**I. Research Title:**

**II. Personnel**

**A. Principal Investigator (PI)**

|  |  |  |
| --- | --- | --- |
| Name (Last, First) | Degree(s) | Net ID (e.g., NetID@uic.edu) |
| Department | College | University Status[ ]  Student/Fellow/Resident[ ]  Faculty/Staff |
| Phone Number | UIC E-mail Address |

**III. Purpose of the Protocol Exception:**

[ ]  Document the enrollment of a single non-English speaking subject utilizing the short form. - *Complete section A.*

[ ]  Allow the enrollment of or modification of procedures for a single subject. - *Complete section B.*

[ ]  Allow the enrollment of or modification of procedures for small number of subjects. - *Complete section B.*

[ ]  Allow currently enrolled subjects to continue some or all research activities during a lapse in IRB approval or suspension. Enrollment of new subjects is not allowed, except in extraordinary circumstances. - *Complete section C.*

1. **Use of a Short Form to enroll a single non-English speaking subject**
2. Date the subject was enrolled:
3. Upload a blank copy of the short form consent that was utilized to enroll the subject.
4. **Enrollment or modification of procedures for a single subject or small number of subjects**
5. Subject(s) Study Identification Code - *Do not provide any direct subject identifiers. Use a coded identifier like the one used in study records*.

1. Describe the exception and justify why the exception is needed.

1. Briefly discuss the impact of the exception on the risks and benefits to the individual subject. Note whether the exception affects the validity of the study.

1. Informed Consent: Indicate whether the exception will be discussed with the subject. If so, describe how the exception will be presented to the subject. Upload any written materials or script of oral presentation to be provided the subject.

1. If requesting an exception for a small number of subjects, justify why a protocol amendment cannot be submitted to the IRB for review.

1. If the research involves an investigational drug, device, or biologic:
* Upload the sponsor, funding agency, and/or /coordinating site approval for the exception.
* Upload the FDA approval for the exception if an investigational device is involved and the exception may affect the scientific soundness of the plan or the rights, safety, or welfare of the subjects.
1. **Continuation of some or all research activities during a lapse in IRB approval or suspension**
2. Research is currently stopped due to a:

[ ]  Lapse in approval

[ ]  IRB suspension

1. Research activities

[ ]  Requesting to continue *all* research activities in the IRB approved protocol

[ ]  Requesting to continue *only the following activities* from the IRB approved protocol

 List:

1. List below for each subject their coded identification (ID) and the safety concerns or ethical issues justifying why it is in their best interest to continue participation in the requested research activities (Do **not** provide any direct subject identifiers.)

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| Subject Coded ID | Justification for Protocol Exception |
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