**Not “Human Subjects Research” Protocol Template**

Only use this template if you intend to perform not-HSR, which may include Quality Improvement (QI). If you believe the project includes a Human Subjects Research component, do not use this template. You must submit a research application via Huron using a research protocol template found [here](https://www.medstarhealth.org/innovation-and-research/medstar-health-research-institute/research-support/mhri-irb#TemplatesForms4).

If you intend to perform QI, consider reviewing the [QI Determination Worksheet](https://www.medstarhealth.org/-/media/project/mho/medstar/innovation-and-research/medstar-health-research-institute/research-support/human-subject-research-versus-quality-improvement_10124.docx) before completing this protocol to help determine whether the project may be considered Human Subjects Research (HSR).

* Projects that intend to evaluate a device must submit a research application.
* Projects that include an intervention or evaluation of a program/curriculum that is not considered best practice or standard of care must submit a research application.
* Projects where the intervention or activity has already been completed as part of standard/clinical practice or standard educational curriculum, and the intent is now to reanalyze the data and publish as [generalizable knowledge](https://www.medstarhealth.org/innovation-and-research/medstar-health-research-institute/research-support/mhri-irb#BasicGuidance3), must submit a research application.

Please provide complete information for each item below. If a section is not applicable to your project, explain why.

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**Project title:**

**Project location(s):** *Specific MedStar location(s)(departments/units) where the project will take place***:**

**Statement of the local problem or process at MedStar/affiliates that this project seeks to address:**

**If you are not using the** [**MHRI Human Subjects Research Determination Tool**](https://researchdata.medstar.net/redcap/surveys/?s=C4PNNXWYXFHJYMPF)**, please answer the following questions:**

1. Does the activity pose more than [minimal risk](https://www.ecfr.gov/current/title-45/part-46#p-46.102(j)) to participants beyond privacy or confidentiality breaches?
2. How will the results of this project be disseminated/used inside and outside of the MedStar System?
3. Are you expecting the results of your project to be generalizable\*?
4. Provide a justification as to why the project should be considered not-HSR. *Consider the* [*Basic Guidance*](https://www.medstarhealth.org/innovation-and-research/medstar-health-research-institute/research-support/mhri-irb#BasicGuidance3) *on human subjects and research when you provide the justification.*

*\*****Generalizable Knowledge*** *means that*

1. *conclusions are drawn from instances,*
2. *knowledge that is widely or universally applicable outside of MedStar and*
3. *information obtained will advance the scientific, clinical, or academic literature.*

*Activities that meet this definition may be funded or unfunded or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.*

**Project Team Primary contact within MedStar:**

*Name:*

*Email:*

*Phone number:*

*Will any individuals external to MedStar be involved in this project*? Yes/No

**Timeline:**

Anticipated start date:

Anticipated completion date:

**Background:** *Please summarize any relevant background/literature [with references cited below]. Part of the background for QI projects should be presenting the national guidelines or evidence-based best practices being implemented.*

**Project Goals/Aims:** *What questions does this project intend to answer?*

**Project Plan:** *Please describe the following*:

1. Project design (retrospective review of a cohort, pre/post implementation, large data analysis without PHI)
	1. Describe any interventions included as part of this project
2. Define the target population (e.g., characteristics, exposures) and those you would exclude
3. Data collection plan:
	1. Describe what, if any, [protected health information](https://www.medstarhealth.org/innovation-and-research/medstar-health-research-institute/research-support/mhri-irb#BasicGuidance3) or personally identifiable information will be collected or accessed for this project
	2. Estimate the number of patients whose data may be accessed
	3. Estimate the number of patients whose data will be collected

*(e.g. you may need to access 1000 records to identify the 300 patients you are looking for)*

* 1. Include a data management plan that describes how data will be collected, stored, accessed, and managed, including efforts to minimize risks to confidentiality
		1. *Confirm that the project team will use encryption and store data behind the MedStar firewall*
	2. Include strategies you will implement to decrease the risk of a confidentiality breach
1. Evaluation plan to answer your project’s questions (i.e., use of observations, surveys, analysis plan).
	1. What is your primary outcome (*be as specific as you can; include units*)?
	2. What are your secondary outcomes (if any)?

**References:** *insert references here*