Researcher
Checklist

Determining if the Project is Research or Evidence-Based Practice (EBP)

☐ **Determination of Research application**

1. You may need to complete a Determination of Research Application for your project
2. Template at www.genesishealth.com/research under the IRB tab
3. Contact Sarah Castro at castros@genesishealth.com or 563-421-7957 if you would like assistance in determining whether your study meets the definition of research

Documents To Prepare for All Research Projects

☐ **New Research Application**

1. Template can be found in IRBNet at http://www.irbnet.org under "Forms and Templates"
2. Provides a summary of your project along with other key information for the IRB

☐ **Study Protocol**

1. Template at www.genesishealth.com/research
2. Outlines the background evidence for the topic, objectives, study design, data management, and monitoring/safety

☐ **Informed Consent Form**

1. Template at www.genesishealth.com/research
2. Provides research participants full information about a study so they can make an informed decision about whether to participate
3. *You need an informed consent for all studies, except retrospective chart reviews*

☐ **Questionnaires/Surveys**

1. Any questionnaires or surveys used with the study must be prepared and reviewed by the IRB

☐ **Recruitment Materials**

1. Any flyers, posters, e-mails, etc. used to recruit participants to the study must be prepared and reviewed by the IRB

☐ **Other supporting documents**

1. Any educational materials, toolkits, instructions or other study material used to carry out the study must be developed and reviewed by the IRB

Documents Needed for Certain Research Projects

☐ Waiver of Informed Consent Documentation

1. Template can be found in IRBNet at www.irbnet.org under "Forms and Templates"
2. A waiver may be appropriate if the only record linking the participant to the study is the informed consent document (e.g., anonymous survey)

☐ Waiver of Informed Consent

1. Template can be found in IRBNet at www.irbnet.org under "Forms and Templates"
2. A waiver may be appropriate for retrospective chart reviews, ask the research department (563-421-7955 or research@genesishealth.com) if a waiver is appropriate for your study

☐ Waiver of HIPAA Consent

1. Template can be found in IRBNet at www.irbnet.org under "Forms and Templates"
2. A waiver may be appropriate for retrospective chart reviews, ask the research department (563-421-7955 or research@genesishealth.com) if a waiver is appropriate for your study

Research Activities to Complete

Required for all research study team members

☐ **Complete NIH Protecting Human Research Participants training (or equivalent)**

a. https://phrp.nihtraining.com/users/login.php
b. The training takes approximately 1.5 hours to complete and only needs to be completed once.
c. Send the certificate of completion to Sarah at castros@genesishealth.com

☐ **Complete Conflicts of Interest Training**

d. For new researchers only, expected duration = 20 min, required every 4 years
e. Log in to Healthstream – www.healthstream.com/hlc/genesis
f. Click on "Catalog" and type in "Research"
g. Complete the "Conflicts of Interest in Research" Training and send the certificate of completion to Sarah at castros@genesishealth.com

☐ **Complete Conflicts of Interest Disclosure**

h. If you are a new researcher, you will receive an e-mail from Genesis COI Smart asking you to complete a disclosure survey
i. If you have completed a research project before, you are already asked to disclose once a year (no additional action needed)

☐ **Register in IRBNet.org**

j. Genesis uses IRBNet for all IRB submissions, go to www.irbnet.org
k. Click on "new user registration" in the upper right-hand corner and follow all steps to create an account
l. The IRBNet user guide can be found at www.genesishealth.com/research

IRB Application Documents

The following documents need to be uploaded into IRBNet (www.irbnet.org) for a "New Project" submission

- ☐ New Research Application
- ☐ Study Protocol
- ☐ Informed Consent with line numbers (go to "page layout" tab in Word, click on line numbers, choose continuous)
- ☐ Informed Consent without line numbers (clean version for IRB stamping)
- ☐ Waiver of Informed Consent (if applicable)
- ☐ Waiver of Informed Consent Documentation (if applicable)
- ☐ Waiver of HIPAA Consent (if applicable)
- ☐ Any applicable Questionnaires/Surveys
- ☐ Any recruitment materials
- ☐ Other relevant study documents (e.g., education materials, checklists, instructions)

Modifications are often required after IRB review. You will submit all changes in IRBNet as a "Response/Follow-up" package (see IRBNet User Guide for instructions on how to create a new package). Your final IRB package should include the following:

- ☐ A final, clean copy of all documents submitted with your "New Project" submission (all relevant documents from the list above)
- ☐ For any documents that required modification, a second copy of the documents with the requested changes red-lined using track changes (track changes can be found under the "Review" tab in Word) – *this allows the IRB to review requested changes quickly and easily*