|  |
| --- |
| Appendix: Continuation Worksheet  |
| When to Use this FormUse 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 |       |

|  |
| --- |
| 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if applicable and provide explanation for any **unchecked** item  | [ ]  No preliminary results[ ]  No subjects were withdrawn/dropped from the study[ ]  No screen failures occurred explanation for unchecked items:       |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) |       |

|  |
| --- |
| Subjects By DemographicsList 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 |       |       |       |       |       |       |       |