Instructions for Protocol Submissions

*The following information will help you as you complete the Project Approval form. The form is located on pages 3-4 of this document.*

PICO format for research questions. PICO is a useful model to help structure answerable questions. It has four components as described as follows. The most common type of clinical question is about how to treat a disease or condition (interventions). However, not all research questions are about interventions. Other types of questions may arise looking for risk factors, frequency, diagnosis, prognosis/prediction but the PICO format can still be used:

* Population/Patient:
	+ Who will be studied? What setting? What is the health concern? Inclusion/exclusion criteria.
	+ Include the most important characteristics of the patient and problem. This should include the primary complaint or problem and possibly co-existing conditions or characteristics of the patient that may affect diagnosis (e.g. age, sex, ethnicity).
* Intervention (or exposure, variable of interest):
	+ What therapy, drug, risk factor, tests?
	+ Includes the main intervention, prognostic factor or exposure being considered.
	+ Not every question will have an intervention.
* Comparison or control:
	+ What alternative to intervention or exposure? Confounding variables?
	+ Includes the main alternative you are considering. You may be deciding between two tests or between two courses of treatment.
	+ A specific comparison is not always included.
* Outcome:
	+ Clinical, functional, economic?
	+ Desired outcome (e.g. elimination of symptoms, accurate diagnosis) risk of disease, accuracy of a diagnosis, rate of occurrence of adverse outcome)
* Example:
	+ P: For persons entering a health care facility,
	+ I: is hand rubbing with a waterless, alcohol-based solution
	+ C: as effective as standard hand washing with antiseptic soap…
	+ O: for reducing hand contamination?

Stakeholders

Stakeholders are those that may be affected by or have an effect on the project. They are categorized into internal (sometimes called key/primary stakeholders) and external stakeholders. *Internal stakeholders* are those that are actively involved and have an influence on the project such as operations and those who are served or affected by the project. Examples might include FWMEP, a collaborating agency, funder, nursing staff, IT etc. *External stakeholders* are those that have a less direct interest and influence on the project but are still impacted. They are not directly involved in decision making. This might include other agencies, the public, population groups, regulatory agencies, etc.

Patient centered care/research:

* Relationship-based primary care that meets the individual patient and family’s needs, preferences, and priorities. <http://pcmh.ahrq.gov/page/patient-centered-care>
* Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
* Inclusive of an individual’s preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life;
* Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
* Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives. <http://www.pcori.org/research-we-support/pcor/>.



Research Project Protocol

Project Title:

Research team (List the individuals and their roles):

Research Project. . .

Background (~500 words 5-7 references):

Hypothesis / Research Question(s):

Design (i.e. retrospective, cohort, cross sectional, etc)

Methods and instruments (Chart review, survey, etc):

Intervention type (blinded, non-inferiority, etc):

Procedures to which humans will be subjected:

Measures (Data points to be obtained and analyzed):

What is the total number of subjects to be enrolled at this site?

Are advertisements being used to recruit patients? ☐ Yes ☐ No

 If yes, please attach copy of the advertisement.

Will there be payments to subjects? ☐ Yes ☐ No If yes, how much?

Inclusion criteria

Exclusion criteria

How will the data be analyzed and represented (Statistical Tests):

Study Timeline:

Study Site(s):

Resources needed:

Impact on Patients/Individuals and Populations:

Plans for dissemination of findings:

Plans for implementation of findings:

Description of how this project is patient-centered:

Project limitations:

This study is part of a multi-center project: ☐ Yes ☐ No If yes, identify # of sites: \_\_\_\_

This study involves the use of an Investigational New Drug (IND): ☐ Yes ☐ No

This study involves laboratory/clinical procedures NOT part of ordinary management:

 ☐ Yes ☐ No If yes, who will pay for these?

Human subjects from the following special population(s) may be involved in this study:

☐ Infants (<1 year) ☐ Children (1-17 years) ☐ Elderly (>59) ☐ Pregnant Women

☐ Prisoners ☐ Mentally Disabled ☐ Mentally Retarded ☐ None of these