Office of Research, Grants and Contracts
Standard Operating Procedures (SOP)

SOP Title	Determination of Activities that Need IRB Review				
Date Last Revised	12/06/2018	**Date Created**	08/22/2018	**Revision #**	
SOP Number	23	**Required by:**	☒OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☐Researcher	☒Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

To describe procedures for determining the types of activities that qualify as human subjects research or clinical investigations and therefore require prior Institutional Review Board (IRB) review and approval.

2.0 GENERAL INFORMATION AND SCOPE

In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a Northern Kentucky University (NKU) faculty, staff, or student conducts human subjects research. It is the responsibility of each Principal Investigator (PI) to seek IRB review for approval prior to initiation of any projects that meet the federal definition of human subjects research.

Steps for determining if IRB review is required:

Step 1: Does the project meet the definition of research? (No = IRB review not required)

Step 2: Does the project meet the definition of human subjects? (No = IRB review not required)

Step 3: Is the project no more than minimal risk and does it fall into one of the exempt categories? (Yes = Exempt IRB review required)

Step 4: Is the project no more than minimal risk and does it fall into one of the expedited categories? (Yes = Expedited IRB review required)

Step 5: If the study is not approvable as exempt or expedited a convened board required

3.0 PROCEDURES

1. The PI is responsible for making a preliminary decision to determine if the project meets the federal definition of human subjects research. The NKU IRB has several diagnostic tools and decisions trees to aid the PI in making this determination and IRB staff is available for consultation. The PI can contact the IRB Administrator or the IRB Chair for assistance in making this determination.
2. In cases where it is not clear whether the study requires IRB review, the IRB Administrator, Manager of Research Compliance, or IRB Chair may request that the PI complete a preliminary application through Mentor IRB to aide in making the determination.

4.0 REFERENCES

45 CFR 46

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Research: A systematic investigation designed to develop or contribute to generalizable knowledge [45CFR 46.102(d)]. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed not to be research:

> (1) 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.
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> (2) Public health surveillance 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, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
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> (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
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> (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human subjects (DHHS): A living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens [45 CFR 46.1.02].

Intervention: Includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes [45 CFR 46.102 (e)(2)].

Interaction: Includes communication or interpersonal contact between investigator and subject.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably except that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

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.

Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Clinical Trial (OHRP/NIH): A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other controls) to evaluate the effects of the interventions on biomedical or behavior health-related outcomes).

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	11/15/2018	☐
IRB Chair	☒	11/15/2018	☐
Institutional Official	☒	11/15/2018	☐

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	12/06/2018	☐	Addition of revised common rule information.
IRB Chair	☒	12/06/2018	☐	
Institutional Official	☐		☐	