Summary Required

- Smart form located in Designer (left-hand column)
  - Click Designer
  - Select Start a Wizard
  - Click on Project Summary
  - Complete the form in its entirety.
    - Select the appropriate responses for your project. If a response is not appropriate, please select n/a or None of the above.
    - Example questions:
<table>
<thead>
<tr>
<th><strong>Example Questions (this is not the complete form)</strong></th>
<th><strong>Example Responses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Board</td>
<td>AAH IRB/ AAH RSPP (HSR determinations are not waived to an external IRB)</td>
</tr>
<tr>
<td>Submission Type</td>
<td>AAH RSPP Human Subject Research (HSR) Determination</td>
</tr>
<tr>
<td>Service Domain</td>
<td>Select the appropriate response (i.e., cardiovascular, CV surgery, GI, Ortho, etc.)</td>
</tr>
<tr>
<td>RAPR Recommendations Addressed?</td>
<td>N/A is appropriate for HSR determinations</td>
</tr>
<tr>
<td>Amendment/Modification</td>
<td>Select N/A</td>
</tr>
<tr>
<td>Project Classification</td>
<td>NA - HSR Determination</td>
</tr>
<tr>
<td>IND/IDE/HDE Number/Exemption Info</td>
<td>Select n/a</td>
</tr>
<tr>
<td>Research Locations</td>
<td>Select all that apply</td>
</tr>
<tr>
<td>AAH Review Fee Information</td>
<td>Review fees are not required for HSR Determinations</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>Select the appropriate response</td>
</tr>
<tr>
<td>PI Attestation</td>
<td>(PI= primary investigator) This is a required field</td>
</tr>
</tbody>
</table>

**Submit This Package**

- Once e-signed by the primary investigator (PI), click on "Submit this Package," The IRB will contact you with a:
  - Request for clarification;
  - Determination that the project will require regular IRB review (i.e., a completely new Project submission including ethics training, etc.); or
  - Determination that the project meets the criteria for non-Human Subject Research (or that AAH is not engaged, per federal definitions) and that no further submissions are required for the protocol to proceed as submitted.

**Students:** You may check the status of your request on the website. If you have full access to IRBNet, an email may also be generated when documentation of the results is available. If a determination letter is not located within your project file, please complete revisions as needed.

If a determination letter is located within your project file, please submit it to your school so they may upload it to myClinicalExchange.

If revisions are required, you will receive an email (example below) and may also review the revisions requested in IRBNet.
How to obtain the determination letter:

[Image]

How to make revisions:

If the reviewer has questions or requests additional resources, they will Unlock the package and enter comments. Anyone with Full Access to the project will receive an email from the reviewer via IRBNet. After the revisions have been completed, the package must be Relocked to inform IRB the project is ready for review.
• **Directions to Relock:**
  - Go to Designer
  - Click Relock and Mark Revision Complete above the Red Unlocked Symbol

<table>
<thead>
<tr>
<th>Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Affiliation</strong></td>
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</tbody>
</table>
| **Affiliation Directions:** | 1) To affiliate with "Advocate Aurora Health, Downers Grove, IL" you can do this by:  
  a) Going to your User Profile and clicking the "USER PROFILE" link in the upper-right corner  
  b) Under the "Affiliations" heading click the blue "Add an Additional Affiliation"  
  c) Select "Advocate Aurora Health, Downers Grove, IL"  
  d) Enter your email and telephone number and click the confirmation email |
| **Research Institute** | To access the Advocate Aurora Smart Forms through the "Start a Wizard" button on the Designer page, you will need to update the listed Research Institution for this project to Advocate Aurora Health. You can complete this change by following the steps outlined below: |
Step by Step Directions for Section II: Study Information

You are asked to answer 8 questions in Section II – Study Information. While the form itself is brief, your responses to the questions must fully describe all aspects of your project. One-sentence responses or vague responses are not acceptable.

- **Question 1:** Is the project designed to contribute to generalizable knowledge?
  - Results from evidence-based practice projects and performance improvement projects are not considered “generalizable knowledge”.
  - Even though the form uses the term “study” in quite a few places, your project is not a study. Always refer to it as a “project”. Choose NO from the drop-down menu.

- **Question 2:** Describe the reasons for conducting the proposed project.
  - The reasons for conducting the proposed project are those things you have discussed and written about when doing your proposal for class.
  - The background and significance that you identified from the literature combined with a demonstrated need from the identified project site should be included in this response.
  - Include a summary statement that captures the benefits of the project for the patients, the site, or the employees.

- **Question 3:** Provide a brief synopsis of the project, including objective(s)
  - Your objective(s) must be realistic, clearly written, and measurable.
  - Each objective should measure only one outcome.
  - How will you recruit your participants?
  - If there is an intervention, what will that entail? Be specific. What is expected of the participants?
  - Is your preceptor de-identifying any data for you? Are you using aggregate data from a report? How will you get that report?
  - Is there any kind of follow-up contact with the participants?

- **Questions 4, 5, 6, & 7:** See form

- **Question 8:** Describe the subject population/type of data to be studied
  - Begin with how the participants will be informed that their participation is
voluntary, and they are free to leave the project at any time.

- Describe each step of your project.
- How long will it take?
- Describe in detail what type of data you are collecting
- Describe how you are obtaining your de-identified data (Students will NOT have access to identified patient data. If you are an Advocate Health employee, you must remember you are not functioning as an employee when you are completing academic projects. You DO NOT have access to patient records or data in your student role. You must make arrangements with your preceptor to de-identify data or conduct your project using only aggregated data from reports). Describe your data in detail. Describe the way it will be deidentified before you see it in detail.
- Do your participants have a particular condition or, if they are employees, work on a particular unit?
- What is the age range for your participants? If employees, is the amount of experience or education why you want them in your project?
- State any specific criteria that you will use to decide if a participant is selected or excluded from your project.
- Go into detail about exactly how the data will be de-identified. The IRB is making sure that your participants cannot be linked to their data.
- This question sometimes repeats some information from the previous response but that is acceptable.
- How will data be stored during the project?
- What will happen to your data when the project ends?
- How will you disseminate your results?