SOP Title	Initial Review of Research - Expedited Review				
Date Last Revised	12/06/2018	Date Created	08/09/2018	Revision #	
SOP Number	22	Required by:	☒OHRP ☐Funding Agency ☐OLAW		
Applicability	☒ RGC Internal	☐Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for the expedited review of human subjects research at Northern Kentucky University regardless of funding source.

2.0 GENERAL INFORMATION AND SCOPE

All human subjects research conducted at NKU or by NKU's faculty, staff, or students must be prospectively reviewed and approved by the IRB designated by this institutions' Office of Research Grants and Contracts. No human subject research may be initiated or continued at NKU or by NKU s faculty, staff, or students without prospective approval of the NKU IRB.

The Institutional Review Board (IRB) uses an expedited review process to review studies that meet the present no more than minimal risk to subjects and involve only procedures listed in one or more of the expedite categories set forth by the Office of Human Research Protections (OHRP). Expedited review procedures allow the IRB to review and approve studies that meet the criteria without convening a meeting of the full IRB. The IRB Chair or one or more experienced reviewers conducts expedited initial review.

The expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.110. Also, expedited reviewers ensure that the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 unless the IRB waives the requirements in accordance with federal regulations.

Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity in accordance with non-expedited procedures set forth in the DHHS.

The IRB agenda for convened (full) board meetings advises the IRB of research studies approved using expedited review procedures. Any member can review any IRB projects submitted and approved as expedited through Mentor IRB.

3.0 PROCEDURES

A. ASSIGNING REVIEWERS

1. Any experienced IRB member may be assigned to review expedited projects.

The expedited reviewer notifies the IRB Administrator if he/she is not available to conduct expedited review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP (SOP #24 (IRB) IRB Member and Consultant Conflict of Interest). The IRB Administrator will document reviewer study assignment in the Mentor IRB system.

B. SCREENING AND SUBMISSION

1. The PI, IRB Administrator, or reviewer may make the preliminary request for expedited review based on an assessment of the protocol ensuring that it falls into one or more of the categories specified within the federal regulations. However, the IRB member or IRB Administrator makes the final determination regarding whether a protocol is eligible for expedited review. The PI will submit the application via Mentor IRB following procedures for protocol submittal (SOP #12 (IRB) Submitting a New Protocol).

2. Upon submittal, an IRB Administrator will conduct a pre-review of the project to ensure the application has been completed, required documents have been uploaded, and training has been completed by research personnel. At this time, the IRB Administrator will either confirm the expedited category or consult with the Manager of Research Compliance to confirm the expedited category. If the submission is incomplete or the protocol does not qualify for expedited review, the IRB Administrator or Manager of Research Compliance will communicate with the PI via the Mentor IRB system and change the review type. The IRB Administrator will complete a pre-review worksheet to verify the completion of pre-review in Mentor IRB.

3. Mandatory Training: All researchers listed on an IRB protocol must complete the four required trainings (History and Ethical Principles, Assessing Risk in Social and Behavioral Sciences, Informed Consent, and Privacy and Confidentiality) in the CITI training system.

   Study – Specific Training: If the study is deemed clinical trial by NIH, the IRB Administrator will verify the additional Good Clinical Practices Training. If any of the research personnel will come into contact with human blood, the IRB Administrator will email the PI and NKU's Department of Safety and Emergency Management to facilitate the required Bloodborne Pathogen training and to determine any additional vaccinations requirements (i.e. Hep B).

   Population – Specific Training: If the study involves a vulnerable or unique population, the IRB may request that the researchers complete additional training modules including but not limited to Research with Prisoners, Research with Children, or Research in Public Elementary and Secondary Schools in the CITI training system.

C. IRB EXPEDITED REVIEW

1. The IRB Administrator or Manager of Research Compliance ensures the documentation of federally mandated specific findings (e.g. Subpart B, C, D, or waiver of informed consent, or waiver of documentation of informed consent).

2. After confirming that the project is completed and the expedited category is appropriate the Manager of Research Compliance, IRB Administrator, or IRB Chair will assign an IRB reviewer for review. Typically, only one reviewer is assigned per project, however, more reviewers may be assigned if necessary.

3. The reviewer is responsible for reviewing the application upon assignment to determine that all of the research procedures fit one or more of the expedited categories specified in the federal regulations. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects.

4. The reviewer will have access to:
   a. The application (via application sections) within Mentor IRB
   b. The informed consent/assent process and forms including waiver requests
   c. HIPAA forms, if applicable
   d. Recruitment materials
   e. Data collection instruments
   f. Materials/letters of support for off-site research
   g. Information regarding any potentially vulnerable populations including forms for research involving individuals with impaired consent capacity, pregnant women, fetuses, and/or neonates, prisoners, or children

5. All expedited reviews will utilize various review checklists available in Mentor IRB to ensure that the minimum requirements have been met. If additional revisions are required, the reviewer will send the revisions to the PI through Mentor IRB. The reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111. . Expedited reviewers ensure that the PI will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117, unless the IRB waives the requirements in accord with federal regulations. The expedited reviewers only raise those controverted issues or request changes that they have determined do not meet the federal criteria for approval or NKU IRB policies.

D. REVIEW OUTCOME(S)

1. The reviewer makes one of the following recommendations by completing the review checklists available in Mentor IRB as soon as possible but no later than 10 business days from assignment. If the reviewer cannot complete the review within 10 business days, the reviewer must contact the IRB Administrator or Manager of Research Compliance.

   a. Revisions required, resubmit to the Reviewer. Revisions are required before approval can be granted. After revisions are completed, the PI resubmits to the reviewer. The PI is responsible for submitting any requested revisions in the Mentor IRB system. The reviewer determines whether the revisions are sufficient for approval of expedited status, and, if so, the IRB Administrator or Manager of Research Compliance sends an approval letter to the PI. If the reviewer determines the revisions are insufficient, he/she may request that the PI make

further revisions. This review and revision process continues until the research is either approved or disapproved as expedited.

b. Revisions required. After revisions are completed and verified by the IRB Administrator or Manager of Research Compliance, approval can be granted. The PI is responsible for submitting any requested revisions in the Mentor IRB system. The IRB Administrator or Manager of Research Compliance determines whether the revisions are sufficient for approval of expedited status, and, if so, the IRB Administrator or Manager of Research Compliance sends an approval letter to the PI. . If the IRB Administrator determines the revisions are insufficient, he/she may request that the PI make further revisions. This review and revision process continues until the research is either approved or disapproved as expedited.

c. Disapproved of expedited status with rationale for disapproval and recommendations for submission of expedited or full review which may require additional documents or additional information in the Mentor IRB system. The expedited reviewer may not disapprove research.

d. Approval.

2. The reviewer can also recommend that the activities do not require IRB oversight (not meeting the definition of human subjects research). In these cases, the IRB Administrator or Manager of Research Compliance must confirm this finding and issue the final determination letter of not human subjects research – IRB review not required.

E. APPROVAL OF EXPEDITED PROTOCOLS

1. After review, completion and confirmation of the expedited status via one of the three processes listed above, the Manager of Research Compliance issues the approval notice through the Mentor IRB system to the PI.

2. Research approved under an expedited category does not require continuing review unless the IRB deems necessary (45 CFR 46.109(f)(1)). If the IRB requires continuing review of an expedited project the rational for doing so much be documented (see SOP #27 (IRB) Continuation Review).

3. If continuing review is not required, approximately one month prior to the anniversary of approval, Mentor IRB will automatically send an email to the PI which reminds them to terminate the protocol when appropriate (see SOP #15 (IRB) PI - Terminating a Protocol).

4. If continuing review is required, the PI will receive reminder as the expiration date approaches reminder him/her to submit a continuing review (see OP #14 (IRB) PI - Submitting Continuing Review) or study termination (see SOP #15 (IRB) PI - Terminating a Protocol).

5. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, the PI may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The PI may send the request to the IRB Chair, IRB Administrator, or Manager of Research Compliance for final resolution. If the PI is still dissatisfied with IRB decision, he/she may send the study to the full IRB for review.

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.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

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	☐		☐	