TriHealth IRB Notes 

1. The revised TriHealth IRB Informed Consent (IC) template (version 1/14/19) is available on the Hatton Research website.
    - NEW studies (reviewed by the IRB on or after 1/21/19) that involve informed consent must utilize the revised IC template (version 1/14/19). **This will help investigators comply with the IC requirements of the revised Common Rule.**
    - An investigator must use the bracketed prompts within the IC template to customize the template for a research study. **Blue bracketed text** must be customized**. Red bracketed text** must be customized or deleted based on the study design.
    - The "informed consent template with LAR" document is no longer available for new research. The revised IC template (version 1/14/19) includes red bracketed LAR signatures lines for an investigator to retain/delete, as appropriate for a patient population.
    - The "informed consent guidance" document is no longer available for new research.
    - The "HIPAA Main" document is no longer available for new research. The TriHealth IC template (version 1/14/19) includes an embedded HIPAA authorization.
    - The "HIPAA Authorization Form for Data Repository Research" and "HIPAA Authorization Form for Biospecimen Repository Research" are only available from the Regulatory Affairs Administrator who will determine if these stand-alone authorization documents may be used for new research.

2. IRB-approved IC documents and authorization documents will be designated as "STAMPED & APPROVED" when provided to an investigator. IRB approval is also documented on the IRB approval letter.
    - The documents are protected (editing is restricted and tracked). Any edits/changes to these documents or any other IRB-approved documents must be reviewed and approved by the IRB prior to implementation.
    - The IRB will not supply a PDF copy of the IRB-approved IC documents and authorization documents.

3. Protocols, study-related documents, and recruitment items should be version controlled and/or dated when submitted to the IRB.

4. IRB-approved **recruitment items** that are patient-facing (for example, brochures and posters) receive an IRB approval stamp. IRB approval is also documented on the IRB approval letter.

5. IRB-approved patient questionnaires, diaries, educational materials, patient cards and copyrighted materials do not generally receive an IRB approval stamp. IRB approval is documented on the IRB approval letter.
    - The IRB can utilize an IRB approval stamp on any items that have gone through rounds of revisions during the Board review process if these items are not version controlled or dated by the investigator.
    - The IRB can utilize an IRB approval stamp on items that generally do not receive an IRB approval stamp if a stamp is requested by a client/sponsor.

6. TriHealth IRB is a new member of SMART IRB. This may help with reliance arrangements and may facilitate the use of a single IRB for multi-site research. A list of institutions participating in SMART IRB can be found at https://smartirb.org/participating-institutions/.