NEW YORK STATE DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS RESEARCH
CONTINUING REVIEW REVIEWER FORM

Principal Investigator Name: Click or tap here to enter text. IRBNet # Click or tap here to enter text.

Project Title: Click or tap here to enter text.

Type of Review: ☐ Expedited Criteria # Click or tap here to enter text. ☐ Convened Board

Current Approval Dates: Click or tap to enter a date. to Click or tap to enter a date.

Current Risk Level: ☐ No greater than minimal risk ☐ Greater than minimal risk

Reviewer: Click or tap here to enter text. Are you the Primary Reviewer ☐ Yes ☐ No

Conflict of Interest Disclosure:
As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? ☐ Yes* ☐ No

*If yes, please do <u>not</u> perform the review and contact the IRB Office: 518-474-8539

Section 1: Principal Investigator & Research Staff	Yes	No
1a. Has there been any change in the status of the Principal Investigator (PI), Study Coordinator or research team (e.g. additions and removals) since the most recent approval of the project?	☐	☐
1b. Are there any conflict of interests that have been identified and submitted with this Continuing Review package? If Yes, the IRB determination should have been submitted with the Continuing Review Packet.	☐	☐
Reviewer Comments: Click or tap here to enter text.		

Section 2: Continuing Review Concerns	Yes	No	N/A
2a. Is the protocol consistent with the most recent approved protocol filed with NYS DOH IRB?	☐	☐	☐
2b. Are the publications relative to this research summarized adequately?	☐	☐	☐
2c. Are the preliminary research results and interim findings summarized adequately?	☐	☐	☐
2d. Have there been any problems and/or changes to the research since the last IRB review? Are they summarized adequately?	☐ ☐	☐ ☐	☐ ☐
2e. A summary of unanticipated problems and available information regarding adverse events since the last IRB review is described adequately. Are there additional issues within the reports that require additional action by the NYS DOH IRB? Click or tap here to enter text.	☐ ☐	☐ ☐	☐ ☐
2f. Are there any study-wide or multi-center trial reports received since the last IRB review has been completed?	☐	☐	☐

Section 2: Continuing Review Concerns	Yes	No	N/A
2g. The investigator has been using the current IRB stamped approved informed consent document, if applicable.	☐	☐	☐
2h. If applicable, are the provisions for obtaining and documenting informed consent still appropriate and being followed? If not, discuss in comments section below.	☐	☐	☐
2i. Does the project have a waiver or alteration of informed consent? If yes, which Click or tap here to enter text. Does the project still meet the criteria for for a waiver or alteration of informed consent:	☐	☐	☐
• The research involves no more than minimal risk to participants.	☐	☐	☐
• The waiver or alteration will not adversely affect the rights and welfare of the participants.	☐	☐	☐
• Whenever appropriate, the participants will be provided with additional pertinent information after participation.	☐	☐	☐
2j. Does the project have a waiver or alteration for HIPAA? If yes, which Click or tap here to enter text. Does this project still meet the criteria for a waiver or alteration for HIPAA?	☐ ☐	☐ ☐	☐ ☐
A. The use of disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on the presence, at least, one of the following elements:			
• An adequate plan to protect the identifiers from improper use and disclosure;	☐	☐	☐
• An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and	☐	☐	☐
• Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of protected health information would be permitted by the regulation.	☐	☐	☐
B. The research cannot practicably be conducted without the waiver or alternation.	☐	☐	☐
C. Research cannot practicably be conducted without access to & use of protected information.	☐	☐	☐
Comments: Click or tap here to enter text.			

Section 3: Participants	Yes	No	NA
3a. Does the number of subjects enrolled correspond to the number approved for enrollment?	☐	☐	☐
3b. Is there a summary of withdrawal of subjects from the research since the last IRB review is described adequately?	☐	☐	☐
3c. Is the participant accrual summarized adequately?	☐	☐	☐
3d. The research plan adequately provides for monitoring the data collected to ensure the safety and confidentiality of the participants?	☐	☐	☐
3e. Are the risks still minimized by use of procedures consistent with sound research design and which do not unnecessarily expose subjects to risk? If no, please comment: Click or tap here to enter text.	☐	☐	☐

3f. Are the risks to subjects still reasonable in relation to benefits? If no, please comment: Click or tap here to enter text.	☐	☐	☐
	Yes	No	NA
3g. When some or all the participants are likely to be vulnerable (people with decisional impairments, education or economic disadvantages, children, pregnant women, fetuses, human in vitro fertilization, and prisoners) to coercion or undue influence, additional safeguards have been included in this study to protect the rights and welfare of these subjects.	☐	☐	☐
3h. The monetary incentive indicated does not appear to be coercive for the participant population identified, if applicable.	☐	☐	☐
3i. Have there been any participant recruitment issues or any other types of complaints identified by the PI or research staff that require additional action by the NYS DOH IRB? If yes, explain in detail: Click or tap here to enter text.	☐	☐	☐
Section 4: Regulatory Criteria for Approval **Please check whether each criterion continues to be met for continued approval.**	Yes	No	NA
The following information is designed to assist the reviewer in determining that all Federal required criteria for IRB approval codified in 38 CFR Part 16.111, FDA regulations, and the Revised Common Rule are met.			
4a. Selection of subjects is fair and equitable.	☐	☐	
4b. The number of subjects initially requested and approved has not been exceeded.	☐	☐	
4c. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals lacking decision making capacity, economically or educationally disadvantaged persons, students or any others whom may be at increased susceptibility to harm, additional safeguards have been included in the study to protect rights and welfare of these subjects.	☐	☐	☐
4d. Risks are minimized through sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐	☐	
4e. Risks are reasonable in relation to anticipated benefits.	☐	☐	
4f. Provisions protecting the privacy of subjects and the confidentiality of data/records are adequate and appropriate	☐	☐	
4g. The informed consent **process** is adequate (or has previously been waived by the IRB).	☐	☐	☐
4h. Informed consent is obtained from each prospective participant or the subject's legally authorized representative, if applicable.	☐	☐	☐
4i. The investigators are qualified to perform the research, all required training is complete and current, and there have been no conflicts of interest identified.	☐	☐	
4j. When appropriate, does the research plan make adequate provision for monitoring the data collected to ensure the safety of participants (Mechanisms (as stated in protocol) should be in place to track protocols and study personnel and provide assurances that data are valid and are collected according to professional standards. These tasks should be accomplished in a way that safeguards participants' safety, privacy, and confidentiality within the system.)?	☐	☐	
Comments about Regulatory Criteria for Approval: Click or tap here to enter text.			
Section 5: Reviewer's Recommendations *Primary* *Reviewers must upload this form in IRBNet when review is complete.*			

☐	This project is approved. Any comments below are suggestions only. ***(To be used only in the expedited review process)***.
☐	I recommend approval of this project pending **minor modifications** (***convened Board*** or required modifications (***expedited review***) as stated below or attached to this form.
☐	This project can only be approved after **major modifications** have been made as stated below and the project is reviewed again at a full board meeting of the IRB to ensure all required modifications are satisfactory. ***(To be used only if project is going to be reviewed by convened Board.)***
☐	I do not recommend approval of the project for the reasons indicated below. ***(To be used only if project is going to be reviewed by the convened Board. If disapproval is being recommended for project undergoing expedited review, the box below must be checked instead.)***
☐	Deferred for review by the convened IRB. ***(To be used only in the expedited review process – Please specify deferral reason below under B.)***

A. SUMMARY:
Click or tap here to enter text.

If an expedited review, does the submission meet the criteria requirements? ☐ Yes ☐ NO

When is the Study Anticipated to be completed: Click or tap to enter a date.

B. Requested Modifications or Deferral Reasons to Full Board as applicable: Click or tap here to enter text.

Only complete C or D depending on if study is required to have an annual review or meets the criteria for §46.109.

C. For Annual Review Studies Only:
Next review is in: ☐ 6 months (high risk only) ☐ 12 months

D. Certain research that poses minimal risk to study participants, and is eligible for expedited review is not required to undergo annual continuing review (unless specifically mandated by the IRB (46.109[f][1][i])). As a reviewer if you are recommending an annual review of this study and it meets the criteria on the next page NOT to be annually reviewed, you are required to specify the reason for the annual review. Otherwise make a determination for how often there should be a Post-Approval Monitoring Review of this study.

The recommended PAM period is: ☐ 12 months ☐ 24 months or ☐ 36 months

Do you feel an annual review is necessary? ☐ Yes ☐ No

List the PAM Tool from Attachment B: Click or tap here to enter text.

Reviewer: Click or tap here to enter text. **Date:** Click or tap to enter a date.

ATTACHMENT A: Determining Continuing Review Frequency for Minimal Risk Studies

45 CFR 46.109: Unless an IRB determines otherwise, continuing review of research is **NOT** required in the following circumstances:

A. Research eligible for expedited review in accordance with §46.110: Research that (1) presents no more than minimal risk to human subjects and (2) involves one or more of the following research categories:
   1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
      (a) Research on drugs for which an investigational new drug application (21 CFR 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 where an investigational device exemption (IDE) application or an abbreviated IDE application for a non-significant risk (NSR) device (21 CFR 812) is not required.

   2. The collection of blood specimens for research purposes using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits for volume: (a) from non-pregnant adults who weigh at least 50 kg, the amounts collected should not exceed 550 ml in an 8-week period; or (b) from children and other adults, the amount of blood to be collected should not exceed the lesser of 150 ml or 3 ml per kg in an 8-week period. Examples:
      (a) Finger stick, heel stick, or ear stick with reasonable limits on frequency and with volumes consistent with clinical practice employing these methods.
      (b) Venipuncture with reasonable limits on frequency and with the total volume of clinical and research specimens limited as defined above.
      (c) Collection of blood from an in-dwelling peripheral venous catheter placed for research purposes with volume limits as defined above.
      (d) Collection of blood from an in-dwelling catheter already in place for clinical purposes, with the total volume of clinical and research samples limited as defined above.

   3. Prospective collection of biological specimens, excluding blood, for research purposes by noninvasive or minimally invasive means. Examples:
      (a) Tissues and fluids that the body produces continuously or sheds as a normal process, which are collected in a non-disfiguring manner.
      (b) Tissues and fluids if routine patient care indicates a need for removal or extraction.
      (c) Dental plaque and calculus.
      (d) Tissues from non-facial, non-genital skin punch biopsies in adults that do not require sutures.
      (e) Specimens collected in adults by curettage, urethral, vaginal or rectal swabs.
      (f) Specimens collected from the external auditory canal or nares.

   4. Collection of additional data and biological specimens, excluding blood specimens, for research purposes during procedures already being performed for clinical purposes, provided the additional collection does not entail more than a minimal increase in risk, pain or discomfort. Examples:
      (a) Collection of additional bodily fluids (e.g., peritoneal fluid, bone marrow or cerebrospinal fluid)

(b) Reasonable extension of anesthesia, sedation or operating room time to allow collection of additional data or specimens.
(c) Tissue collected from pap smears.

5. Collection of data through noninvasive or minimally invasive procedures (not requiring the addition of general anesthesia or sedation for research purposes) routinely employed in clinical practice. Examples:
   (a) Physical sensors that are applied either to the surface of the body or at a distance.
   (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.
   (d) Allergy skin-testing in subjects not known or suspected to have serious allergies to the allergen being tested.
   (e) Procedures in adults involving a single exposure to ionizing radiation with an effective dose not exceeding 0.1 mSv (the amount typically associated with a chest x-ray) provided appropriate shielding techniques are employed.

6. Secondary use of materials (data, documents, records, or biological specimens) that have been or will be collected for purposes other than the currently proposed research project. Examples:
   (a) Secondary use of data collected from another research study, provided the use is compatible with the original terms of consent, if any.
   (b) Secondary use of clinical or educational records.
   (c) Use of banked specimens in biorepositories.

7. Activities at statistical and data coordinating centers or biospecimen repositories that are not responsible for the primary oversight of the study and are not involved in the primary collection of data or specimens, which may be ongoing at other sites. Example:
   (a) Multicenter clinical trial where data are gathered under separate IRB approval(s) for the performance sites, but received and managed by a central coordinating center that does not otherwise participate in the clinical intervention or interact directly with subjects.

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

9. Surveys, interviews, self-reports, direct and indirect observations of individual and group behavior, other verbal or computer-assisted interactions or assessments, non-I invasive physical or behavioral tasks, manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health, and epidemiologic research. Examples:
   (a) Measures of performance on cognitive, perceptual, neuropsychological, behavioral and other related tasks employing non-invasive technologies (e.g., paper and pencil assessment, computerized tasks, remote data collection using mobile devices).

(b) Interviews, questionnaires, surveys, focus groups, and internet-based data collection on personal experience, identity, language, relationships, attitudes, beliefs and practices.
(c) Psychiatric diagnostic or symptom assessments in healthy or mentally ill populations conducted by clinicians or trained interviewers (with appropriate mechanisms for clinical back-up or referral).
(d) Measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers).
(e) Methods used in ergonomics and human factors research including cognitive, human-computer, physiological and bio-mechanical measures in consumer, industrial, and biomedical settings.
(f) Qualitative and quantitative data collection through observation, participant observation and interaction with groups in naturalistic settings (including the internet).
(g) Surveys on personal and family finances, consumer preferences and decision-making.
(h) Assessments of compliance with medication or treatment regimens.
(i) Surveys to establish effectiveness of public health interventions.

10. Establishment of subject recruitment databases. Examples:
    (a) Collection of identifiable information for the purpose of establishing subject pools.
    (b) Disease-specific patient registries.
    (c) Screening protocols including interviews, questionnaires and physical assessments that could be under one of the categories listed above.

11. Research previously approved by the convened IRB and now subject to continuing review where one of the following conditions apply:
    (a) (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
    (b) no subjects have been enrolled and no additional risks have been identified; or
    (c) the remaining research activities are limited to data analysis; or
    (d) a non-significant risk (NSR) determination was initially made by a convened IRB for research involving medical devices and the research was determined to present no greater than minimal risk to the subject; or
    (e) 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.

12. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    (a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

ATTACHMENT B: Determining a PAM TOOL for Minimal Risk Studies that do not require Annual Review

PAM Assessment Tools:

- ❑ Administrative Check-in: IRB Administration sends an email to the PI at a designated time to assess the status of the project. The check-in will remind PIs of their obligation to submit amendments and event reports to the IRB. Based on the response from the PI, project time lines will be adjusted accordingly, or the project will be closed in IRBNet.
  Administrative Check-in is different from a Continuing Review as it is informal and no documents to complete just an email to respond to. If a study is in data analysis, follow-up or will be completed within a year this is a tool to recommend. The Check-in will occur around the time the study is anticipated to be completed. It is good to recommend if a PI is new or you feel a check-in is needed, but there is not a justification for an annual review.

- ❑ Full On-Site Assessment (aka Compliance Review): recommended for studies that have had adverse events, expired trainings and non-compliance issues. Performed by RCO.

- ❑ Self-Assessment: Usually recommended for low risk studies, with no human intervention or consenting

- ❑ Consent Document Review: For studies with Informed Consents. Conducted by either RCO or Researcher if no issues with consenting previously. Checklist is completed and reviewed by RCO if completed by Researcher. Researcher may be informed to submit all signed consent/assent signature pages for all participants enrolled during a specified period for review by the RCO.

- ❑ Consent Process Review: For studies with Informed Consents. Conducted by the researcher by completing a checklist during the consenting process for one or more participants. Completed checklists are submitted to RCO for review.

- ❑ Consent Process Observation: Performed by the RCO usually part of the Full On-Site Assessment unless there has been an issue with consenting reported.

- ❑ Project Team Review: Conducted by IRB Administrative Staff. PI submits a current Project Team form and training certificates in IRBNet at the request of IRB Administration.
  IRB Administrative Staff will verify that all team members meet training requirements, and there is a Conflict of Interest Form on File for each staff member.