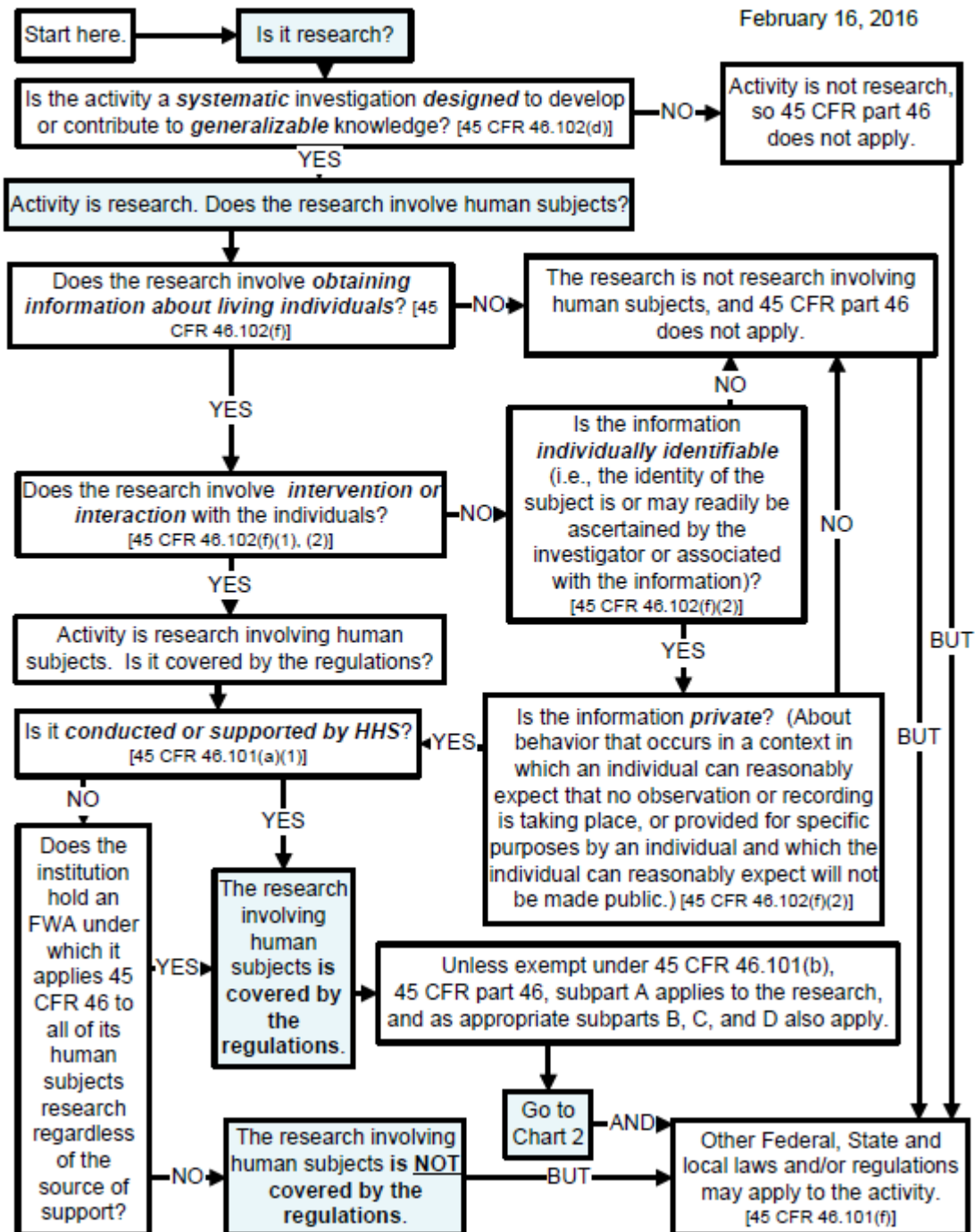


**PIEDMONT HEALTHCARE SCIENTIFIC REVIEW COMMITTEE (PHSRC) SUBMISSION FORM**

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?**



## **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 affirm knowledge of this project and support its conduct by the project team.