



SOP Title	Initial Review of Research - Exempt Review				
Date Last Revised	12/06/2018	Date Created	08/07/2018	Revision #	
SOP Number	21	Required by:	<input checked="" type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
Applicability	<input type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input checked="" type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

1.0 PURPOSE

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

2.0 GENERAL INFORMATION AND SCOPE

All human subjects research conducted by NKU’s faculty, staff, or students must be prospectively reviewed and approved by the NKU IRB. No human subject research may be initiated or continued at NKU by NKU faculty, staff, or students without prospective approval of the NKU IRB.

Research procedures that meet the categories set forth by the federal regulations (45 CFR 46.104) may qualify for exemption. At Northern Kentucky University, projects that meet the federal definition of human subjects research and fall into an exempt category must be submitted to the NKU IRB through Mentor IRB.

3.0 PROCEDURES

A. ASSIGNING REVIEWERS

Any IRB member may be assigned to review exempt protocols including those requiring limited IRB review.

An experienced IRB Administrator may conduct the review of exempt protocols that do not require IRB review if delegated the responsibility by the Manager of Research Compliance or IRB Chair.

B. SCREENING AND SUBMISSION

1. The PI, IRB Administrator, or reviewer may make the preliminary exemption request based on an assessment of the protocol by verifying that it falls into one or more of the categories specified within the federal regulations. While the PI may make the preliminary request for exemption, the IRB reviewer, Chair, or IRB Administrator makes the final determination of exemption eligibility. The PI will submit the application via Mentor IRB following procedures for protocol submittal (SOP #12 (IRB) PI – Submitting a New Protocol).
2. Upon submittal, an IRB Administrator will conduct a pre-review of the protocol to ensure the application is complete, required documents have been uploaded, and training has been completed by research personnel. At this time, the IRB Administrator will either confirm the exemption category or consult with the Manager of Research Compliance to confirm the

exemption category. If the submission is incomplete or the protocol does not qualify for exemption, 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. During the review, the reviewer ensures that the research does not:
 - a. Specifically target prisoners
 - b. Include the observation of children where the researcher participates in the activities being observed (this applies to exemption category #2 only)
 - c. Survey or interview techniques which include children as subjects (this applies to exemption category #2 only)
4. 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 Audra Points in the Department of Safety and Emergency Management to facilitate the required Bloodborne Pathogen training and offer any additional vaccinations (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 EXEMPT REVIEW

1. After confirming that the protocol is completed and the exemption category is appropriate, one of three things may happen:
 - a. If delegated by the Manager of Research Compliance or IRB Chair, an experienced IRB Administrator may review and verify exemption of studies that do not require limited IRB review.
 - b. The IRB Administrator will assign the Manager of Research Compliance as the reviewer.
 - c. The Manager of Research Compliance or IRB Administrator may assign an IRB reviewer for review and verification of exemption. An IRB member must review exempt projects that require limited IRB review.
2. The reviewer is responsible for reviewing the application upon receipt to determine that all of the research procedures fit one or more of the exemption categories specified in the federal regulations. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects.

3. During the review, the reviewer ensures that the research does not include any of the following:
 - a. Specifically target prisoners
 - b. Survey or interview techniques which include children as subjects (this applies to exemption category #2 only)
 - c. The observation of children where the researcher participates in the activities being observed (this applies to exemption category #2 only)

4. Any person reviewing the protocol 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 exemption 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 comments to the PI through Mentor IRB.

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 recommended. 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 verification of the exempt 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 verified as exempt or disapproved as exempt (moving to expedited or convened (full) review).
 - b. *Revisions required. Resubmit to the IRB Administrator.* After revisions are completed, the IRB Administrator or Manager of Research Compliance can issue final approval. 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 verification of the exempt 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 exempt.
- c. *Disapproved* of exemption 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.
 - d. *Approval* (verification of exemption).
2. The reviewer can also recommend that the activities do not fall under IRB purview (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. VERIFICATION OF EXEMPT PROTOCOLS

1. After verification of the exemption status, the Manager of Research Compliance or an experienced IRB Administrator issues the final verification of exemption protocol through the Mentor IRB system to the PI.
2. When the IRB has certified a research study as exempt, the IRB does not require continuing review. The exemption approval period does not expire. 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.
3. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she 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.

(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).

(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.

(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 expect 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	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>
IRB Chair	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>
Institutional Official	<input checked="" type="checkbox"/>	11/15/2018	<input type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	12/06/2018	<input type="checkbox"/>	Addition of revised common rule information.
IRB Chair	<input checked="" type="checkbox"/>	12/06/2018	<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	