**NEWMAN UNIVERSITY**

**APPLICATION FOR PROJECT/PROPOSAL APPROVAL**

**INSTITUTIONAL REVIEW BOARD (IRB)**

The ‘APPLICATION PROCEDURES BY REVIEW TYPE’ (following this form) can assist you in determining what type of IRB review to request as well as which review category to choose.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| REQUEST FOR: | Full Review | | |  | | | |
| (Select one) | Expedited Review | | |  | | | | |
|  | Expedited Review Category | | | Choose a category | | | | |
|  | Limited Exempt Review | | |  | | | | |
|  | Limited Exempt Review Category | | | | Choose a category | |
|  | Exempt Review  Exempt Review Category | | | Choose a category | | | | |
| **Name of Principal Investigator(s):** | | | First Name Last Name | | |
| (For a student project, Principal Investigator must be a NU faculty member; student is listed as Co-Investigator) | | | | | |
| **Department/Program Affiliation:** | | Department | | | |
| **Campus Address:** | | Building Room No. | | | |
| **Street Address (if not on Campus):** | | Institution  Street  City State 00000 | | | |
| **Name of Co-Investigator(s):** | | First Name Last Name  First Name Last Name  First Name Last Name | | | |
| **Co-Investigator is:** | | Choose an item. | | | |
| **Type of Project:** | | Choose an item. | | | |
| **Title of Project/Proposal:** | | Project Title | | | |
| **Expected Completion Date:** | | Date | | | |

1. **A brief description of the research in non-technical language:**

Click or tap here to enter text.

2. **A description of the benefits of the research to the human subjects, if any, and of the benefits to human or scientific knowledge:**

Click or tap here to enter text.

3. **A description of the subjects, how the subjects are to be selected, how many are to be used, and indicate explicitly whether any are minors (under age 18 per Kansas law ) or otherwise members of "vulnerable" populations, e.g., prisoners, elderly, handicapped, etc.:**

Click or tap here to enter text.

4. **A description of how the subjects will be used:**

Click or tap here to enter text.

5. **A description of the risks and discomforts, if any, to the subjects. Risks or discomforts may be physical, psychological, or social. Some research involves neither risks nor discomforts but rather violations of normal expectations of daily life. Such violations, if any, should be specified:**

Click or tap here to enter text.

6. **A description of the means to be taken to minimize each risk or violation, including the means by which the subject's personal privacy is to be protected and confidentiality of information received maintained (e.g., disposition of questionnaires, interview notes, recorded audio or videotapes, etc.):**

Click or tap here to enter text.

7. **If a waiver of written informed consent is desired, a justification of the request:**

Click or tap here to enter text.

8. A copy of any consent form that is to be used with the subjects, including a line for signature and date, must be attached. **The consent form is to be placed on NU departmental letterhead.** Consent forms must be retained for three years.

9. **Any other information pertaining to the researcher's ethical responsibilities to the subjects:**

Click or tap here to enter text.

10. Any questionnaire or survey forms used for actual administration or as guides for interviews must be attached.

**The Principal Investigator agrees to abide by the federal regulations for the protection of human subjects and to maintain raw data (including audiotapes and videotapes) and consent forms for a minimum of three (3) years beyond the completion of the study. If the data collection or testing of subjects is to be performed by student assistants, the Principal Investigator will assume full responsibility for supervising the students to ensure that human subjects are adequately protected.**

|  |  |
| --- | --- |
| X | Date |

Signature of Principal Investigator

**APPLICATIONS PROCEDURS BY REVIEW TYPE**

EXEMPTED REVIEW

There are several cases that may “exempt” your protocol from full IRB review. If you request an exemption, you need to submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The following categories are exempt from full review:

|  |  |
| --- | --- |
| **Exemption Category Description** | **Conditions/Allowances/Limitations** |
| 1. Research, conducted in established or commonly accepted educational settings; | Not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. |
| 1. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording); | Recorded information cannot readily identify the subject or any disclosure of responses outside of the research would not reasonably place subject at risk. No children. |
| 1. Research involving benign behavioral interventions (BBI) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection; | Recorded information cannot readily identify the subject or any disclosure of responses outside of the research would not reasonably place subject at risk.  May not include medical interventions. Subject prospectively agrees.  BBI must be:   * Brief in duration * Painless/harmless * Not physically invasive * Not likely to have a significant adverse lasting impact on subjects * Unlikely that subjects will find interventions offensive or embarrassing   There can be no deception unless participant prospectively agrees. No children. |
| 1. Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other ‘primary’ or ‘initial’ activity; | * Information is publically available; or * Information is recorded so subject cannot readily be identified and investigator does not contact subjects and will not re-identify the subjects; or * Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA; or * Research information is collected by or on behalf of federal government using government generated or collected information obtained for non-research activities. |
| 1. Research and demonstration projects supported by a Federal Agency/Dept. and designed to study, public benefit or service programs; | Must be posted on a federal web site. |
| 1. Taste and food quality evaluation and consumer acceptance studies; |  |
| 1. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required; | All requirements for broad consent are met. |
| 1. Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required. | Privacy and confidentiality protections are adequate; broad consent was obtained; documented or documentation waived; and no plan to return research results. |

LIMITED EXEMPTED REVIEW

The IRB will use the expedited review procedure to review research for which limited IRB review is a condition of exemption. If you request a limited exempt review, you need to submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The IRB conducts a limited review of privacy and confidentiality for all the following exempt categories with the stated limitations:

|  |  |
| --- | --- |
| **Limited Exemption Category Description** | **Limitations** |
| 1. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording); | Information is recorded with identifiers. |
| 1. Research involving benign behavioral interventions (BBI) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. | Information is recorded with identifiers. |
| 1. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required; | There is a change made for research purposes in the way material is stored or maintained. |
| 1. Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required. |  |

EXPEDITED REVIEW

Expedited review is provided for research that involves no more than minimal risk or for review of minor changes in previously approved research protocols. In order to approve research covered by the regulations, an IRB subcommittee will determine that all of the following requirements are satisfied. (The list below is utilized for all projects under IRB review):

1. risks to subjects are minimized;
2. risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
3. selection of subjects is equitable;
4. informed consent will be sought from each prospective subject or the subject’s legally authorized representative;
5. informed consent will be appropriately documented;
6. when appropriate, the research plan makes adequate provision for monitoring data collected to ensure safety of subjects; and
7. when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Submit ONE copy of the application, the research protocol, and consent form. On the application form, select one of the categories below. The list includes research with human subjects that involves:

1. Collection of hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra-and subgingival plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recording made for research purposes, such as investigation of speech defects.
7. Moderate exercise by healthy volunteers.
8. Study of existing data, documents, records, pathological specimens or diagnostic specimens.

FULL REVIEW

Full committee review is required for all research involving greater than minimal risk to subjects. In addition, full review is required for all research activities involving vulnerable subject populations, including fetuses, pregnant women, human in vitro fertilization, prisoners, children, elderly, and psychiatric patients.

Submit ONE copy of the research protocol, consent form, and abstract of your research proposal.