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:

* Individuals with Impaired Decision-Making Capacity
* Non-English speakers
* Economically or educationally disadvantaged populations
* Institutionalized Individuals (not prisoners)
* 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](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-appendix_f.docx)

Pregnant Women: [Appendix H](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-appendix_h.docx)

Prisoners: [Appendix D](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_d.docx)

## 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 individuals with impaired decision making ability? Choose one of the following.

[ ] No: Section complete, go to Section 2.

[ ] Yes: Answer one of the following:

[ ] 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.

Click here to enter text.

### 1.3

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

Click here to enter text.

### 1.4

Specify how risks are minimized for this population.

Click here to enter text.

### 1.5

Describe how capacity to provide consent will be evaluated.

Attach any instrument or tools used to evaluate capacity.

Click here to enter text.

### 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.

Click here to enter text.

### 1.7

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

Choose an item.

If selected ‘YES’ explain here:

 Click here to enter text.

### 1.8

Explain the plan to reassess ability to consent if capacity fluctuates.

Click here to enter text.

### 1.9

Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.

Click here to enter text.

### 1.10

If subjects lacking capacity to consent will be enrolled, document the plan for obtaining surrogate consent from a legally authorized representative.

Click here to enter text.

## Section 2: Including and/or Targeting Non-English Speakers for Participation

### 2.1

Are non-English speakers specifically targeted for inclusion?

Choose an item.

### 2.2

Provide justification for targeting non-English speakers for inclusion.

Click here to enter text.

### 2.3

Provide plan for obtaining consent

Click here to enter text.

Consent forms in the language(s) spoken by participants and in English must be provided with your IRBNet submission application.

[ ]  Oral/Verbal Consent w/info sheet

[ ]  Translate documents – English to Non English

[ ]  Short form w/translator

## Section 3: Targeting Economically or Educationally Disadvantaged Populations

### 3.1

Are economically or educationally disadvantaged populations specifically targeted for inclusion?

Choose an item.

### 3.2

Provide justification for targeting economically or educationally disadvantaged populations for inclusion.

Click here to enter text.

### 3.3

Specify how risks are minimized for this population.

Click here to enter text.

## Section 4: Targeting Minority Groups for Participation

### 4.1

Are minority groups specifically targeted for participation?

Choose an item.

### 4.2

Provide justification for targeting minority groups for participation.

Click here to enter text.

### 4.3

Specify how risks are minimized for this population.

Click here to enter text.