# TriHealth IRB Notes

1. Per **21 CFR 56.101(a)**, an IRB must protect the rights and welfare of subjects involved in research. The recruitment of subjects is the beginning of the informed consent process and the involvement in research. The pressure to recruit and enroll subjects may raise ethical challenges for researchers. As such, please consider the following:
    - ALL recruitment plans and tools must be submitted to the IRB for review and approval prior to use.
    - Researchers must explain the logistics and timing of subject recruitment in the protocol and/or IRB Submission.
    - Any plan for telephone recruitment must explain who will access medical records to identify potential subjects for the purpose of contacting them for recruitment so that the Board can consider the preparatory research provision, **45 CFR 164.502(a)(1)(i)**. Researchers must submit a **Request for Partial Waiver of Authorization for Recruitment** if independent contractors or non-employees will work with the research team to access medical records to identify potential subjects for recruitment.

2. Subjects who are blind or visually impaired can often make their own healthcare decisions and consent for research independent of an LAR (legally authorized representative). TriHealth IRB partnered with TriHealth legal to develop the following guidance for the **Informed Consent of the Blind or Visually Impaired (who Make Own Healthcare Decisions)**:
    - A designated study team member orally presents the IRB-approved informed consent document and HIPAA authorization. Sufficient time is allowed for questions to be asked and answered.
    - An Impartial Witness must observe the informed consent and authorization process. An Impartial Witness may be a subject advocate or someone not affiliated with the study team. A family member is not recommended to serve as an Impartial Witness.
    - The subject signs and dates the informed consent document and authorization if the subject understands and consents to participate in the study. The subject may use an "X" or other mark in place of an actual signature if the subject is unable to sign and date. The state of Ohio accepts an "X" or mark as a signature (providing it is witnessed).
    - The Impartial Witness signs and dates the informed consent document and authorization. This allows the Impartial Witness to attest that the information in the informed consent document and authorization was accurately explained, the subject apparently understood the information, and informed consent for study participation and authorization was given freely.
    - The study team member obtaining informed consent signs and dates the informed consent document.
    - A signed copy of the informed consent document and authorization is provided to the subject.
    - If the investigator has any doubt about the subject's comprehension of the informed consent document, the investigator should not enroll the subject in the study.
    - Please check the IRB approved informed consent document and authorization for Impartial Witness lines prior to consenting a subject who is blind or visually impaired. Your documents may require modification to include the Impartial Witness lines. This generally can be performed by the IRB Board Chairman in an expedited manner.

3. Per **45 CFR 46.116(a)(3)**, the information described in an informed consent document must be **"understandable to the subject"**. The National Comprehensive Cancer Network provides a free informed consent language database at https://www.nccn.org/clinical_trials/informed_consent.aspx. Researchers may consider referencing the database as they develop and prepare an informed consent document for IRB submission and review.

4. Per **21 CFR 312.66**, **312.53(c)(1)(vii)**, **56.108(b)(1)** and **45 CRF 46.108(a)(4)(i)**, investigators must report all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) to the IRB. UPIRTSO are **serious**, **unanticipated**, AND **possibly related** to the study:
    - A problem or event is **SERIOUS** if it results in significant harm or places subjects or others at a greater risk of harm than was previously known or recognized.
    - A problem or event is **UNANTICIPATED** when it was unforeseeable at the time of occurrence.
    - A problem or event is **RELATED** if it is possibly related to the research activities.
    - A problem or event could be a single occurrence, a small number or occurrences, or multiple occurrences (determined to be unanticipated based on aggregate analysis).

5. Investigators must use the **Unanticipated Problem Submission Form** to submit an UPIRTSO within 5 business days of occurrence or within 24 hours in the event of death:
    - The IRB will review the submission and determine if actions are required (possibly including, but not limited to, revision of the protocol, revision of the informed consent document, increased monitoring, suspension of research). The investigator and study team will be notified of the Board determination and the IRB will report the UPIRTSO to the FDA or OHRP and appropriate institutional officials.
    - The IRB recognizes that investigators may be uncertain if a problem or event meets the criteria of an UPIRTSO. **If there is any doubt, the investigator should use the Unanticipated Problem Submission Form to submit the problem or event for IRB evaluation.** The IRB Chairman will determine if the problem or event may be an UPIRTSO and require evaluation by the Full Board.

6. Investigators may submit **Serious Adverse Events** that do NOT meet the criteria of a UPIRTSO for IRB review and acknowledgment. An investigator may submit these to the IRB using the **IND/IDE Safety Submission Form**. These submissions may be required by sponsors and/or preferred by investigators. These submissions are not required by the IRB.