Determination Checklist

The following document is designed to help investigators determine if their proposed activities require IRB review.

- For a research project: Please utilize sections **A and B**.
- For a Quality Improvement Projects: Please skip ahead to the **Quality Improvement** section.

Is it human subject research under DHHS Regulations? (Both A and B)

A. "Human"

1. Does activity involve human subjects (obtaining information **about *living*** individuals)? Yes ☐ No ☐

2. Does activity involve the prospective collection of data or information through **intervention** or **interaction** with the individual? Yes ☐ No ☐

- **Intervention**: Physical procedure by which data are gathered **or** manipulations of the subject or the subject's environment are performed for research purposes.
- **Interaction:** Communication or interpersonal contact with individuals, including electronic interaction.

3. Does activity involve the collection or use of **Individually Identifiable** and/or **Private Information**? Yes ☐ No ☐

- **Individually Identifiable:** Information contains one or more elements that identify the individual **or** can be combined with other available information to ascertain the identity of the individual.
- **Private Information:** Information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or psychological information) **or** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

If "**Yes**" to Q1 **and** Q2, ***or*** Q1 **and** Q3, activity involves human subjects per DHHS regulations. Continue to section B (research determination).

B. "Research"

1. Is the activity **systematic**? Yes ☐ No ☐

- **Systematic:** Activity that involves data collection, either quantitative or qualitative, and data analysis to answer a question.

2. Is the activity an **investigation**? Yes ☐ No ☐

- **Investigation:** Activity that involves development, testing, evaluation, and/or search for information

3. Is the activity designed to **generate or contribute to generalizable knowledge**? Yes ☐ No ☐

- **Generalizable knowledge:** Activity that draws general conclusions (knowledge gained may be applied to other populations outside of study), informs policy, or is universally or widely applicable; contributing to generalizable knowledge **normally** involves public dissemination of that knowledge. ***Note**: If the intent of the project is Quality Improvement, publication does not necessarily render the project human subject research; see Quality Improvement section below.*

If "**Yes**" to Part A **and** "**Yes**" to Part B Q1 - Q3, activity meets the definition of human subject research per DHHS regulations and requires IRB review. To start the process to submit your project to the RSRB for review use the **Click Study Manual.**

Quality Improvement

Does the project involve quality improvement (QI)?

1. The goal of the project is to improve performance on a specific service(s), site(s), or program(s) as described by a **SMARTIE Aim statement** (e.g., we wish to equitably improve a metric from X to Y over the next Z months/years). Yes ☐ No ☐

2. There are no hypothesis-driven research questions being answered beyond the QI initiative. Yes ☐ No ☐

   *If "**No**" is selected or for additional information on research activities, please refer to sections **A and B** above.*

3. The unit/site administrators approve this as a QI project to be systematically implemented; activities do not require the consent of individual participants. Yes ☐ No ☐

4. If there is a possibility of publishing the outcomes of the QI initiative, the personnel involved will include the following statement with manuscripts: ***"This project was undertaken as a QI initiative, and as per the University of Rochester's Guideline for Determining Human Subject Research, did not meet the definition of research according to 45CFR46."*** Yes ☐ No ☐

If "**Yes**" to ***ALL*** items Q1-Q4, the activity is considered a Quality Improvement Project and does **"not"** require IRB review.

Notes

- *If at any time the answer to any of the above questions is "No," additional information is required from the Investigator or study staff to ensure an appropriate determination is made as to whether the activity involves human subject research. To start the process to submit your project to the RSRB for review, use the* **Click Study Manual.**

- *Activities determined to be QI projects (not research according to the respective regulatory definitions) are not under the oversight of the IRB. Therefore, such activities, and personnel conducting those activities, are under the oversight and responsibility of the respective department.*

If "**No**" to any of the items Q1-Q4, additional information is required from the Investigator or study staff to ensure an appropriate determination is made as to whether the activity involves human subject research. To start the process to submit your project to the RSRB for review, use the guide located **Click Study Manual.**

For *UR Medicine* projects for which there are questions regarding completion of the QI section, contact Anna Cannioto to submit your project for review at the weekly "QI QICC" Forum.
(585-275-8428) or **Anna_Cannioto@urmc.rochester.edu**