**Prior to Completing this IRB Application**

It is important to note that an IRB application should only be completed if the project, by definition, is a human subjects research activity. Prior to completing the application that follows, consider if the project you are proposing is actually human subject research requiring Institutional Review Board (IRB) review. Many times lengthy applications are received by the IRB for non-research projects. These projects usually are quality assurance, program evaluation, or institutional effectiveness purposes and do not require IRB review or oversight. These types of non-research projects generate data collected from humans, just like human subjects research, but do not meet the federal definition of regulatory research requiring review by an IRB. This is mainly because the results generated are not applicable outside of the immediate research environment and will not contribute to any larger body of knowledge on the project’s topic (i.e. not generalizable). In addition, the information gathered in these other types of projects is NOT about the person responding per sae, but the respondent is being asked for information about a program, process, or work/education environment. This type of information may be gathered in the form of a survey, telephone calls, focus groups etc or other research-like methodology.

With that being said, if conducting research is your intent (your results are about people and will be generalizable and you have a strong hypothesis with supporting research questions) there are expectations as to the scientific quality, methodology, and ethical content contained in this application. These areas must be full developed before the IRB can give final approval to conduct the project.

If you are unsure of the definition of “evaluation” or “human subject research”, please read the linked information sheet which contrasts [evaluation activities from human subject research activities](https://www.neomed.edu/wp-content/uploads/IRB_EvaluationVsResearchChart.docx).    Although not research, these other types of non-research data collecting activities described are scholarly and may be published and presented provided they are portrayed as those types of activities which are separate from human subject research.  For more information on quality assurance, quality improvement/organizational effectiveness contact the NEOMED Office of Institutional Research 330-325-6333, or view the video presentation “[Research, Quality Improvement and Program Evaluation.  What’s the Difference and Who Cares?”](https://neomed.mediasite.com/Mediasite/Play/f0285373984c4ad1917bb3364e5c95241d).

|  |
| --- |
| logo  Institutional Review Board (IRB)  Office of Research and Sponsored Programs  **FOR USE WITH STUDIES INVOLVING BEHAVIORAL or BIOMEDICAL**  **HUMAN SUBJECTS RESEARCH**  **EXEMPT, EXPEDITED AND FULL BOARD REVIEW PROCESS FORM** Form APRIL2023 |

**Application Instuctions:**

Please answer all questions contained in this application.   If a question is non-applicable, type “N/A” to indicate you have read the question.  Please submit a signed, scanned copy to:  Trish Wilson, Regulatory Affairs Coordinator, [paw@neomed.edu](mailto:paw@neomed.edu).  Please submit the application as one complete document, not separate e-mails or attachments.  Individual e-mailed attachments over several different e-mails will not be accepted.  Full board review materials for projects above minimal risk must be submitted three weeks prior to the IRB’s scheduled meeting date.  Please expect an exempt or expedited review for minimal risk research to take a minimum of 10 business days.  Please plan accordingly since application revisions may be required after the application’s initial review which require additional time to complete.

For is list of common errors made when completing this application, please [click here](https://www.neomed.edu/wp-content/uploads/IRB-Application-Errors.pdf).

**PRINCIPAL INVESTIGATOR ASSURANCE:**

I agree to follow all applicable policies and procedures of Northeast Ohio Medical University (NEOMED) and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to the following:

* Perform the research as approved by the IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel with adequate resources;
* Understand that the parameters of the research cannot be modified without approval by the NEOMED IRB (except where necessary o eliminate apparent immediate hazards to participants);
* Agree to maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
* Will retain research-related records for audit for period of at least three years after the research as ended (or longer, according to sponsor or publication requirements) even if I leave the University;
* I will file an Amendment Form with the NEOMED IRB to amend the study (to request a change in PI) or to terminate the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g. sabbatical or extended leave);
* Agree to inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.
* All student conducted/mentored projects must have a faculty member as PI list on this application.

|  |
| --- |
| **Principal Investigator Signature:**  **I verify that the information provided in this IRB Application is accurate, complete and an appropriate activity for submission to the IRB. Please be reminded the NEOMED IRB’s only authority is to review, approve, and provide oversight of activities that meet the federal definition of human subject research and does not include projects conducted for the purpose of class, course, or program evaluation, quality improvement, or institutional effectiveness. For information on these types of projects, please contact the Office of Institutional Research at 330-325-6333.**  Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If this is a student project, signature of student: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| APPLICATION PACKAGE CHECKLIST |

1. **Materials appearing in the list below must be developed, in written form and submitted as part of this application package.**

Check the boxes to indicate which documents will be included in this package. (To check the box double click the box, click on

“checked” under default option.)

**The Application Form**

**Questionnaires/surveys or other data collection instruments.**

**Consent form(s) or an Information Sheet**.

All studies must include either a Consent Form or an Information Sheet, depending on the type of study. An Information Sheet is used for minimal risk studies and does not require the Investigator to retain a signed copy on file, while a Consent Form is used to document consent by signature of the subject and must be signed and retained

by the PI. The NEOMED Consent Form template and Information Sheet template may be found on the [NEOMED IRB website](https://www.neomed.edu/irb/forms/#1488300617804-cecf0228-02ce).

**Advertisement Materials** (e.g., emails, fliers, websites) Include anything that will be used to promote your study

**HIPAA/Data Use form**. You are required to complete a HIPAA Application for the use of identifiable health information in research. HIPAA applications can be found on the [NEOMED IRB website.](https://www.neomed.edu/irb/forms/#1488300761978-0117cabe-6f0c)

**Human Subjects Training Certificates**

**Certificates must be renewed every three years and must be current for all investigators listed at the time of submission.** Expired or incomplete training of any investigator will delay the review and approval of this application. NEOMED’s training in human subjects research is through CITI and is found at <https://www.citiprogram.org>.

**Letter of commitment**. Provide documentation that indicates support of this project if you are conducting research at institutions/agencies outside NEOMED, or with individuals who are not NEOMED employees or students.

**Please specify any additional materials relevant to the study that are included:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
| PROTOCOL NAME AND DURATION |

**PROTOCOL TITLE:**

**PROJECT PERIOD: Start Date:**

**End Date:**

**If this is a student mentored project for academic credit, please list the name of the program/course below:**

|  |
| --- |
| PERSONNEL |

1. **All personnel listed below must complete current human subject research training at** [**www.citiprogram.org**](http://www.citiprogram.org) **prior to submitting this application. Training that is “in process” or “expired” will not be accepted.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***PERSONNEL*  (Name, Degrees)**  **-List PI first**  **-List everyone engaged in the research\*** | ***EMAIL*** | ***PHONE*** | ***NEOMED DEPARTMENT* (Institution’s name if outside of NEOMED)** | ***CITI HUMAN SUBJECT TRAINING***  ***DATE***  **-must be less than three years old to be valid** | ***ROLE-***  **-List 1 PI only (no Co-PI)**  **-List Co-Investigators -List student investigators –List Consultants** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**\* Add additional rows, if necessary**

1. **PERSONNEL ROLES**

Please list below each person appearing in section 1 “Personnel” and explain the role each will play in the project.

|  |
| --- |
| Response to 2: |

|  |
| --- |
| FUNDING SOURCE AND COI |

1. **FUNDING SOURCE**

Please check the appropriate boxes by double clicking the box, then selecting “checked” under default value.

Do you currently have, or anticipate having, a sponsor or funding agency ( including if you plan on applying for funds) for this project?  No  Yes

If yes, identify the sponsor or funding agency:

Is the sponsor a for-profit corporation?  No  Yes

1. **CONFLICT OF INTEREST**

Do any of the study investigators listed in this application have a financial or other personnel conflict of interest that may effect the performance or reporting of the research performed in this application? Conflicts of interest may be actual or apparent. Please see NEOMED’s policy titled [“Financial Conflict of Interest in Research.”](https://www.neomed.edu/3349%E2%80%9020%E2%80%9030-financial-conflict-of-interest-in-research/)

No  Yes If yes, please attach the COI management plan currently on file in the General Counsel’s Office.

Have you submitted or do you intend to submit the study to any Federal Agency for sponsorship?

No  **Yes**: PHS policy requires assurance that the composition of the proposed study population benefits all persons at risk of the condition under study.

|  |
| --- |
| EXEMPT, EXPEDITED, or FULL BOARD REVIEW |

According to federal regulations, a protocol may be approved by the IRB through either an exempt, expedited, or full board review of the study. An exempt or expedited review is completed by 1 IRB member, a full board review is reviewed at a convened meeting of the 12 member committee and is used to review research determined to be above minimal risk to subjects. Please check below which type of review should be considered for your study:

1. **TYPE OF REVIEW REQUESTED- Exempt, Expedited or Full Board**

Please select the type of review category you are requesting by double clicking the box.

EXEMPT RESEARCH REVIEW:

(An exempt review procedure consists of a review of research involving the IRB chairperson or by one or more experience reviewers designated by the chair.)

*CATEGORIES*

Educational Settings: 46.104(1)

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Educational Tests and Survey Procedures: 46.104(2)

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) if at least one of the following criteria is met:

**Please select:**

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB** review to make the determination required by §46.111(a)(7).

Are provisions in place to protect the privacy of subjects and to maintain the confidentiality of data? Yes No

Benign Behavioral Interactions: 46.104 (3)

(i) Research involving benign behavioral interventions 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 and at least one of the following criteria is met:

**Please select:**

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB** review to make the determination required by §46.111(a)(7).

Are provisions in place to protect the privacy of subjects and to maintain the confidentiality of data? Yes No

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Secondary Research: 46.104 (4)

Secondary research use of information or biospecimens for which consent is not required:

**Please select:**

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Federal Department or Agency: 46.104 (5)

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Taste and Food Evaluations: 46.104 (6)

Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED RESEARCH REVIEW

(An expedited review procedure consists of a review of research involving the IRB chairperson or by one or more experience reviewers designated by the chair.)

*CATEGORIES*

Category 1- Clinical Studies of Drugs and Medical Devices

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

**Please select:**

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2- Collection of Blood

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

from other adults and children [[2]](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html" \l "footnote2), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3- Biological Specimens Prospective Collection

Prospective collection of biological specimens for research purposes by noninvasive means.  
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Category 4- Noninvasive Clinical Procedures

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5- Materials collected for Non Research Purposes

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). This listing refers only to research that is not exempt.)

Category 6- Collection of Data for Research Purposes

Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7- Individual or group characteristics or behaviors that are not exempt

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) and (b)(3). This listing refers only to research that is not exempt.)

Category 8- Continuing review of research previously approved by the convened IRB as follows:

where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

where no subjects have been enrolled and no additional risks have been identified; or

where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FULL BOARD REVIEW

(A full board review procedure consists of a review of research involving the entire IRB committee at a convened meetingor and involves the presentation of the proposed research to the committee by the project’s PI.)

The research presented in the application is above minimal risk of harm to participants and does not meet any of the above criteria for exempt or expedited review. Review by the convened IRB committee is required.

|  |
| --- |
| DETAILED STUDY DESCRIPTION |

In order to review your proposal, the Institutional Review Board must have very specific, detailed information. Please use non-technical language that is understood by nonscientific members to summarize the proposed research project. Define all abbreviations and terms not part of common language and use simple words and sentence structure as much as possible.

1. **BRIEF STATEMENT OF THE RESEARCH HYPOTHESIS AND SUPPORTING RESEARCH QUESTIONS**

**A** **hypothesis** is a tentative statement about the relationship between two or more variables.It is a specific, testable prediction about what you expect to happen in a study. Please see “[IRB Application Errors”](https://www.neomed.edu/wp-content/uploads/IRB-Application-Errors.pdf) page 3, #5 for help on formulating a hypothesis with supporting research questions and scientific objectives.

|  |
| --- |
| Response to 5: |

1. **PURPOSE OF THE STUDY**

What are the specific scientific objectives (aims) of the research?

|  |
| --- |
| Response to 8: |

1. **BACKGROUND**

State the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps which the project is intended to fill. Describe previous work in animal and/or human studies that provide a basis for the proposed research and that support the expectation of obtaining useful results without undue risk to human subjects.

|  |
| --- |
| Response to 9: |

1. **CITATIONS**

List citations below or attach a copy of literature review*.*

|  |
| --- |
| Response to 10: |

1. **PROVIDE A BRIEF DESCRIPTION OF THE PROCEDURE(S) INVOLVING THE HUMAN SUBJECTS. Include all clinical procedures, surveys, focus groups or other interactions with participants.**

|  |
| --- |
| Response to 11: |

|  |
| --- |
| **CHARACTERISTICS OF THE SUBJECT POPULATION AND METHODS/PROCEDURES** |

1. **SUBJECT POPULATION**

Check all appropriate boxes below (double click the box, then select “checked” under default value )

|  |  |
| --- | --- |
| Adults  Biomed Science Academy Students  Cancer patients  Children  Cognitively or psychologically impaired  Comatose  Elderly  Exclusion of minorities  Females Only  Fetuses  Human *in vitro* fertilization  Institutional residents | Males Only  NEOMED students/employees  Non-English speaking  Patients  Physically Handicapped  Pregnant women  Prisoners or parolees  Terminally ill  Traumatized (Physical)  Traumatized (Emotional  **Other. Please explain\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**12. NUMBER AND AGE-RANGE OF SUBJECTS**

Indicate the anticipated number and age-range of subjects to participate in the study.

1. Total number of subjects to be invited to participate (e.g. recruited) in the study ? : \_\_\_\_\_\_\_\_\_\_\_
2. Out of the number of subjects recruited above, how many do you expect to actually participate (e.g. enroll) in the study? \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Total number of participants expected to enrolled for multi-center research (if applicable):\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Age-range of participants: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**13. LOCATION(S) OF RESEARCH TO BE CONDUCTED AT**

NEOMED (Rootstown)

Teaching hospital or university (s), please list: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other locations, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS**

Read through the list carefully. Check all appropriate boxes:

|  |  |
| --- | --- |
| Audio and/or visual recording  Behavioral observation  Controlled substances  Approved drug for non approved  use, experimental  Deception  Device approved, non-approved use  Existing data (data bank, data archives)  EEG  Electrical stimulation  Genetic research  Human biological specimens (biopsy, blood drawing,  fetal tissue, stem cells, urine or fecal sample, excess  pathological)  Survey/questionnaire (must attach survey or questionnaire to application)  Interviewsand Focus Groups  Microorganisms or recombinant DNA  Physical exercise | Placebo(s)  Physical Manipulation  Proton beam  Radiation  Radioisotopes  Randomizations  Potential development of commercial products from  biological materials  PI or Co-PI is the treating healthcare provider for  participants  Surgical or autopsy tissue  Test(s), pen/pencil/computerized  Treatment  Venipuncture (<450cc)  Other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Describe each of the following in the space below:**

* 1. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes.
  2. Identify method(s) that will be used to identify and recruit prospective subjects. Attach a copy of any planned advertisements/notices and letters to potential subjects.
  3. Explain criteria for inclusion and exclusion of participants, including criteria based on age, gender, pregnancy or childbearing potential, or racial/ethnic origin.
  4. Explain how eligibility will be determined, and by whom.
  5. Explain if vulnerable subjects will be included. If so, identify the subject groups and justify their involvement.
  6. Explain if you will be performing clinical procedures as part of this research proposal.

|  |
| --- |
| Responses to 15:  a)  b)  c)  d)  e)  f) |

1. **FOR RESEARCH INVOLVING SURVEYS, QUESTIONNAIRES, INTERVIEWS AND FOCUS GROUPS**

**If YOU ARE DISTRIBUTING A SURVEYS**:

Per NEOMED Policy, if you are conducting a survey of NEOMED faculty, staff, or students you must complete the a [Survey Request Form](https://neomed.sjc1.qualtrics.com/jfe/form/SV_79FVekNIuxNeFlr) and submit to the Office of Institutional Research (OIR). The OIR’s role is to minimize the occurrence of survey fatigue, improve the integrity of Neomed data, and reduce oversampling Neomed students, faculty, employees. The OIR also provides support in the design and distribution of surveys, as well as in the analysis of survey results. Questions regarding the survey process may be sent to rlarson@neomed.edu.

**Describe each of the following in the space below:**

* + 1. Setting
    2. Mode of administering the instrument (e.g., by telephone, one-on-one, e-mail or group)
    3. Provisions for maintaining privacy and confidentiality
    4. Duration (This is not the project period, how long it takes to complete survey, focus group, etc.)
    5. Intervals of administration
    6. Overall length of participation.
    7. Type of Survey Software to be used (Note: We do not accept Survey Monkey due to privacy issues unless it is a Gold or Platinum Edition) It is recommended that NEOMED’s inhouse software “Qualtrics” be used through the Office of Institutional Research.

|  |
| --- |
| Responses to 16:  a)  b)  c)  d)  e)  f)  g) |

**COVID SAFETY PLAN**

For research involving in-person interactions or interventions with subjects:

In the space below, describe your COVID safety plan for keeping subjects and your research team safe:

|  |
| --- |
| Response: |

1. **DATA COLLECTION, STORAGE AND CONFIDENTIALITY**

**Describe each of the following in the space below:**

1. Explain how data will be collected and recorded.
2. Explain if data will be **anonymous** or **confidential**. (For help in this determination, refer to [“IRB Application Errors](https://www.neomed.edu/wp-content/uploads/IRB-Application-Errors.pdf))
3. Explain how the data will be kept secure, including who will have access to data and/or codes, whether subject identifiers will be released, and to whom (person, group or agency) the information may be released.
4. Explain what will happen to the data once they have been collected, analyzed, and reported (presentation/publication); provide timeline.

|  |
| --- |
| Responses to 17:  a)  b)  c)  d) |

1. **POTENTIAL RISKS AND DISCOMFORTS**
2. Describe the potential risks/discomforts associated with each intervention or research procedure.
3. If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility.
4. Describe the overall risk classification of the research: minimal, greater than minimal, significant, or unknown
5. Describe those procedure(s) to be utilized to prevent/minimize any potential risks or discomfort.

|  |
| --- |
| Responses to 18:  a)  b)  c)  d) |

1. **POTENTIAL BENEFITS**
2. Describe any potential benefits subjects may receive as a result of their participation in the research.
3. Describe potential benefits to society that may be expected from this research.
4. Describe the risk/benefit ratio of the research, compared with that of the available alternatives.

|  |
| --- |
| Responses to 19:  a)  b)  c) |

1. **COMPENSATION FOR PARTICIPATION**

Describe all plans to compensate subjects, if applicable. Include cash or gift card compensation, services or other benefits instead of cash (e.g., travel reimbursement), and those conditions that may need to be fulfilled before full or partial compensation. Include prize drawings for items and gift cards in this section. If no payment/compensation/incentive is planned, that should be stated below.

**REGARDING GIFT CARDS AND CERTIFICATES**: Please note that gift cards and any other form of cash or cash equivalent are taxable regardless of the amount. The NEOMED accounting department must track the amounts each research participant receives. Any compensation or combination of compensations that add up to $600 for the calendar will be reported to the IRS by the issue of a 1099 Statement. All research participants receiving gift cards/certificates must be asked to complete an acknowledgement form before receiving the gift card. If your study requires that participant names be kept anonamyous, participants must complete the [Receipt of Compensation Acknowledgement--Anonymous Form](https://www.neomed.edu/gift-card-ack-form-anonymous/). All participants in studies which are not anonymous must complete the general [Gift Card Acknowledge Form](https://www.neomed.edu/gift-card-ack-form/). The instructions and processes for uploading these forms to the Accounting office may be found on the [Form Instructions](https://www.neomed.edu/gift-card-instructions/). Questions regarding this process may be sent to purchasing@neomed.edu.

|  |
| --- |
| Response to 19: |

1. **FINANCIAL OBLIGATIONS OF THE SUBJECTS**
2. Describe any financial obligations subjects will incur as a result of participating in the study.
3. Describe whether subjects have to pay for any of the treatment(s) they receive or tests performed in the research.

|  |
| --- |
| Response to 21:  a)  b) |

1. **EMERGENCY CARE AND COMPENSATION FOR RESEARCH-RELATED INJURY**
   1. If the research presents greater than minimal risk, describe what emergency care is available in case of research-related injury.
   2. Identify who will be responsible for the cost of such care.
   3. Identify whether subjects will be compensated for out-of-pocket expenses or lost wages if they suffer a research-related injury

|  |
| --- |
| Response to 22:  a)  b)  c) |

|  |
| --- |
| **INFORMED CONSENT/ASSENT PROCESS** |

1. **ADULT INFORMED CONSENT PROCESS (Including parents and guardians)**

All regulatory research requires an informed consent process which includes communication to subjects prior to, during, and following their participation in a study. Except in certain circumstances, the communication should be both written and verbal. Include each of the following in your description of the consent process:

1. Describe how and where the consent process will take place.
2. Describe how the consent process will be structured to enhance independent and thoughtful decision-making. Include those steps which will be taken to avoid coercion or undue influence.
3. Describe whether the subjects or their legally authorized representatives understand the information provided.
4. Describe whether all adult subjects have the capacity to give informed consent, or the likely range of impairment. If subjects are impaired, explain how, and by whom, their capacity to consent will be determined (See #24 informed assent for adults who are impaired).
5. Identify who will be inviting subjects to participate and what will they say. Identify by name and training the individual(s) authorized to describe the research to subjects/representatives and to invite their participation.
6. Identify and justify any personal identifiers that may be recorded.
7. Explain and justify if any information about the research purpose and design will be withheld from potential or participating subjects (non-disclosure), and describe plans for post-study debriefing.
8. If any of your anticipated participants are non-English speakers, or English is their second language, identify how the informed consent form and all written materials (e.g., recruitment letter, survey) have been translated in the native language of your partcipants. Describe the consent process using participants’ native language (e.g., will a translator be used, who will serve as the translator in your study).

|  |
| --- |
| Response to 23:  a)  b)  c)  d)  e)  f)  g)  h) |

1. **INFORMED ASSENT (For minors and persons impaired to give informed consent)**

In addition to the questions above, answer the following:

1. Identify the reading level of the assent form. How has this level been confirmed? (e.g., computer program, education expert)
2. Explain the process of assent for minors, including how you provide information at an age appropropriate level of your subject population (if applicable)
3. Explain the process of assent for persons who are impaired (e.g., cognitively), including how you provide information at an understandable level and based on the needs of the participant.
4. Explain any actions that may be taken when minors or persons who are cognitively impaired *dissent* in the informed consent process, or who wish to withdraw at any point of the study.
5. Explain any actions that may be taken when minors or persons who are cognitively impaired *dissent* to more than minimal risk studies (if applicable)

|  |
| --- |
| Response to 24:  a)  b)  c)  d)  e) |

1. **CONSENT/ASSENT DOCUMENTATION:**

Specify which method of consent will be used in your study (Check all that apply):

Informational Sheet

Adult Consent Form

Parental or Guardian Consent Form

Minor/Impaired Person Assent Form

Waiver of Documentation of Signed Consent (Go to item #26 if checked)

1. **WAIVER OF SIGNED CONSENT FORM:**

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (Please check the appropriate box, IF YOU ARE REQUESTING A WAIVER OF SIGNED CONSENT)

That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

**- or-**

That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

**Note: Even if a waiver of signed consent has been granted, an informational sheet must be provided to subjects unless the research purpose and design involves non-disclosure or deception, or a valid justification can be made to the IRB for not using an Information Sheet.**