

Principal Investigator:	Click here to enter text.
Study Title:	Click here to enter text.

International Setting: Please complete if your research will be conducted outside of the US.

1. Where will the research be conducted?

[Click here to enter text.](#)

2. Describe the cultural norms in this setting with respect to research, individual autonomy, consent, age of majority, etc. in this setting:

[Click here to enter text.](#)

3. Will all of the subjects be fluent in English? ☐Yes ☐No

If no, describe how communication will take place with subjects

[Click here to enter text.](#)

Consent

4. Describe how consent will be obtained from subjects: (**Note:** Any request for a waiver of the requirements for informed consent must include appropriate justification. Complete **Supplement A** to request a waiver of consent).

[Click here to enter text.](#)

5. Describe how the investigators will ensure that subjects understand the nature of the research:

[Click here to enter text.](#)

6. If consent forms are to be used with non-English-speaking subjects, how will translations be obtained?
Provide a copy of all translated consent forms for review

Click here to enter text.

Expertise and Consultation

7. What are the investigator's qualifications to conduct research in this setting?

Click here to enter text.

8. Will the investigator be collaborating with local persons (e.g., researchers, universities, community leaders, etc.)? ☐ Yes ☐ No

If yes, describe:

Click here to enter text.

9. Does that country where you will be conducting this research require review by a local IRB or ethics committee? ☐ Yes ☐ No

If yes, describe and provide a copy of the notice of approval:

Click here to enter text.