

PIEDMONT HEALTHCARE SCIENTIFIC REVIEW COMMITTEE (PHSRC) SUBMISSION FORM

In keeping with Piedmont Hospital's commitment to excellence in research the PHSRC review is focused on scientific question(s), methodology, merit, and feasibility of research. Consider the following decision tree that will be used to determine whether or not your proposal would be classified as research:

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46? February 16, 2016 Start here. Is it research? Activity is not research Is the activity a systematic investigation designed to develop so 45 CFR part 46 or contribute to generalizable knowledge? [45 CFR 48.102(d)] does not apply. Activity is research. Does the research involve human subjects? The research is not research involving Does the research involve obtaining human subjects, and 45 CFR part 46 information about living individuals? [45] CFR 46.102(f)] does not apply. NO YES Is the information individually identifiable (i.e., the identity of the Does the research involve intervention of subject is or may readily be NO⊳ interaction with the individuals? NO ascertained by the [45 CFR 46.102(f)(1), (2)] investigator or associated with the information)? YES [45 CFR 46.102(f)(2)] Activity is research involving human BŪT YĒS subjects. Is it covered by the regulations? Is the information private? (About Is it conducted or supported by HHS? BUT behavior that occurs in a context in [45 CFR 46.101(a)(1)] which an individual can reasonably expect that no observation or recording NO YES is taking place, or provided for specific Does the purposes by an individual and which the institution ndividual can reasonably expect will not The research hold an be made public.) [45 CFR 46.102(f)(2)] involving FWA under human which it Unless exempt under 45 CFR 46.101(b), YES> subjects is applies 45 45 CFR part 46, subpart A applies to the research, covered by CFR 46 to and as appropriate subparts B, C, and D also apply. the all of its egulations human subjects research Go to regardless The research involving Chart 2 Other Federal, State and of the human subjects is NOT local laws and/or regulations BUT source of covered by the may apply to the activity. support? regulations. [45 CFR 46.101(f)]

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DEFINITIONS:

- * Research': This requirement has two key elements, 1) a systematic investigation, and 2) the design meaning goal, purpose, or intent is to develop or contribute to *generalizable knowledge*
- * Generalizable knowledge: knowledge that contributes to the theoretical framework of an established body of knowledge where the results are expected to be generalized to a population beyond the site of data collection or population studied.
- * Human subject: a *living* individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.

NOTE: projects not meeting the definitions of 'human subjects' AND 'research' are NOT subject to the regulatory authority of the IRB.

Please ensure your proposal fully speaks to the areas below, when applicable. Mark the boxes to affirm statements, when applicable and add comments when necessary. Be as clear and complete as possible to avoid requests for additional information that can delay forwarding for IRB review.

INVESTIGATOR(S) AND RESOURCES

☐ The individual(s) conducting the research are properly trained and competent to perform as required in the proposal. ☐ The individual(s) conducting the research have completed the research learning requirements administered through the WCG Academy.
Comments:
OBJECTIVES
☐ The objectives are clearly stated as well as the method(s) to achieve them.
Comments:
BACKGROUND AND RATIONALE
 □ The justification for conducting this study is clear. □ Any preliminary data to justify this study is included. □ Not applicable □ This project does not compete with any existing protocol that includes similar aim(s) or population(s)
Comments:

STUDY DESIGN
 □ The study design is appropriate to achieve the objects □ The inclusion/exclusion criteria are appropriate □ The endpoints are identified and are appropriate □ Study measures are listed and all tools will be included in the submission □ Not applicable □ There are adequate and appropriate safety measures □ The sample size and power calculations are appropriate
Comments:
STUDY PROCEDURES
□ All procedures are clearly identified. □ Not applicable □ All RESEARCH procedures are clearly identified. □ Not applicable Comments:
SUBMISSION REQUIREMENTS Go to https://www.piedmont.org/research/research-eforms-and-systems for templates and guidance.
□ Completed PHSRC submission form
□ Detailed proposal considering the areas outlined above.
□ informed consent document, if applicable.
□ supplemental study documents (if applicable): brochures, surveys, diaries, etc
□ data collection items and tools, when applicable
Title
Signature Printed name and department
*As principal investigator, I accept responsibility for this project and assure that the project team are qualified to conduct it. Department head signature Department head printed name *As department head I offirm knowledge of this project and support its conduct by the project team are qualified to conduct it.
*As department head I affirm knowledge of this project and support its conduct by the project team.