APPLICATION FOR INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH

DEPARTMENT of RESEARCH

OFFICE USE	DATE RECEIVED:	DATE VERIFIED COMPLETE	APNTS PROTOCOL NUMBER

1. PROJECT TITLE

2. PRINCIPAL INVESTIGATOR

Last Name:		First Name:
Dept. or Unit:	Phone:	E-mail:
Affiliation:	APNTS Affiliate: ☐ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or Non-APNTS Affiliate ☐ Affiliate of (Institution):	

3. CO-INVESTIGATOR(S) (or Advisor)

Last Name:		First Name:
Dept. or Unit:	Phone:	E-mail:
Affiliation:	APNTS Affiliate: ☐ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or Non-APNTS Affiliate ☐ Affiliate of (Institution):	

Last Name:		First Name:
Dept. or Unit:	Phone:	E-mail:
Affiliation:	APNTS Affiliate: ☐ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or Non-APNTS Affiliate ☐ Affiliate of (Institution):	

Last Name:		First Name:
Dept. or Unit:	Phone:	E-mail:
Affiliation:	APNTS Affiliate: ☐ Faculty ☐ Staff ☐ Grad Student ☐ Undergrad Student ☐ Visiting Scholar, or Non-APNTS Affiliate ☐ Affiliate of (Institution):	

4. TIME FRAME

Proposed Start Date:	Anticipated Completion:

5. EXEMPT/EXPEDITED REVIEW

Are you requesting **Exempt or Expedited Review**?

- ☐ Yes, Exempt Review (Application reviewed by one IRB member)
- ☐ Yes, Expedited Review (Application reviewed by at least two IRB member)
- ☐ No, Full Review (Application reviewed by full IRB)

6. CONFLICT OF INTEREST

Does any **investigator** or any other person responsible for the design, conduct, or reporting of this research have any perceived or potential conflicts of interest that may impact the integrity of the data? ☐ **Yes** ☐ **No**
If **Yes**, explain:

7. SUMMARY OF THE RESEARCH (Lay Language)

Provide a brief description of the background and purpose of research using ***non-technical*** language that can be readily understood by someone outside of the discipline. ***Use complete sentences (limit 200 words).***

8. RESEARCH OBEJECTIVES

List the specific aims of the research study, including hypotheses and/or research questions.

9. LOCATION OF THE RESEARCH

List the specific site(s) at which the APNTS research will be conducted.

LOCATION NAME	STREET ADDRESS	CITY, STATE OR COUNTRY

Please attach letters of support/agreement showing that you have permission to conduct research at each location.

10. RESEARCH METHODS AND PROCEDURES

A. Describe completely the study design/methodology and all the procedures to which human subjects will be subjected. Be sure to estimate the time required from each

participant. If more than one visit/session will be required, described the time commitment in detail. Also outline specifically how data will be collected. Note if audio, video, etc. will be used.

B. The IRB must approve all measures that will be administered to subjects (e.g., interview schedules, surveys, psychological measures). List all measures here and attach copies to this application:

Measure 1		☐ Attached ☐ Will Follow
Measure 2		☐ Attached ☐ Will Follow
Measure 3		☐ Attached ☐ Will Follow

11. SUBJECT POPULATION

A. Provide the total number of subject (e.g., number of subject records, number of specimens) needed to reach the enrollment goal of the study.
MALES: **FEMALES:**

B. Specify the age range of the population(s) to be studied. Mark all that apply.
☐ 0-7 years ☐ 8-17 years ☐ 18-64 years ☐ 65+ years

C. Specify the population(s) to be studied. Mark all that apply.

☐ Children (18 years) ⟶ complete sections 12 d, e, f, and g
☐ Decisionally impaired ⟶ complete sections 12 d, e, f, and g
☐ Non-English speaking ⟶ complete sections 12 d, e, f, and g
☐ Pregnant Women ⟶ complete sections 12 d, e, f, and g
☐ Prisoners ⟶ complete sections 12 d, e, f, and g
☐ Healthy volunteers
☐ APNTS Students, faculty, or employees
☐ Unknown (e.g. non-targeted surveys)

D. State the rationale for selecting a specific vulnerable population.

E. Describe the expertise of project personnel for dealing with the specific vulnerable population.

F. Explain the suitability of the facilities for the special needs of the vulnerable population.

G. State how the number of subjects is sufficient to generate meaningful results.

12. SUBJECT SELECTION, IDENTIFICATION AND RECRUITMENT

A. Describe the step-by-step method(s) that will be used to select subjects (i.e., sampling strategy). State who (investigators and/or key personnel) will recruit subjects and what procedures will be used to determine subject eligibility. Specifically, what are the criteria for inclusion and exclusion?

B. Attach copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, oral/written scripts), and explain how and from where recruitment will take place.

   Are attachments included? ☐ Yes ☐ No

C. Explain how you will assure that selection and recruitment of subjects is equitable.

13. USE OF DECEPTION

Will subjects be deceived about the purpose of the research study or any of the study's elements? **If Yes**, describe how and when deception will occur, as well as your plans for debriefing the subject. ☐ Yes ☐ No

14. INCENTIVES TO PARTICIPATE

Will subjects receive compensation or other inducement (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? **If Yes**, describe the inducement. *Note that compensation should be pro-rated (e.g., per visit) and not contingent upon study completion.* ☐ Yes ☐ No

15. INFORMED CONSENT PROCESS

A. Indicate type(s) of consent processes to be used in the research study. Provide copies of all recruitment materials.

☐ Informed Consent Document
☐ Informed Consent-Addendum
☐ Assent Form
☐ Verbal Assent (script)
☐ Parental Permission Form
☐ Permission Form, Legally Authorized Representative

B. Explain the steps that will be taken to avoid coercion or undue influence. If any of the researchers have an association with the subject (e.g. students, employees), what special safeguards are in place? ☐ N/A

16. PRIVACY AND CONFIDENTIALITY

A. Does the research require access to personal-identifiable private information? **If Yes**, describe the steps you will take to ensure protection of the subjects' privacy. Include a discussion of how and where the data will be kept, for how long and who will have access to the data. ☐ Yes ☐ No

B. Will personal or sensitive information (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health) be accessed or collected from subjects? ☐ Yes ☐ No

If Yes, list type(s) of information:

C. Explain how you will protect the confidentiality of identifiable date. Be sure to outline how and where the date will be kept, for how long, and who will have access to the data.

D. Will you be obtaining a ***Certificate of Confidentiality***?

☐ Yes ⟶ *Provide a copy to the IRB* before *you begin the research*
☐ No

E. Explain any circumstances where it would be necessary to break confidentiality.
☐ N/A

F. Indicate point at which identifiers will be separated or permanently removed from the data. ☐ N/A

G. Indicate what will happen to the data at the end of the study. Check all that apply:

☐ Documents will be shredded/tapes or files erased. How long will data be kept?
☐ Data will be archived
☐ Other, specify:

H. Indicate how study results might be disseminated. Check all that apply:

☐ Classroom Presentation
☐ Thesis
☐ Publication/Journal article
☐ Sharing with Industry of Agency
☐ Conferences/Presentation
☐ Other, specify:

17. RISKS, HARMS, AND DISCOMFORTS ☐ N/A

A. Indicate all risks/harms/discomforts that may apply to the research study:

☐ Physical injury or discomfort
☐ Psychological stress
☐ Risk to reputation
☐ Social or legal risk
☐ Other, specify:

☐ Breach of confidentiality
☐ Discovery of previously unknown condition *(e.g. disease, suicidal intensions, depression, genetic predisposition)*
☐ Economic risk
☐ Invasion of privacy (subjects or other individuals)

B. For each category of risk checked above, describe the specific risk and include the frequency/likelihood of occurrence, potential severity of the harm/discomfort and the possible (long-term) consequences.

C. Will participants in your study be asked to increase their level of physical or psychological performance beyond that ordinary encountered in daily life or during the performance of routine physical or psychological tests? **If Yes**, explain: ☐ Yes ☐ No

18. MINIMIZING RISKS ☐ N/A

Describe the steps you will take to minimize the risks or harms identified.

19. REASONABLY ANTICIPATED BENEFITS

List the potential direct or indirect benefits that subjects and/or society may expect as a result of this research study. *Compensation is not be considered a benefit.*

20. ASSESSMENT OF RISKS AND BENEFITS

Weigh the potential risks with regard to the potential benefits. Provide evidence that benefits outweigh risks.

Principal Investigator Date	**Co-Investigator Date**
Co-Investigator Date	**Co-Investigator Date**

IMPORTANT NOTE: Please check to make sure that the following are included: site permission letter, verbal script, letter, informing subject or parent/guardian, and informed consent form. Also, please make sure that the copies of the measurement tools match the description of information being sought in description and/or abstract.