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

* Population Groups (Select targeted population groups only):	
☑ **Adults**	If Minors are included, the study will be routed to the Department of Pediatrics Chair for Pediatric Risk Assessment.
☐ Minors who are Wards of State	
☐ Minors	
☐ Patients	
☐ Pregnant Women	
☐ Fetuses	
☐ Prisoners	
☐ Adults incapable of giving consent	
☐ Adults with diminished capacity	
☐ Handicapped subjects	
☑ **Students**[1]	[1]Students and Employees over whom Key Personnel have a supervisory role may **not** be enrolled in this study.
☑ **Employees**[1]	
☐ Healthy Controls[2]	[2]Healthy Controls must be given a Notice of Privacy Practices.
☐ Deceased subjects[3]	[3]Complete and attach a Decedent Research Notification on page 13.2. Waiver of Consent and HIPAA Authorization.
☐ Blanket Protocol	

Population Groups excluded from participation in this study:	If pregnant women are excluded from the study, a pregnancy test must be administered to eligible female subjects prior to enrollment.
☑ **Pregnant Women**	

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

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

Biobank

* Does this study involve the collection, use, tracking, banking (storage) or distribution of human biological specimens? ○ Yes ◉ **No**	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.

Procedures

Check all that apply:	* 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 "Related Links" section on the eIRB home page.
☐ 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:	Enter blood volume in ml.
Will the Operating Room be used in this study? ○ Yes ◉ **No** **If Yes**, Anesthesia time in minutes required (for research purposes):	Include only research time, not clinical care time.

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:	