TriHealth IRB Notes 

Per **45 CFR 46.116(a)(1)** and **21 CFR 50.20**, before involving a human subject in research, an investigator must obtain legally effective informed consent from the subject (or legally authorized representative). The regulations only allow for specific exceptions and waivers to the requirement for informed consent. Indeed, the **Belmont Report** describes the ethical principle of **Respect for Persons** that requires human subjects be given the opportunity to choose what will happen to them. Given the ethical importance for informed consent and the regulatory requirements for research, the IRB considers deviations in the informed consent process to be **significant**.

Major informed consent deviations that impact the rights and welfare of subjects must be reported to the IRB using the **Protocol Deviation/Non-Compliance Form** within 10 days of becoming aware of the issue. The IRB will evaluate informed consent deviations and determine the corrective measures and site actions that are required. Major deviations include, but are not limited to, the following:

- Failure to obtain informed consent
- Informed consent obtained after the start of study procedures
- Using an informed consent document that is not IRB approved
- Using an incorrect version of the informed consent document
- Using an informed consent document for the wrong study
- Informed consent signatures not obtained (missing, incorrect, and/or unauthorized signatures)
- Date of informed consent not documented or falsified
- Informed consent obtained by individuals who are not delegated to consent and/or trained to consent
- Incomplete sections of the informed consent document (*e.g.* sections with checkboxes for optional study procedures and/or sub-studies are not complete)
- No verification of the consent process and/or documentation that a copy of the informed consent document was provided to the subject
- Missing or lost informed consent document
- Not following the IRB approved consent process (as described in IRB approved protocol and/or IRB approval letter)
- Unauthorized and/or unapproved consent via legally authorized representative
- Using an English informed consent document and informed consent process for subjects who do not understand, speak, or read English
- Not using or documenting the use of an impartial witness during the consent of a subject who is blind or visually impaired and/or unable to read an informed consent document

Minor informed consent deviations that DO NOT impact the rights and welfare of subjects must be documented by researchers on the **Protocol Deviation Log**. Minor deviations may include typos made during documentation of informed consent (*e.g.* printed name of subject is indicated with "nickname", using incorrect notations or marks in checkboxes). The **Protocol Deviation Log** must be submitted to the IRB with an investigator's annual **Continuing Review Report**. The IRB will review the minor deviations for **patterns** of non-compliance and determine if corrective measures and site actions are required.