****

**Quality Improvement (QI) Determination Worksheet for Investigators**

**Instructions:**

1. Complete this worksheet to help determine if your project is QI vs Human Subjects Research.
2. Each row may include 0, 1, or 2 checks (i.e., some items may be yes for both Human Subjects Research and QI).
3. After completing the form below, interpret your results:

* More ‘yes’ marks under Human Subjects Research or if you have indicated Human Subjects Research to a question with an \* in the first column, your project is likely research. Your next steps:
  + Prepare a research protocol and submit to the IRB through Huron.
    - Ensure your CITI training & MedStar disclosure of outside interest (in COI Smart System) is current.
  + You will need a Huron account to submit your application electronically in the eIRB system.
* More ‘yes’ marks under QI suggests your project is QI. Note that some journals and conferences require a formal determination for QI projects. This determination must be made before intervention or data collection. Your next steps:
  + If you believe your project is QI **and** you do not need IRB documentation, you may begin your project.
  + If you are uncertain and/or want formal determination, submit to the IRB.
    - Describe your protocol as QI and submit through the Huron system.
    - The “Short title” & “Brief description” in your IRB application should indicate the project is QI.
    - Remove all references to research in the protocol.

1. Additional information

* Projects designed to develop and test a device (e.g. an algorithm, predictive model, mobile app) may be FDA regulated as medical devices requiring IRB oversight. Investigators conducting this work should submit to the IRB or seek consultation **prior to initiating their work**.
* Both Human Subjects Research and QI can be shared via publication and presentation.

If you have further questions or if you have not used the Huron system, please contact MHRI’s IRB Office at ORI.helpdesk@medstar.net or MedStar Health’s Compliance Office at [researchcompliance@medstar.net](mailto:researchcompliance@medstar.net).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Human Subjects Research** | **Y** | **Quality Improvement** | **Y** |
| **Primary Purpose\*** | Designed to develop or contribute to generalizable knowledge. |  | Designed to implement knowledge, assess a process, improve a program or delivery of care within accepted standards. |  |
| **Endpoint\*** | Answer a research question. |  | Improve a program, process, or system within MedStar Health. |  |
| **Risks\*** | May put participants at more than minimal risk. |  | Does not increase risk to individuals, except for possible risks to privacy or confidentiality of data. |  |
| **If you answer “Yes” to any question above in the Human Subjects Research column, prepare a research protocol and submit to the IRB through Huron** | | | | |
| **Design** | Follows a specific protocol designed to answer discrete research questions.  May be single or multicenter. |  | May follow a protocol but generally is an iterative process and may not be replicable.  Generally, single-center only (multiple MedStar Health hospitals are considered single-center). |  |
| **Benefits** | May or may not benefit current participant(s). Intended to benefit future patients/individuals. |  | Has the potential to directly benefit an established process, system or program. May or may not benefit patients or individuals. |  |
| **Analysis** | Statistically prove or disprove a hypothesis. |  | Compare program, process, or system to established standards/best practices. May include statistical analysis. |  |
| **Adoption of Results** | Intent to contribute to generalizable knowledge. |  | Intent to utilize results locally (e.g., for system enhancement). |  |
| **Publication/Presentation** | Investigator intends to share results |  | QI practitioners are encouraged to share systematic reporting of insights and may include publication/presentation. |  |
| **Total** | Total Number of “Y” in Human Subjects Research |  | Total Number of “Y” in QI |  |
|  |  |  |  |  |

Adapted from Johns Hopkins Medicine: <https://www.hopkinsmedicine.org/institutional_review_board/forms/QI_determination_worksheet.docx>