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4.1.1 Healthy Children

You have indicated that this research will involve healthy children. Please provide information about the healthy children that are subjects in this study.

1. * **Please justify the risks to healthy children participating in the project.**

2. * **In the PI's opinion, what is the level of risk to the healthy child subject?**
   - ○ **No greater than minimal risk to the subject (45 CFR 46.404)**
   - ○ **Greater than minimal risk but presents the prospect of direct benefit to the individual subject (45 CFR 46.405)**
   - ○ **Greater than minimal risk with no prospect of direct benefit to the individual subject but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406)**
   - ○ **The research does not fit within any of the other categories, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)**

   Clear

3. * **Who are you proposing to obtain parental permission from for healthy children?**
   If the study falls under the category 45CFR46.406 or 45CFR46.407, two parents' signatures will be needed as per 45CFR46.408.
   - ○ **One parent**
   - ○ **Two parents**
   - ○ **Requesting parental waiver**

   Clear

4. * **Will assent from healthy children be obtained?**
   The IRB must determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.
   If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research

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Question a will appear if "obtaining assent" or "both" is selected in question 4. Question b will appear if "request to waive assent" or "both" is selected.

- ○ **Obtaining assent**
- ○ **Request to waive assent**
- ● **Both (assent will be obtained from some, but not all, child subjects)**

Clear

a. **How the assent for healthy children will be obtained and documented. Please be sure to include a signature line for the "Assent of Child" on the written consent form (if applicable).**

b. **Please choose from the following as to why a waiver of child assent is requested:**

- ○ **A waiver of assent is justified based upon the following:**
  - **i. The research involves no more than minimal risk to subjects**
  - **ii. The waiver will not adversely affect the rights and welfare of the subjects**
  - **iii. The research could not practicably be carried out without the waiver; and**
  - **iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**
- ○ **Capability of some or all of the children is so limited that they cannot reasonably be consulted.**
- ○ **The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.**

Clear

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4.1.2 Children with a Disease, Disorder, or Condition

You have indicated that this research will involve children with a disease or disorder. Please provide information about the children with a disease or disorder that are subjects in this study..

1. * **Please justify the risks to children with a disorder or condition participating in the project.**

2. * **In the PI's opinion, what is the level of risk to the child with a disease, disorder, or condition?**
   - ◯ **No greater than minimal risk to the subject (45 CFR 46.404)**
   - ◯ **Greater than minimal risk but presents the prospect of direct benefit to the individual subject (45 CFR 46.405)**
   - ◯ **Greater than minimal risk with no prospect of direct benefit to the individual subject but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406)**
   - ◯ **The research does not fit within any of the other categories, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)**

   Clear

3. * **Who are you proposing to obtain parental permission from for children with a disease, disorder, or condition?**
   If the study falls under the category 45CFR46.406 or 45CFR46.407, two parents' signatures will be needed as per 45CFR46.408.
   - ◯ **One parent**
   - ◯ **Two parents**
   - ◯ **Requesting parental waiver**

   Clear

4. * **Will assent from children with a disease, disorder, or condition be obtained?**
   The IRB must determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.
   If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being (

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only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Question a will appear if "obtaining assent" or "both" is selected in question 4. Question b will appear if "request to waive assent" or "both" is selected.

- ○ **Obtaining assent**
- ○ **Request to waive assent**
- ● **Both (assent will be obtained from some, but not all, child subjects)**

Clear

a. **Please specify from which children assent will be obtained (including age range), as well as how the assent of the children will be obtained and documented.**
Please be sure to include a signature line for the "Assent of Child" on the written consent form (if applicable).

b. **Please choose from the following as to why a waiver of child assent is requested:**

- ○ **A waiver of assent is justified based upon the following:**
  - i. **The research involves no more than minimal risk to subjects**
  - ii. **The waiver will not adversely affect the rights and welfare of the subjects**
  - iii. **The research could not practicably be carried out without the waiver; and**
  - iv. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**
- ○ **Capability of some or all of the children is so limited that they cannot reasonably be consulted.**
- ○ **The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.**

Clear

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4.1.3 Wards of State

You have indicated that this research will involve children who are wards of the state. Please note that if Wards of the State are enrolled, approval from the Department of Children and Family Services (DCFS) will be required.

1. * **Please clarify how the consent of the legal guardian(s) of the ward(s) of the state will be obtained. How will the investigator ensure that the appropriate person grants permission for each ward to participate in the research?**

2. **If wards of the state will be enrolled and the research is greater than minimal risk with no prospect of direct benefit to subjects, please describe your plan to appoint an advocate for potential subjects who are wards of the state.**

3. **Please attach approval from the DCFS.**

+ Add

Name

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4.2 Decisionally Impaired

1. **Please provide a rationale for the inclusion of decisionally-impaired subjects.**

2. **Will all subjects have a legally-authorized representative or power of attorney?** ***A legally-authorized representative is one who has been legally given the authority outside the context of this research protocol to make health care decisions on behalf of the potential subject.***

   - ○ **Yes**
   - ○ **No**
   - ● **Some May/Some May Not**

   Clear

Questions a-b will appear if "yes" or "some may/some may not" is selected. Questions c-g will appear if "no" or "some may/some may not" is selected.

   a. **Please explain why some or all of the study population is expected to have legally authorized representatives already in place.**

   b. **Please document the consent process for legally authorized representatives, if not already described in the Consent section.**

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c. *Additional information can be found here: "Illinois Medical Patients Health Act" 755 ILCS 40/ Health Care Surrogate Act*

Please provide a description of any therapeutic benefits to the subject that may reasonably be expected from the research.

d. **Please provide an outline of proposed procedures for determining that the potential subject does not have an operative and unrevoked living will, durable power of attorney for health care, or declaration for mental health treatment.**

e. **Please provide an outline of the proposed procedures for providing information about the research protocol to the potential subject's physician so that the physician can evaluate the person's decisional capacity to participate in the proposed research.**

f. **Please document the consent process, proxy consenter will be identified and v**

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witness to the consent process.

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g. **Please clarify how the subject will be made aware of the research and his/her participation as well as the identity of the proxy/surrogate as soon as feasible. If this is not feasible, please explain why not. Note that once informed of participation, if the subject objects and the surrogate is not a court appointed guardian, the subject should be withdrawn from the research.**

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4.3 Subordinates of the Research Team or Employees of the UChicago or the UCMC

The IRB recommends that employees and students assigned to a particular investigator or laboratory should not be directly recruited for participation in any study conducted by that investigator or laboratory, although such employees and students may, on their own, volunteer to participate. The IRB recommends that students and employees should be recruited through general announcements, bulletin board postings or advertisements, rather than individual solicitations.

1. **Please clarify how investigators will avoid coercion when enrolling subjects. Please be sure to specify the nature of the employment or supervising/reporting structure for subjects that may be involved.**

2. **If approval has been obtained from a Program Director or relevant hospital administrator, please attach here.**

+ Add

Name

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4.4 Undergraduate Students

1. **Please describe the plan to ensure status/grades are not affected and to minimize coercion.**

2. **Please provide any additional information regarding the participation of undergraduate students which may be useful to the Dean in determining whether students may be included in the research. (Submissions planning to enroll undergraduate students will be forwarded to the Dean of Students for review.)**

3. **Please upload any relevant documentation concerning undergraduates in this research.**

+ Add

Name
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4.5 Prisoners

For the prisoner population, "minimal risk" is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons."

1. * **In the PI's opinion, what is the category of research involving prisoners?**
   - ☐ **It is a 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. [45 CFR 46.306(a)(2)(i)]**
   - ☐ **It is a 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. [45 CFR 46.306(a)(2)(ii)]**
   - ☐ **It is 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) provided that the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register of intent to approve such research. [45 CFR 46.306(a)(2)(iii)]**
   - ☐ **It is research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice in the Federal Register of the intent to approve such research. [45 CFR 46.306(a)(2)(iv)]**
   - ☐ **It is research that involves epidemiological studies, including epidemiological research related to chronic diseases, injuries, and environmental health, in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research. [68 FR 36929]**

2. * **Please describe the advantages that may accrue to the prisoner through his or her participation in the research, particularly in comparison to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison. The possible advantages should not be of such a magnitude that the prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.**

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3. * **Are the risks of the research commensurate with risks that would be accepted by non-prisoner volunteers?**
   ○ **Yes** ● **No** Clear

   STOP - This research may not be performed. Please consult with the IRB office.

4. **Please describe your proposed procedures for the selection of subjects. Procedures for the selection of subjects within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.**

5. * **Describe how a prisoner will be informed in advance that participation in the research will have no effect on his or her parole. Before the IRB can approve this research, it must receive adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.**

6. * **If applicable, describe the provisions for follow-up examination or care of participants after the end of their participation, should the investigator or the IRB determine that there is a need for follow-up examination or care. Include a description of how the varying lengths of individual prisoners' sentences will be taken into account as well as a description of how participants will be informed of these provisions.**

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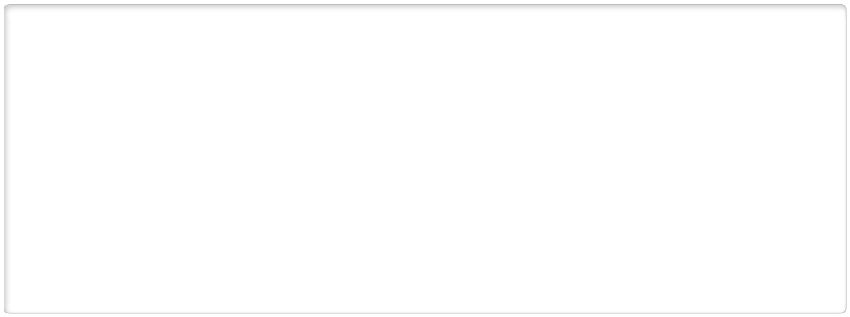

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4.6 Pregnant Women, Fetuses

1. * **In the PI's opinion, what is the risk to subjects presented by this research?**
   - ○ **Greater than minimal risk with prospect of direct benefit ONLY to fetus**
   - ○ **Greater than minimal risk with prospect of direct benefit to pregnant woman only OR to both pregnant woman and fetus**
   - ○ **Minimal risk to pregnant woman and fetus without the prospect of direct benefit, but the research proposes the development of important biomedical knowledge which cannot be obtained by any other means**
   - ○ **Minimal risk with prospect of direct benefit ONLY to fetus**
   - ○ **Minimal risk with prospect of direct benefit to pregnant woman only OR to both pregnant woman and fetus**
   - ○ **None of the Above**

   Clear

2. **Who are you proposing to obtain consent from?**
   If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent can be obtained from pregnant woman. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father should be obtained as outlined at 45CFR46.204(e).
   - ○ **Both parents of the fetus (prospect of direct benefit is solely to the fetus)**
   - ○ **Pregnant woman only**
   - ○ **Waiver of consent requested**

   Clear

3. * **Please explain why the identified risks are the least possible for achieving the objectives of the research.**

4. **Please explain how it will be verified that ea[illegible] will be fully informed and kept fully informe[illegible]**

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5. * **Will inducements, monetary or otherwise, be offered to terminate a pregnancy?**
   ○ **Yes** ○ **No** Clear

6. * **Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?**
   ○ **Yes** ○ **No** Clear

7. * **Will individuals engaged in the research have any part in determining the viability of a neonate?**
   ● **Yes** ○ **No** Clear

   *** STOP ** Please consult the IRB before proceeding with this application.*

Selecting "yes" in question 5, 6, or 7 will result in the message to STOP and consult the IRB office prior to continuing.

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4.8 Non-Viable Neonates

1. * **Please justify the inclusion of nonviable neonates in the research by describing any preclinical studies and/or clinical studies that have been conducted which provide data for assessing potential risks and benefits to neonates.**

2. * **In the PI's opinion, what is the risk to subjects presented by this research? In the PI's opinion, what is the risk to subjects presented by this research?**
   - ○ **Minimal risk to the neonate with the prospect of direct benefit**
   - ○ **More than minimal risk to the neonate with the prospect of direct benefit**
   - ○ **No added risk to the neonate resulting from the research**

   Clear

3. * **Please explain why the identified risks are the least possible for achieving the objectives of the research.**

4. * **Will vital functions of the noenate be artificially maintained?**
   ○ **Yes** ○ **No** Clear

Selecting "yes" in question 4, 5, or 6 will result in the message to STOP and consult the IRB office prior to continuing.

5. * **Will the research terminate the heartbeat or respiration of the neonate?**
   ○ **Yes** ○ **No** Clear

6. * **Will there be added risk to the neonate resulting from the research?**
   ● **Yes** ○ **No** Clear

*** STOP ** Please consult the IRB before proce*

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Selecting "no" in response to question 7 will result in the message to STOP and consult the IRB office prior to continuing.

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7. * **Is the purpose of the research the develo knowledge that cannot be obtained by an**
   ○ **Yes** ● **No** Clear

   ** STOP ** Please consult the IRB before proceeding with this application.

8. **Please describe how the parents will be approached to consent to the participation in research of a nonviable neonate.**

9. **Please describe how it will be verified that each individual providing consent will be fully informed and kept fully informed regarding the reasonably foreseeable impact of the research on the neonate.**

10. * **Please confirm that individuals engaged in the research will have no part in determining the viability of a neonate.**

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4.9 Non-English Speakers

Please attach any translated consent document(s) in the Consent Procedures section, along with certification of translation. Please ensure that any translated surveys, advertisements or other documents are attached in the appropriate sections of this form.

1. * **Please describe the non-English speaking population(s) to be enrolled.**

2. * **Describe the process of how you will explain the study and ensure that the non-English speaking subjects understand the study and their participation in research. For example, please discuss the use of translators, translated consent documents, etc.**

3. * **Please indicate the method of translation:**
   - ☐ **Translated short form consent will be used with qualified interpreter/translator *(Limited Use)***
   - ☐ **Investigator will provide IRB with translation of approved consent form**

4. **Please provide the qualifications of the interpreter. For whom does the interpreter work? If the interpreter is not a member of the study team, who will ask the interpreter to serve in this role for the study and how will this be done?**

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5. **Please indicate who will be responsible for updating subjects of study progress during the course of the study, including notifying subjects of any changes to the research, updating subjects on study risks, collecting complaints, etc.**

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