INSTRUCTION SHEET: Application for Review of Research Involving Human Subjects

Principal Investigators (PI) and co-Investigators using human research subjects are required to complete an online training program before submitting an application to the Institutional Review Board (IRB), to be re-taken every 3 years. To complete the training, titled "Human Participant Protections Education for Research Teams," go to http://phrp.nihtraining.com/users/login.php. Once the training module has been completed, print out your "Completion Certificate." A copy of the certificate is to be submitted with this IRB application. If you have completed a similar course approved by another research institution you should provide equivalent proof of completion.

Please answer all questions in this electronic application to the fullest extent possible. Following completion and submission of the electronic application, you should print a hard copy. You should attach additional material in hard copy form as required. If a question is not applicable to your research, please write "NA": Do not leave any question blank. In order to distinguish your typed responses, please use a different font than that of the form. The order of questions in the application must not be changed. All attachments must be labeled and sequentially ordered as separate appendices, with each appendix referenced in the application. Upon submission of the electronic application, a file will be opened by the IRB. When supporting materials and signatures are received by the IRB Executive Secretary, review of the project will be scheduled.

The full application must include original signatures of the investigator(s). If the PI (or co-Investigators) has an academic affiliation (e.g., full-time faculty member at a university), approval signatures from that institution are also required (e.g., departmental chair). In the case of student projects, original signatures of the faculty sponsor and department chair must be included. For any projects involving other institutions (e.g., when participants will be recruited from more than one institution), the approved IRB application from the relevant institution(s) must be submitted with this application. If you are required to revise the application and return it to this IRB, or if any amendments are made to the design of the project after approval has been received, new signatures and dates are necessary on all submitted re-applications to indicate that all parties have approved all changes.

Application checklist:

___ Typed, complete application form with all required signatures
___ Notification letter of approved topic from Office of the Institute Director
___ "Human Participant Protections Education for Research Teams" Completion Certificate
___ Consent form(s) that will be given to human subjects
___ Copy of any scripts, posters, flyers, and/or letters to be used to recruit subjects
___ Narrative script for any audio or videotape stimulus used during data collection
___ Copy of all survey instruments/measures to be completed by subjects (e.g., standardized instrument, newly developed or amended measure), including instructions and relevant citations
___ Copy of any screening tools used to establish inclusion or exclusion (e.g., demographic, medical history forms)
___ Letter of permission or IRB approval to use additional site(s)
___ Copy of grant application if research is being submitted to an external agency for funding

Please send one hard copy and one electronic copy of the completed application to:

Richard Herman
Executive Secretary IRB
20 West 74th Street
New York, NY 10023
r.herman@wawhite.org

Project ID#_____

Application for Review of Research Involving Human Subjects

A. PROJECT TITLE*:

Project Title

*If part of a larger program and/or if funded by an external agency, also provide the title of the larger program and/or grant title

B. INVESTIGATORS:

Principal Investigator

Address:

City | State | Zip Code:

Phone: | Fax:

E-mail:

WAWI Status: ◯ White Society Member ◯ Sullivan Society Member ◯ WAWI Extern ◯ Other (specify):

If PI is a Faculty Investigator, name primary institutional affiliation and title:

Department:

Address:

City | State | Zip Code:

Phone: | Fax:

E-mail:

If PI is a Student Investigator, name the school where currently enrolled and faculty sponsor:

Department:

Address:

City | State | Zip Code:

Phone: | Fax:

E-mail:

Type of student project: ◯ Doctoral dissertation ◯ Pre-doctoral research ◯ Master's thesis ◯ Other (specify):

C. SOURCE OF FUNDING:

- ◯ Not Seeking Funding
- ◯ Externally Funded: Sponsor and Sponsor ID: _____
- ◯ Seeking Funding: Sponsor: _____ Application Deadline: _____

A full copy of the grant proposal must be on file with the WAWI IRB or appended to this application.

◯ Appended ◯ On File

D. DATA COLLECTION:

1. Name all site(s) where data will be collected:

2. If the proposed research is to be conducted in whole or in part at another institution/organization, provide name(s) of participating institution(s) and indicate their role(s) in the study. If the subjects are to be drawn from an institution or organization (i.e., hospital, social service agency, employer, prison, school, etc.) which has responsibility for the subjects, then documentation of permission from that institution and its IRB or equivalent must be submitted before final WAWI approval can be given.

E. SUMMARY OF PROPOSED RESEARCH:

Provide a brief description, in lay terms, of the proposed research. The description must include a) the rationale and significance of the research, b) method and procedures (i.e., what are the subjects specifically being asked to do, the number of subjects to be recruited), and c) the hypotheses or aims of the study. Please limit your summary to one page.

F. SUBJECTS:

1. Number of subjects: #Male ☐ # Female: ☐

2. Subject Population (check all that apply):

- ☐ Adults
- ☐ Prisoners*
- ☐ Physically Ill*
- ☐ Pregnant Women*
- ☐ Special racial or ethnic group. Specify* ☐
- ☐ Minors (under 18)*
- ☐ Mentally Disabled/Developmentally Delayed *
- ☐ Physically Disabled*
- ☐ Students/Candidates*

*Rationale for use of special groups or subjects whose ability to give voluntary informed consent may be in question, must be fully explained and justified below. Append additional material as necessary.

3. Subject Selection: Describe how subjects will be identified and recruited. Be precise and attach a copy of any and all recruitment materials to be used, as an appendix (e.g., advertisements, flyers, letters, scripts).

4. Initial Contact: Describe who will make initial contact, and how it will be made. If subjects are chosen from approved records, indicate who gave approval for use of the records. Written documentation of the cooperation/ permission from the holder or custodian of the records must be attached. (The official holder of the record, i.e. primary physician, therapist, or clinic must make initial contact of subjects identified through record's search.) Only WAWI clinic records with signed informed consent for their use from the patients will be available. Other organizations may require that you also receive HIPPA permission from an appropriate office or officer at their site. If required, a copy of the HIPPA approval should be attached. (*Note: WAWI is not a "covered entity" under HIPPA considerations.)*

5. What are the criteria for inclusion and/or exclusion of subjects? The basis of exclusion from the study should be stated when subjects are asked to complete screening questionnaires.

6. Will subjects receive any inducements before participating or rewards or compensation after participating?

◯ Yes ◯ No

If **Yes**, please describe how much and in what form (e.g., cash, travel expenses, meals, lottery, etc.) Note that this information must also be included in the consent form. If using a lottery or raffle inducement, describe who will be responsible for conducting it and the procedure for prize delivery.

G. RISKS:

1. Do any of the procedures involve physiological measurements, treatments, or intervention/invasion of the body by mechanical, electronic, biological or any other means?

◯ Yes ◯ No

If **Yes**, describe in detail the intervention, the means to administer the intervention, the behavior expected of subject(s) and the behavior of the investigator during the administration of the intervention; how data will be gathered and recorded; identify any anticipated and possible consequences of the procedure for the subject (s); what steps will be taken to assure proper operation and maintenance of the means used to administer the intervention; competence/qualifications of investigator; and name, title, affiliation, telephone number of individual who will supervise the procedure.

2. Does the study involve the administration of any prescribed or proscribed/prohibited drugs?

◯ Yes ◯ No

If **Yes**: a. Name the drug(s) and dosage(s):

b. Is it:

c. Route of administration:

d. Is this an FDA-approved use?

e. Will the subject be at risk of harm in any way?

If **Yes**, identify type of harm; possibility that it will occur; action(s) to be taken to lessen possibility of occurrence; and action(s) to be taken in case of an adverse reaction.

3. Identify anticipated and possible physiological consequences of this procedure for the subject(s); identify the site where the procedure/administration is to be carried out; indicate the investigator's competence/qualification to conduct this procedure; and give name, title, affiliation, and phone number of individual who will supervise the procedure.

4. Do you deceive subjects in any way?

◯ Yes ◯ No

Note, a study is considered deceptive if false information is given to subjects, false impressions created, or information relating to the subjects' participation is withheld. For example, a "stereotype threat" situation, where subjects complete a competency test and are then told they failed the test (regardless of their performance), is considered deceptive.

If **Yes**, describe in detail the deception involved, including any instructions to subjects or false impressions created; why deception is necessary to accomplish the goals of the research; and plan for debriefing subjects. Attach a copy of any debriefing statement in an appendix.

5. Does the research involve subjects who are likely to be vulnerable to coercion or undue influence, such as children (under 18), students/supervisees, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons?

◯ Yes ◯ No

If **Yes,** what, if any, additional safeguards have been included to protect the rights and welfare of these subjects?

6. Does the research involve any of the following?

a. Major changes in diet or exercise? ◯ Yes ◯ No

If **Yes**, describe:

b. Administration of physical stimuli other than auditory and visual stimuli associated with normal classroom activities? ◯ Yes ◯ No

If **Yes**, describe:

c. Use of a new medical device?

◯ Yes ◯ No

If **Yes**, describe:

d. Possible invasions of privacy of subjects, or their families, including use of personal or medical information?

◯ Yes ◯ No

If **Yes**, describe:

e. Any probing for information that **might** be considered personal or sensitive, or **might** make a subject feel demeaned, embarrassed, appreciably anxious, or his or her privacy violated?

◯ Yes ◯ No

If **Yes**, describe:

f. Any procedure involving invasion of the body, i.e., touching, contact, attachment to instruments, withdrawal of specimens? ◯ Yes ◯ No

If **Yes**, describe:

g. Presentation to the subject of any materials that he/she **might** find offensive, threatening or degrading?

◯ Yes ◯ No

If **Yes**, describe:

h. Describe any other possible risks not mentioned above.

7. For any procedures involving potentially substantial risks to the physical, psychological or social welfare of the human subjects, explain why your selected methodology is preferable to or outweighs any alternative approaches.

8. If there are any substantial risks cited above, assess their likelihood and seriousness.

a. Describe the procedures for protecting against or minimizing these risks.

b. Describe alternative and accepted procedures or methods of treatment, if any were considered, and why they will not be used

c. Describe why these risks are reasonable in relation to the anticipated benefits.

H. CONFIDENTIALITY OF DATA:

Specify the steps to be taken to guard the anonymity of subjects and the confidentiality of their responses. Safeguards to protect confidentiality should also be spelled out to subjects in the attached consent form and should include a description of the ultimate disposal of data (see consent form examples in section K).

1. Please describe how data confidentiality will be maintained (e.g., deleting names and any other identifying information).

2. Please describe how your data will be stored and for how long (e.g., in a locked file cabinet accessible only to the researchers). Please note: data must be stored for a minimum of 5 years after completion of the study, per federal guidelines. You must also indicate if partially completed protocols will be included in the study or eliminated. Describe how data will be destroyed.

3. Will you gather information from a subject while a recording (video and/or audio) is taking place?

◯ Yes ◯ No

If **Yes**, describe how these data will be used (e.g., coding by trained observers, presentation for educational purposes), and what safeguards will be employed to protect confidentiality of data (e.g., blurring faces, erasing spoken names). In the case of educational presentation of recorded data, is it possible that the subjects might be identified? If so, this must be reflected in the consent form.

Note: **You will need explicit permission from subjects for taping, outlined in the consent form**.

I. INFORMED CONSENT:

Informed consent is necessary for all research involving human subjects and must be documented. Use of subjects unable to give personal consent for reasons of age, mental state, legal or other such status, requires that consent be secured from parents or legal guardians.

Attach a clean original of the written consent form as an appendix to this application (note: do not include extraneous information, such as "Appendix C," on the consent form; add a separate cover page so the consent form is exactly as subjects will see it). At the end of the review process, if the project is approved, this copy will be stamped with IRB approval and returned to you. This stamped copy is to be replicated and presented to subjects. If presented orally, a written copy of the oral presentation must be submitted. The Principal Investigator must sign the consent along with the participant. A sample consent form and guidelines are part of this application as "Section J Attachment".

J. REQUIREMENTS FOR INFORMED CONSENT

Be sure to provide the prospective subjects with sufficient opportunity to consider whether or not to participate. Do not coerce or use undue influence that would affect a subject's decision to participate. No subject may be involved in research unless the subject's prior written consent has been obtained. The consent form should be in language that subjects can easily understand (8th grade level). Review the instructions below before preparing the consent form.

A well-written consent form should include the following:

1. Statement identifying the researcher's affiliation and status;
2. Statement that the study involves research and the purpose(s) of the research;
3. Time required for the subject's participation;
4. Description of the procedures to be followed and identification of any that are experimental;
5. Description of any reasonably foreseeable risks or discomforts to the subjects;
6. Description of any benefits to the subject or to others that may reasonably be expected from the research;
7. Disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;
8. Statement describing the extent to which confidentiality of records identifying the subject will be maintained;
9. For research involving more than minimal risk, an explanation as to whether there will be any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
10. An explanation of whom to contact for answers to pertinent questions about the research and subjects' rights;
11. The name of the person to contact in the event of a research-related injury to the subject;
12. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; withdrawal will not effect subject's relationship with WAWI or with any other relevant organization or institution.

When appropriate, one or more of the following elements of information should also be provided to each subject:

13. Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
14. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
15. Any additional costs to the subject that may result from participation in the research;
16. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
17. Statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
18. Approximate number of subjects involved in the study.

Following is a sample consent form. ***Using the items listed above, please revise this form so that it meets the requirements of your research project****.*

William Alanson White Institute

Informed Consent Form for Human Research Subjects

You are being asked to volunteer in a research study called *(INSERT TITLE OF PROJECT)*, conducted by *(INVESTIGATOR'S NAME, POSITION, DEPARTMENT, FACULTY SUPERVISOR AND SCHOOL/DEPARTMENT IF APPLICATBLE)*. The purpose of the research is *(DESCRIBE IN LAY TERMS, INCLUDING NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE)*.

As a participant, you will be asked to *(DESCRIBE THE PROCEDURES AND TIME INVOLVED, SITE, DATES, POSSIBLE RISKS AND/OR DISCOMFORT.)* Of these procedures, the following are experimental *(IF APPLICABLE, LIST EXPERIMENTAL PROCEDURES*). While there is no direct benefit to you for participation in the study, it is reasonable to expect that the results may provide information of value for the field of *(INSERT FIELD). (DESCRIBE COMPENSATION, IF ANY).*

Your identity as a participant will remain confidential. Your name will not be included in any forms, questionnaires, etc. This consent form is the only document identifying you as a participant in this study; it will be stored separately and securely in *(IDENTIFY LOCATION)* available only to the investigator *(IF APPLICABLE, LIST OTHERS WHO MAY HAVE ACCESS)*. Data collected may be destroyed (*AT THE END OF A LEGALLY PRESCRIBED TIME*) or stored for further research. Results will be reported only in the aggregate. *(EXPLAIN OTHERWISE IF THIS IS NOT THE CASE.)* If you are interested in seeing these results, you will send the principal investigator your name and address on the enclosed postcard.

For research involving more than minimal risk, (*INCLUDE SAME INFORMATION DESCRIBED IN SECTION H ABOVE*).

(NOTE: REVIEW ITEMS 1 THROUGH 18 ABOVE FOR ADDITIONAL INFORMATION YOU MAYN EED TO INCLUDE.)

If you have questions about the research you may contact the investigator, *(NAME, OFFICE PHONE)* or the department chair, *(NAME, OFFICE PHONE, NAME AND OFFICE PHONE OF FACULTY SPONSOR IF APPLICABLE)*. If you have questions concerning your rights as a subject, you may contact the Director of the William Alanson White Institute's Institutional Review Board, *(NAME)* at *(XXX) XXX-XXXX*. You may contact *(NAME, TITLE, and PHONE NUMBER)* for answers to any questions you may have in relation to a research-related injury. *(INCLUDE THIS STATEMENT* ***ONLY*** *IF YOUR PROJECT HAS ANY RISK OF PHYSICAL INJURY.)*

Your participation in this research is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have fully read the above text and have had the opportunity to ask questions about the purposes and procedures of this study. Your signature acknowledges receipt of a copy of the consent form as well as your willingness to participate.

_____

Name of Participant

_____ _____

Signature of Participant Date

_____

Name of Investigator

_____ _____

Signature of Investigator Date

Following is a sample assent form (for subjects under 18 or who are not otherwise legally able to provide consent). ***Using the items listed above, please revise this form so that it meets the requirements of your research project****. Wording must be at a level comprehensible to the subject.*

William Alanson White Institute

Assent Form for Human Research Subjects

I am being asked to be in a study called *(INSERT TITLE OF STUDY)* being done by *(INSERT INVESTIGATOR'S NAME),* a *TEACHER/STUDENT* at *(NAME OF INSTITUTION*). This study will look at *(DESCRIBE PURPOSE OF THE STUDY IN SIMPLE WORDS).*

If I will be in the study, I will be asked to *(DESCRIBE THE PROCEDURES, TIME INVOLVED AND, PLACE)*. For being in the study, *(DESCRIBE BENEFITS/COMPENSATION PARTICIPANT WILL RECEIVE FOR BEING IN THE STUDY.)*

The fact that I am in a study will be kept a secret. I don't have to be in this study if I don't want to be. I can change my mind at any time and leave the study at any time, and without saying why.

My (GUARDIAN/PARENT[S]) said it is okay for me to be in this study. If I have any questions about this study, I can ask my parents or talk to the investigator.

If I sign below, it means that I have read this form and I would like to be in this study.

_____ _____

My name Today's date

_____ _____

Investigator's signature Date

K. APPLICATION ENDORSEMENTS

Applications will not be reviewed without the appropriate endorsements.

Principal Investigator:
I certify that a) the information provided for this project is accurate; b) no other procedures will be used in this project; and c) any modifications in this project will be submitted for approval prior to use.

_____ _____

Signature of Investigator Date

NOTE: PLEASE ADD ADDITIONAL LINES FOR ANY CO-PIs.

Faculty Supervisor (for student projects):
I certify that this project is under my direct supervision and that I am responsible for insuring that the investigator complies with all provisions of approval.

Name: _____

_____ _____

Signature of Faculty Sponsor ***Date***

Department Chair (for faculty and student projects):

I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

Name: _____

_____ _____

Signature of Department Chair Date

NOTE: APPROVAL OF THIS PROJECT BY THE IRB ONLY SIGNIFIES THAT THE PROCEDURES ADEQUATELY PROTECT THE RIGHTS AND WELFARE OF PROPOSED HUMAN SUBJECTS AND IS NO GUARANTUEE OF ACCESS TO SUBJECT POPULATION(S).

End of application