TriHealth IRB Notes 

1. Per **45 CFR 46.109(f)(1)(i)**, annual continuing review is not required for research projects that undergo EXPEDITED REVIEW on or after January 21, 2019. These research projects will be granted a **3 year IRB approval**.
    - This does not apply to FDA regulated studies that undergo expedited review. All FDA regulated studies must be reviewed at least annually.
    - This does not apply to studies that were reviewed by expedited review before January 21, 2019.
    - 60 days prior to the 3 year IRB approval expiration date, an investigator can apply to the IRB for Re-Approval of research.

2. Per **45 CFR 46.116(a)(3)**, the information described in an informed consent document must be **"understandable to the subject"**. Researches must use clear, concise text in the informed consent document. The text must be presented so that a layperson without a medical background can understand the informed consent document.
    - Researchers can avoid many IRB Conditions of Approval by clearly explaining the purpose of a study and using layperson descriptions of study procedures and risks in the informed consent document.

3. Per **45 CFR 46.111(a)(2)** and **21 CFR 56.111(a)(2)**, an IRB must determine if study risks are reasonable to anticipated benefits (if any) to subjects, and the importance of the knowledge that may be expected to result from a study.
    - An IRB does NOT want to see subjects exposed to risks/inconveniences if a study has **dubious scientific validity**.
    - Every study should include a **justification of sample size**. An inadequate sample size may needlessly expose subjects to study risks without allowing for results that provide scientific benefits to society.
    - Protocol sample size should describe the appropriate number of subjects for a study design. Protocol sample size should represent the number of subjects for researchers to find **meaningful results**.

4. Per **45 CFR 46.116(f)(3)(iii)**, an IRB CANNOT approve a request for Waiver of Informed Consent if researchers can "practicably" carry out the research with informed consent.
    - The distinction between **retrospective chart review** and **prospective chart review** is important when an IRB considers a request for waiver of informed consent.
    - With prospective chart review (data does not currently exist in charts), there is typically an opportunity to engage potential subjects and obtain informed consent since they will be coming in prospectively for regular care visits and informed consent is warranted and practicable.
    - With retrospective chart review (data currently exists in charts), there may not be an opportunity to engage potential subjects and obtain informed consent since they may not be coming in for regular care visits. In this situation, it may not be practicable to find and contact all of the targeted subjects to obtain consent (and including only a part of the subject population that may potentially be located and consented will impact analysis and the scientific validity of the study).

5. Per **45 CFR 46.111(a)(3)**, an IRB must determine if the **selection of subjects** for a study is equitable taking into account the purpose and setting of the research. A research protocol must be written so that an IRB understands the **subject population**, including subject age and potential vulnerability. A research protocol should also explain if pregnant patients may be included in the research.