**Hardin-Simmons University Institutional Review Board**

**Vulnerable Populations Consideration Form**

Instructions: Please complete this form and email along with the Application to IRB@hsutx.edu. This is a supplemental form; it will **not** be accepted without a completed application.

Title of Proposed Project: Click or tap here to enter text.

Which of the following special populations does your research include? (Check all that apply)

[ ] Children – **Go to Section 1**

[ ] Pregnant Women or Fetuses- *(Research in this category is aimed at pregnancy or fetuses, not as a part of the general population).* **Go to Section 2**

[ ] Neonates – **Go to Section 3**

[ ] Decisionally Impaired – **Go to Section 4**

[ ] Prisoners – (*Research in this category is aimed at prisoners only, not as a part of the general population*) **Go to Section 5**

[ ] Students – **Go to Section 6**

# **Section I- Children**

* 1. Please indicate the type of risk to children that is expected. (Check one)

[ ] Category 1- Minimal Risk

[ ] Category 2- Greater than a minimal risk but presents direct benefit to individual subjects *(Must complete Category 2 subsection)*

[ ] Category 3- Greater than a minimal risk and no direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition. *(Must complete Category 3 subsection)*

* 1. What provisions will be made for soliciting the assent of the children and permission of their parents or guardians? Click or tap here to enter text.
	2. Will any of the children be wards of the state? [ ] Yes [ ] No
		1. If yes, is this research related to their status as wards?

 [ ] Yes [ ] No

* + 1. If yes, will the research be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. [ ] Yes [ ] No
		2. [45 CFR 46.409](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1404) requires that if this research is approved, then each child who is a ward must have an advocate in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is ***not associated in any way*** (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

*Who will be acting as the advocate(s)? Please list names and roles*: Click or tap here to enter text.

**Category 2 Subsection**

1. How is the risk present greater than minimal risk? Click or tap here to enter text.
2. How is the risk justified by the anticipated benefit to the subjects? Click or tap here to enter text.
3. How is the anticipated benefit at least as favorable to the subjects as that presented by alternative approaches? Click or tap here to enter text.

**Category 3 Subsection**

1. How is the risk present is greater than minimal risk? Click or tap here to enter text.
2. How do(es) the intervention or procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations? Click or tap here to enter text.
3. How is the intervention or procedure likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition? Click or tap here to enter text.

# **Section 2- Pregnant Women or Fetuses**

1. Have appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses? [ ] Yes [ ] No

Please give background information: Click or tap here to enter text.

1. Does the risk to the fetus caused solely by interventions or procedures have the prospect of direct benefit for the woman or the fetus? [ ] Yes [ ] No

OR

If there is no such prospect of benefit, is the risk to the fetus not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means? [ ] Yes [ ] No

1. Please describe how the risk is at least possible for achieving the objectives of the research. Click or tap here to enter text.
2. IF the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman **and the father** is obtained, unless the father is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. Please indicate who will be required to sign the consent form: Click or tap here to enter text.
3. Please check the following to confirm agreement with regulations:
	1. [ ] No inducements, monetary or otherwise, will be offered to terminate a pregnancy
	2. [ ] Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
	3. [ ] Individuals engaged in the research will have no part in determining the viability of a neonate

# **Section 3- Neonates**

1. This research includes which of the following (check all that apply):

[ ] Viable Neonates

[ ] Neonates of Uncertain Viability –(*Must complete Category 1 subsection*)

[ ] Nonviable Neonates – (*Must complete Category 2 subsection*)

1. Have appropriate preclinical studies been conducted and provide data for assessing potential risks to neonates, viable, uncertain, or nonviable? [ ] Yes [ ] No

Please give background information: Click or tap here to enter text.

1. Please check the following to confirm agreement with regulations:

[ ] Individuals engaged in the research will have no part in determining the viability of a neonate.

**Category 1 Subsection- Neonates of Uncertain Viability**

Until it has been ascertained whether or not a neonate is viable, a neonate **may not** be involved in research covered by this subpart unless the following (please check to confirm):

[ ] The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective OR

[ ] The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research

**Category 2 Subsection – Nonviable Neonates**

Nonviable neonates may not be involved in research unless **ALL** of the following conditions are met (Check for each condition):

 [ ]  Vital functions of the neonate will not be artificially maintained

[ ]  The research will not terminate the heartbeat or respiration of the neonate

[ ] There will be no added risk to the neonate resulting from the research

[ ]  The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means

# **Section 4 - Decisionally Impaired**

1. How does the research bear a direct relationship to the decisionally impaired subject’s condition or circumstance? Click or tap here to enter text.
2. How will the subject(s)’ cognition and/or decisional capacity be assessed? Who will complete the assessment? Click or tap here to enter text.
3. Who will serve an independent party to monitor and/or assist in the consent process? Click or tap here to enter text.
4. What methods will be used to enhance the subjects’ ability to achieve decisional capacity with regard to the proposed study (e.g. videos, educational materials, post-test, etc.)? Click or tap here to enter text.

# **Section 5- Prisoners**

1. Please select the following that best describes this research:

**[ ]**  Biomedical or behavioral research conducted or supported by DHHS (eg. CDC, FDA, NIH, etc.).

[ ]  Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

[ ]  Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

[ ]  Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults). **If checked, there are additional guidelines applied in** [**45 CFR 46.306**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.c)**.**

[ ]  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. **If checked, there are additional guidelines applied in** [**45 CFR 46.306**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.c)**.**

1. Will the information presented in language which is understandable to the subject population? [ ] Yes [ ] No
2. Will the prisoners receive advantages through participation in the research when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison? [ ] Yes [ ] No

If yes, then how are these advantages are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired? Click or tap here to enter text.

1. Are the risks involved in the research commensurate with risks that would be accepted by nonprisoner volunteers? [ ] Yes [ ] No

If no, please explain. Click or tap here to enter text.

1. Will control subjects be randomly selected from the group of available prisoners who meet the criteria needed for the research project? [ ] Yes [ ] No

If no, please explain how the selection process will be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Click or tap here to enter text.

1. How will you assure that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole? Click or tap here to enter text.
2. Will each prisoner been clearly informed in advance that participation in the research will have no effect on his or her parole? [ ] Yes [ ] No
3. Will your study require follow-up examination or care of participants after the end of their participation? [ ] Yes [ ] No
	1. If yes, what provisions are included for such examination or care, takin into account the varying lengths of the individual prisoners’ sentences? Click or tap here to enter text.
	2. How will participants be notified of this follow-up examination or care? Click or tap here to enter text.

# **Section 6- Students**

1. Are any of the researchers (including the faculty advisor) intending to recruit undergraduate students at HSU or other institutions? [ ] Yes [ ] No
	1. If yes, which institutions will be included in this study? Click or tap here to enter text.
2. Will the students be his/her own students enrolled in courses, members of a sports team, or in any way under the influence of the researcher?

[ ] Yes [ ] No

* 1. If yes, then please describe what steps will be taken to ensure that the students do not feel coerced or compelled to participate. Click or tap here to enter text.
	2. Will students receive extra credit for participating in the research?

 [ ] Yes [ ] No

If yes, what alternative option will be provided for students who choose not to participate? Click or tap here to enter text.

* 1. Is this study minimal risk? [ ] Yes [ ] No

If yes, explain the risk. Click or tap here to enter text.

If no, what additional protections will be in place to protect the students’ privacy and the student-instructor relationship Click or tap here to enter text.