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| Appendix: Continuation Worksheet | |
| When to Use this Form Use this form to provide explanation for any of the items you left **unchecked** on your Continuation application in the Research Navigator/IRB module. | |
| Check the Item(s) you are providing explanation(s) for | Subjects experienced harm (expected or unexpected)  Subjects experienced benefit  Subjects withdrew from the study  Unanticipated problems involving risks to subjects or others  Complaints about the study  Publications in the literature relevant to risks or potential benefits  Interim findings  Multi-center trial reports  Data safety monitoring reports  Regulatory actions that could affect safety and risk assessments  Other relevant information regarding this study, especially information about risks  In the opinion of the PI, the risks and potential benefits have changed  All modifications to the protocol have not been submitted to the IRB  All problems that require prompt reporting to the IRB have not been submitted |
| Provide details for each of the items CHECKED above |  |

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| Additional Information | |
| Total # of Subjects who have completed all study related interventions and follow ups |  |
| Total # of Subjects who failed screening |  |
| Please check the following if applicable and provide explanation for any **unchecked** item | No preliminary results  No subjects were withdrawn/dropped from the study  No screen failures occurred  explanation for unchecked items: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Subjects By Vulnerable Population Type | | | | |
| Indicate all of the population types you will be including in this study | aborted fetuses  AIDS/HIV patients  children  cognitively impaired  institutionalized (not prisoners)  fetuses  in-vitro fertilization  **men** | | minorities  NYU employees or students  elderly  physically disabled  pregnant women  prisoners  **women** | |
| Employees/Students/ House Staff/Fellows |  | Persons in a Sedated/Traumatized/ Crisis State | |  |
| Children |  | Persons with Cognitive, Social, Economic, or Educational Disadvantages | |  |
| Pregnant Women |  | Non-English speaking Persons | |  |
| Persons over age 65 |  | Other (describe) | |  |
| Persons with Acute/Severe Mental/Physical Disabilities |  | Other (describe) | |  |

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| Subjects By Demographics List the cumulative counts of all subjects who have enrolled (signed consent) in your study to-date: | | | | | | | |
|  | American Indian or Alaskan | Asian or Pacific Islander | Black, not of Hispanic-American Origin | Hispanic-American | White, not of Hispanic-American Origin | Other or Unknown | Total |
| Female |  |  |  |  |  |  |  |
| Male |  |  |  |  |  |  |  |
| Unknown |  |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |  |