**Determination of Human Subjects Research**

*This form is intended to help you determine if your project is research, and therefore requires IRB approval.*

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| **Where will the project be taking place?**  *A performance site is the location where the work described in the project will be conducted.* | |  |  | | --- | --- | | UICOMP | UnityPoint Health Methodist/Proctor/Pekin | | OSF HealthCare\*  Facility Name:  OSF Ministry-Wide\* | Illinois CancerCare  BCDI | | St. Jude Midwest Affiliate\* | Other: | |
|  | \* If you indicated an **OSF HealthCare facility** as the performance site, please “SHARE (Read-Only)” with Stephanie Madrigal in IRBNet for OSF tracking purposes. |

***INSTRUCTIONS:*** *If after completing this form you think your project does* ***NOT*** *require IRB review, please upload this completed form and all relevant supporting documents into* [*IRBNet*](https://www.irbnet.org) *so that a determination letter may be generated.*

***A Peoria IRB “Not Research/Human Subjects Research” determination does not mean an organization, institution, or department must allow a project to begin. It is the Project Leader’s responsibility to obtain appropriate organizational, institutional and/or departmental permissions and approvals prior to initiating the project they are proposing.***

*If after completing this form you think your project* ***REQUIRES*** *IRB review,* ***STOP*** *using this form. Instead, complete the Project/Protocol Review Form and submit the study (including a protocol, informed consent or waiver of informed consent, etc.) to the Peoria IRB via IRBNet.* ***PLEASE NOTE:*** *If think your project* ***REQUIRES*** *IRB review and you have indicated an OSF HealthCare facility as the performance site, you must first complete the* [*OSF Research Application Form*](https://www.osfhealthcare.org/research/investigators-coordinators/starting-new-research/) *and email to* [*osf.clinicalresearch@osfhealthcare.org*](mailto:osf.clinicalresearch@osfhealthcare.org)***before*** *submitting to the Peoria IRB.*

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| **Section 1: Project Information** |

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| **Investigator Name** |  |
| **Project Title** |  |

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| **Section 2: Project Personnel** |

List all PROJECT PERSONNEL: Project personnel are individuals who are performing the work described in the project.

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| **Name** | **Degree** | **Role(s)** |
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| **Section 3: Current Status of the Project** |

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| Has the project already been conducted (i.e. data has already been collected and analyzed)?  Yes  No ***If yes, the Peoria IRB may make a determination that the project does not represent research or human subjects research, but if the Peoria IRB determines the completed project represents research, the IRB CANNOT grant a retroactive research approval.*** |

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| **Section 4: Specific activities that typically do NOT represent “Human Subjects Research” requiring IRB review** |
| **1.** **Quality Improvement/Quality Assurance Activities:** The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.  ***Note: Please SKIP the rest of this section and jump to SECTION 6. COMPLETE the detailed chart on the last page that outlines the differences between a QI project and a research study.*** |
| **2. Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.  ***Note: If a case report contains any of the 18 protected health information (PHI) identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.*** |
| **3.** **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.  The following activity is deemed not to be research:  Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. If the focus includes generalizing to other individuals, then the activity may be research and should be evaluated against the definition of research (which is done below). |
| **4.** **Public Health Surveillance:** Public health activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, access, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. |

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| **Instructions:**   * **If your activity did NOT fall into one of the categories (1-4) described in Section 4 above, continue to Section 5 to assess if you are engaged in human subjects research per the regulations.** * **If your activity DID fall into categories 2, 3, or 4 described in Section 4 above, skip section 5 and submit this completed form and your protocol or project summary, and any other relevant supporting documents to the Peoria IRB via IRBNet for formal assessment.** |

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| **Section 5: Activities subject to**  **HHS human subject research regulations (45 CFR 46)** |

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| **DEFINING RESEARCH & HUMAN SUBJECTS**    **Research** is defined in the Code of Federal Regulations, 45 CFR 46.102(l), as a systematic investigation designed to develop or contribute to generalizable knowledge.  The Belmont Report states “. . . the term ‘research’ designates an activity designed to test a hypothesis or formal protocol that sets forth an objective and a set of procedures to reach that objective.”    **Generalizable knowledge** is information where the intended use of the research findings can be applied to populations or situations beyond that study. Note that publishing the results of a project does not automatically meet the definition of generalizable knowledge.    **Human subject** is defined in the Code of Federal Regulations, 45 CFR 46.102(e), as a living individual about whom an investigator (whether professional or student) conducting research:   * Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR * Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. |
| **1. Is the study a systematic investigation?** (Systematic means having or involving a system, method, or plan.) In other words, do you have a hypotheses or research question and a formulated plan to gather data that might support the hypothesis, or answer the research question?    Examples of studies that are systematic include:   * Gather information for the purpose of hypothesis building or testing * Ask individuals the same sets of questions, or obtain the same kind of information from them. * Apply the same measures in gathering the data – whether through interaction, observation, or experiment. * Utilize data collection methods that can be replicated.   Yes  No |
| **2.** **Is the study designed to contribute to generalizable knowledge?** Generalizable knowledge is information that will contribute to the field or area being studied, and may be of interest or applicable to people outside of your study population. Quality improvement (QI) and program evaluation projects are typically done to assess something specific and the results are not generalized or shared with others. Instead the results are kept with the investigator/department/hospital and are used internally to make improvements or guide decision making.     * Your study contributes to generalizable knowledge if you intend for findings from it to be applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the study. * If the study activities involving people are conducted solely for the purpose of fulfilling a course requirement, they are not considered research because they are not designed to contribute to general knowledge. However, activities involving people that are conducted in conjunction with the requirements of a thesis or dissertation generally are research because the purpose of the thesis or dissertation is by definition to make a contribution to general knowledge.   Yes  No |

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| **Instructions:**   * **If you answered “No,” to either question 1 or 2, skip questions 3-5 and submit this completed form and your protocol or project summary, and any other relevant supporting documents to the Peoria IRB via IRBNet for formal assessment.** * **If you answered “Yes,” to questions 1 and 2, continue to the next set of questions to determine if human subjects are involved in your research.** |

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| **3.** **Does the research involve obtaining information about, or biospecimens from, living individuals?** *This might include information regarding a living person’s (or group of people’s) opinions, thoughts, behaviors, or medical information. This does not include information gathered solely about an organization, event, or processes, or specimens/information from subjects who are now deceased.*    Information about or biospecimens from an individual includes, but is not limited to, the following:   * Ideas, attitudes, attributes, opinions, feelings, experiences, thoughts, behaviors, beliefs, assessments, reflections, etc., reported by a living individual, even when the living individual provides the information while working in a professional capacity. * Information about living individuals that was gathered by another researcher or source. * Information about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery. * Samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein from living individuals.   Yes  No |

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| **Instructions:**   * **If you answered “No,” to question 3, skip questions 4-5 and submit this completed form and your protocol or project summary, and any other relevant supporting documents to the Peoria IRB via IRBNet for formal assessment. If you answered “No” to question 3 and are obtaining information about deceased individuals, please contact the IRB office to request the HIPAA “Research on Decedents” Form.** * **If you answered “Yes,” to question 3, continue to questions 4-5.** |

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| **4.** **Does the research involve obtaining information or biospecimens through intervention or interaction with individuals and uses, studies, or analyzes the information and/or biospecimens?**    Intervention includes:   * Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. * e.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.   Interactions involve:   * Communication or interpersonal contact between the investigator and the subjects, and can be in-person, through email or social media, or by completing a survey or interview or focus group. * e.g., a street interview, an online survey recording posts on a blog or listserv, a mailed questionnaire, etc.   Yes  No |
| **5.** **Will you obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens from individuals?**    Private information includes:   * Information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place. * Information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (e.g., a medical record, emails, certain listserv communications, class papers and exams, etc.) * Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.     Biospecimens include:   * Samples or specimens of material, such as urine, blood, tissue, cells, DNA, RNA, and protein. * Identifiable biospecimen is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.   Yes  No |

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| Instructions:   * If you answered “No,” to questions 4 and 5, your answers indicate that your project is not human subjects research. Please submit this completed form and all relevant supporting documents to the Peoria IRB via IRBNet for formal assessment. * If you answered “No” to questions 4 and 5, but you will need to review the electronic medical record (EMR) to identify potential subjects and you plan to remove the 18 (PHI) identifiers when collecting the data, **STOP** using this form. Instead, complete the Project/Protocol Review Form and submit the study (including a protocol, informed consent or waiver of informed consent, etc.) to the Peoria IRB via IRBNet. If you indicated an OSF HealthCare facility as the performance site, you must first complete the OSF Research Application Form and email to osf.clinicalresearch@osfhealthcare.org before submitting to the Peoria IRB. * If you answered “Yes,” to either question 4 or 5, **STOP**, your project DOES involve human subjects and you will need submit the study (including a protocol, informed consent or waiver of informed etc.) to the Peoria IRB via IRBNet. |

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| **Section 6: How Does QI Differ from Research?** |

Both quality improvement (QI) and research are investigations that may involve human participants, but they differ in important ways. This Worksheet can help you determine if your project is in fact QI, or potentially human subjects research.

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|  | **Human Subjects Research** | **Y** | **N** | **Quality Improvement (QI)** | **Y** | **N** |
| **Purpose** | Designed to develop or *contribute to generalizable knowledge.* |  |  | Designed to implement knowledge, assess a process, *improve a program or delivery of care* with consideration of established or accepted standards. |  |  |
| **Starting Point / Intent** | Intended to *answer a question* or *test a hypothesis.* |  |  | Knowledge-seeking is integral to ongoing management of a program or system, including a health-care delivery system. |  |  |
| **Design** | Follows a specific protocol. *Designed to answer discrete research questions*.  May be single or multicenter. Funding may be external or internal. |  |  | Adaptive, iterative.    Generally single center only.    Generally not externally funded |  |  |
| **Benefits** | Intended *to benefit future patients/individuals*. Might or might not benefit current participants. |  |  | Intended to directly *benefit a process, system or program*; Might or might not benefit patients or individuals. |  |  |
| **Risks** | May put participant at risk |  |  | Does not increase risk to patients, with exception of possible risks to privacy or confidentiality of data. |  |  |
| **Endpoint** | *Answer a research question.* |  |  | *Improve a program, process or system.* |  |  |
| **Analysis** | Statistically prove or disprove a hypothesis. |  |  | Compare program, process or system to established standards/best practices |  |  |
| **Adoption of Results** | Intent to contribute to generalizable knowledge.    Avenues for dissemination could include scientific presentation/publication |  |  | Intent to utilize results locally [e.g. for system enhancement]    Insights from initiatives may be shared  [e.g. in a QI journal] |  |  |
| **Publication/Presentation** | Investigator obliged to share results. |  |  | QI practitioners/investigators encouraged to share reporting of insights. |  |  |

\*Adapted from Children’s Hospital of Pennsylvania: <https://irb.research.chop.edu/quality-improvement-vs-research>

If you tally the higher number of ‘yes’ marks under the Human Subjects Research header, please submit your project (with a protocol) to the IRB.

If you tally the higher number of ‘yes’ marks under the QI header, your project is likely QI and is not human subjects research.