Section 10: Subject Population Groups and Enrollment

Here you will indicate the targeted population groups for participation in your study. Please note that including vulnerable populations (children, prisoners, pregnant women/neonates/fetuses) will result in increased oversight and scrutiny.

In addition, if you are including minors, Pediatrics will review your protocol as a specialty committee.

You can also exclude population groups from your study, such as pregnant women, if there are any potential risks for this group. A pregnancy test will need to be administered before participation by a trained study team member.

The maximum number of subjects to be consented at Duke should allow for participant dropout, etc. and still result in a sufficient population size to reach the research goals.

10. Subject Population Groups and Enrollment

<table>
<thead>
<tr>
<th>Population Groups (Select targeted population groups only):</th>
<th>If Minors are included, the study will be routed to the Department of Pediatrics Chair for Pediatric Risk Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Adults</td>
<td>1. Students and Employees over whom Key Personnel have a supervisory role may not be enrolled in this study.</td>
</tr>
<tr>
<td>- Minors who are Wards of State</td>
<td>2. Healthy Controls must be given a Notice of Privacy Practices.</td>
</tr>
<tr>
<td>- Patients</td>
<td></td>
</tr>
<tr>
<td>- Pregnant Women</td>
<td></td>
</tr>
<tr>
<td>- Fetuses</td>
<td></td>
</tr>
<tr>
<td>- Prisoners</td>
<td></td>
</tr>
<tr>
<td>- Adults incapable of giving consent</td>
<td></td>
</tr>
<tr>
<td>- Adults with diminished capacity</td>
<td></td>
</tr>
<tr>
<td>- Handicapped subjects</td>
<td></td>
</tr>
<tr>
<td>- Students&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- Employees&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- Healthy Controls&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- Deceased subjects&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>- Blanket Protocol</td>
<td></td>
</tr>
</tbody>
</table>

Population Groups excluded from participation in this study:

- Pregnant Women

* Maximum number of subjects to be consented at Duke: 80
  Maximum number of subjects to be consented at all sites:
    For retrospective/repoalory studies:
    Maximum number of patient records / samples to be used:

If pregnant women are excluded from the study, a pregnancy test must be administered to eligible female subjects prior to enrollment.

Enter a single number. If you anticipate consenting a range of subjects, enter the upper limit of the range. The number should represent the maximum number of subjects for the life of the study.
Section 10.1: Subject Procedures and Costs

Make sure to include any potential costs to participants on the consent form.

10.1 Subject Procedures and Costs

<table>
<thead>
<tr>
<th>Biobank</th>
<th>Human biological specimens include blood or its components, healthy or diseased tissue, bodily fluids, DNA/RNA or human stem cells. For more information, see Duke Biobank under the Related Links section of the eIRB Home page.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures</td>
<td>* All Stem Cell Lines must be registered with the Duke University Human Embryonic or Induced Pluripotent Stem Cell Line Registry. A link to the registration form can be found under the &quot;Related Links&quot; section on the eIRB home page.</td>
</tr>
</tbody>
</table>

**Check all that apply:**
- [ ] Genetic Testing
- [ ] Gene Transfer
- [ ] DNA Banking
- [ ] Testing for Reportable Infectious Diseases
- [ ] Human Cell Banking
- [ ] Use of Human Embryonic Stem Cells
- [ ] Use of Human-induced Pluripotent Stem Cells
- [ ] Use of Other Cells Derived from Human Embryos
- [ ] Use of Human/Animal Chimeric Cells
- [ ] Specialized Cell Populations for Cell Therapy

**Will blood be drawn in this study for research purposes?**
- [ ] Yes
- [ ] No

If Yes:
- Maximum amount to be drawn in any 8 week period (ml):
- Number of blood draws per week:

**Will the Operating Room be used in this study?**
- [ ] Yes
- [ ] No

If Yes:
- Anesthesia time in minutes required (for research purposes):

**Costs and Compensation**

* Will there be extra costs to subjects or insurance as a result of the research (e.g. tests, hospitalization)?
  - [ ] Yes
  - [ ] No

* Will there be Subject Compensation?
  - [ ] Yes
  - [ ] No

If Yes:
- Compensation for Travel / Lost Income: $
- Other Subject Compensation: