**To IRB or Not to IRB?**

**Questionnaire to help determine which projects/studies need approval by the Northwest Missouri State University IRB Committee**

Sometimes it may be difficult for you to decide if your project or study qualifies as human subjects’ research or not and if it needs IRB Committee approval. Please use this worksheet to assist you in determining if your project or study needs IRB approval. If you have any questions or are unsure, please reach out to us at irbnwms@nwmissouri.edu

**Instructions:**

1. Does your research involve any human subjects? **Yes**…see number 2. **No**…stop, your project does not need IRB approval.

2. Please read through the following options and place a check mark in the box that most aligns with your project or study.

3. If **all** the check marks are inside the **shaded gray boxes**, then the project is very likely Quality Improvement or Program Evaluation and **not** human subjects’ research. Projects that are **not** human subjects research do not need to be reviewed by the IRB.

4. If you check **any white boxes**, your project or study is research and **needs IRB Committee Approval.** Please complete the IRB Application and submit it and all related materials to the IRB Committee for review.

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| --- | --- | --- | --- |
| **Consideration** | **Question** | **Yes** | **No** |
| **PURPOSE 1** | Are you conducting a **systematic investigationA**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledgeB**? |  |  |
| **PURPOSE 2** | Do you want to apply your study findings to populations outside of the study group or the organization where study is being conducted?  |  |  |
| **PURPOSE 3** | Is the primary aim or motive of the project either to:* Improve care/processes **right now**? **OR**
* Improve operations, processes, or efficiency?
 |  |  |
| **RATIONALE** | Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on:* literature,
* consensus statements, or
* consensus among experts—e.g., guidelines
 |  |  |
| **METHODS 1** | Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback, and incremental changes? |  |  |
| **METHODS 2** | Do the methods include any of the following?* Control group
* Randomization
* Fixed protocol
 |  |  |
| **RISK** | Is the risk related to the project **minimal and no more than usual care or practices** (including the unavoidable minimal risk in implementing any changes made in processes)? |  |  |
| **PARTICIPANTS** | Will the activity **only** involve participants (patients, parents, students, or staff) who are **ordinarily** seen, cared for, or work in the setting **where** the activity will take place? |  |  |
| **FUNDING** | Is the project funded by any of the following?* An outside organization with an interest in the results—e. g. DESE, FDA
* A manufacturer with an interest in the outcome of the project relevant to its products
* A non-profit foundation that typically funds research, or by internal research accounts
 |  |  |

**Definitions:**

**Research definitions:**

Research is defined by the federal government as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research yields valid results through rigid implementation of a fixed protocol. The focus of research is on long-term gains in knowledge across a larger population than who is being studied. IRB approval and informed consent are required.

A. **Systematic investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

B. **Generalizable knowledge** means the project is designed to draw general conclusions, inform policy or generalize findings beyond a single individual or an internal program.

**Quality Improvement (Program Evaluation) definitions:**

Quality Improvement has been defined as systematic, data-guided activities, designed to brin about immediate improvements in delivery of healthcare, education, etc. in particular settings. Initiators of QI projects identify promising improvements, implement small scale changes, monitor results, and decide about additional changes and wider implementation. Quality improvement is a core function of improving **local or internal** processes. No IRB approval or informed consent is required.

**Projects that do not require IRB Application and Approval**

* Classroom projects - If a project is conducted for purposes of a **grade only** and results are **not disseminated outside the classroom**, then these projects do not require an IRB application form (does not meet definition of research where the intent is to contribute to generalizable knowledge).
* Quality improvement projects (does not meet definition of research) [see above definition and use table to determine if your project meets this definition.]
* Oral histories/journalistic activities (does not meet definition of research)
* Projects involving only analysis of de-identified information and/or biospecimens (does not meet definition of human subject)