



IRBNet #:

PI:

APPENDIX C – POPULATIONS WITH ADDITIONAL CONSIDERATIONS

The targeting or inclusion of potentially vulnerable populations in research requires special considerations. Complete this appendix if the proposed research includes or targets"

- Subjects who are mentally, emotionally, or developmentally disabled
- Adults lacking capacity to consent and/or adults with diminished capacity to consent.
- Non-English speakers
- Economically or educationally disadvantaged populations
- Minority groups

Special protections apply and additional information is required if the research project includes children, pregnant women, or prisoners. Additional appendix forms must be submitted for these vulnerable populations.

Children – Appendix F Pregnant Women - Appendix E Prisoners – Appendix D

Section 1 – Targeting or Including Adults Lacking Capacity to Consent and/or Adult with Diminished Capacity to Consent

1.1 Does this research include or specifically target subjects who are mentally, emotionally or developmentally disabled or may otherwise have impaired decision making ability?

No – section 1 complete, go to section 2

Yes

Included, but not targeted Targeted

1.2 Provide justification for including or targeting this population. Include a description of the importance of the knowledge to be gained for the population(s) under study.

1.3 Does the population included or targeted represent the population with the least degree of impairment compatible with the aims of the study?

1.4 Specify how risks are minimized for this population:

1.5 Explain how capacity to provide consent will be evaluated.

Attach any instrument or tools used to evaluate capacity.

1.6 Provide the name(s) and credentials of all those who will evaluate capacity to consent. Explain how each evaluator’s judgment will be impartial.

1.7 Will risks or discomforts be greater for the adults who lack capacity to consent than unimpaired



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subjects? <input type="checkbox"/> No <input type="checkbox"/> Yes, explain how: <input type="checkbox"/> Not applicable
1.8 Explain plan to reassess ability to consent if capacity fluctuates:
1.9 Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.
1.10 If subjects lacking capacity to consent will be enrolled, document the plan for obtaining surrogate consent from a legally authorized representative.
1.11 If surrogate consent will occur, explain whether the researcher will obtain the assent of prospective participants with impaired capacity.

Section 2 – Including and/or Targeting Non-English Speakers for Participation
2.1 Are non-English speakers specifically targeted for inclusion? <input type="checkbox"/> No, non-English speakers will be included but not targeted. Section 2 complete, go to section 3 <input type="checkbox"/> Yes
2.2 Provide justification for targeting non-English speakers for inclusion.
2.3 Provide plan for obtaining consent.
Consent forms in the language(s) spoken by participants and in English must be provided with your IRBNet submission application.

Section 3 – Targeting Economically or Educationally Disadvantaged Populations
3.1 Are economically or educationally disadvantaged populations specifically targeted for inclusion? <input type="checkbox"/> No – section 3 complete, go to section 4 <input type="checkbox"/> Yes
3.2 Provide justification for targeting economically or educationally disadvantaged populations for inclusion.



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3.3 Specify how risks are minimized for this population.

Section 4 – Targeting Minority Groups for Participation
4.1 Are minority groups specifically targeted for participation? <input type="checkbox"/> No – section 4 complete <input type="checkbox"/> Yes
4.2 Provide justification for targeting minority groups for participation.
4.3 Specify how risks are minimized for this population.