The Clinical Coordinator

Clinical Research News You Can Use

SMART IRB

SMART IRB is a national, integrated, comprehensive platform that includes an IRB reliance agreement and an online system. The SMART IRB agreement has been signed by over 575 institutions, including UTHealth and the Memorial Hermann System.

The SMART IRB initiative was launched with support from the CTSA to enable institutions to comply with the Common Rule mandate to use a single Institutional Review Board (sIRB) for multi-site studies, which will go into effect in January 2020. The rule that multi-site studies funded by NIH must use a sIRB has been in effect since January 25, 2018. See NIH Notice NOT-OD-16-094. In addition to academic medical centers and hospitals, several commercial IRBs are also participating members in the SMART IRB platform.

UTHealth IRB as Reviewing IRB: When you have a new multi-site study and would like to use the SMART IRB reliance platform, check to see if all the sites in your study are participants in the SMART IRB platform by visiting the Participating Institutions page of SMART IRB. Please do not commit UTHealth IRB as the reviewing IRB without first speaking with the UTHealth IRB office. UTHealth has limited capacity at this time, both in staffing and infrastructure, to serve as a sIRB. The UTHealth IRB will make determinations on a case-by-case basis whether to accept the role of the reviewing IRB for

a research proposal, and this will be based on type of research study, risks to human subjects in the proposed research, number of sites involved, experience of the UTHealth PI and study team with coordinating multi-site research, etc.

If UTHealth IRB agrees to be the reviewing IRB, you may initiate the process both within iRIS and within the SMART IRB platform. Our SMART IRB expert, Laura Lincoln, BS, IRB Coordinator for Panel 4, will be happy to help you navigate this process. Setting up a new study within the SMART IRB platform is not difficult but includes several steps, such as entering the names of the site PIs for each site, uploading the protocol and consent forms, etc.

Costs for IRB review of federally funded research are usually considered an indirect cost (IDC) that is covered under an institution's Facilities and Administration (F&A) rate and may not be included in the budget; however, the IDC funds do not include the cost of reviewing other sites. Review of other sites is a new task for the IRB, and the cost of reviewing other sites must be included as a direct cost in the grant budget. When the UTHealth IRB will be the reviewing IRB for federally funded studies, do include the review fee in the study budget.

UTHealth as Relying Institution: For studies in which an external IRB will be the reviewing IRB, the UTHealth IRB office will receive a request via the SMART IRB platform. Please follow our usual process for requesting permission to rely on an external IRB via iRIS.

We recommend that you contact the IRB office early in the process. IRB staff will be happy to help you navigate all of the available options to help you make an informed decision. More information is found on the CPHS website here.

Services Offered by UTHealth's Biomedical Informatics Group (BIG)
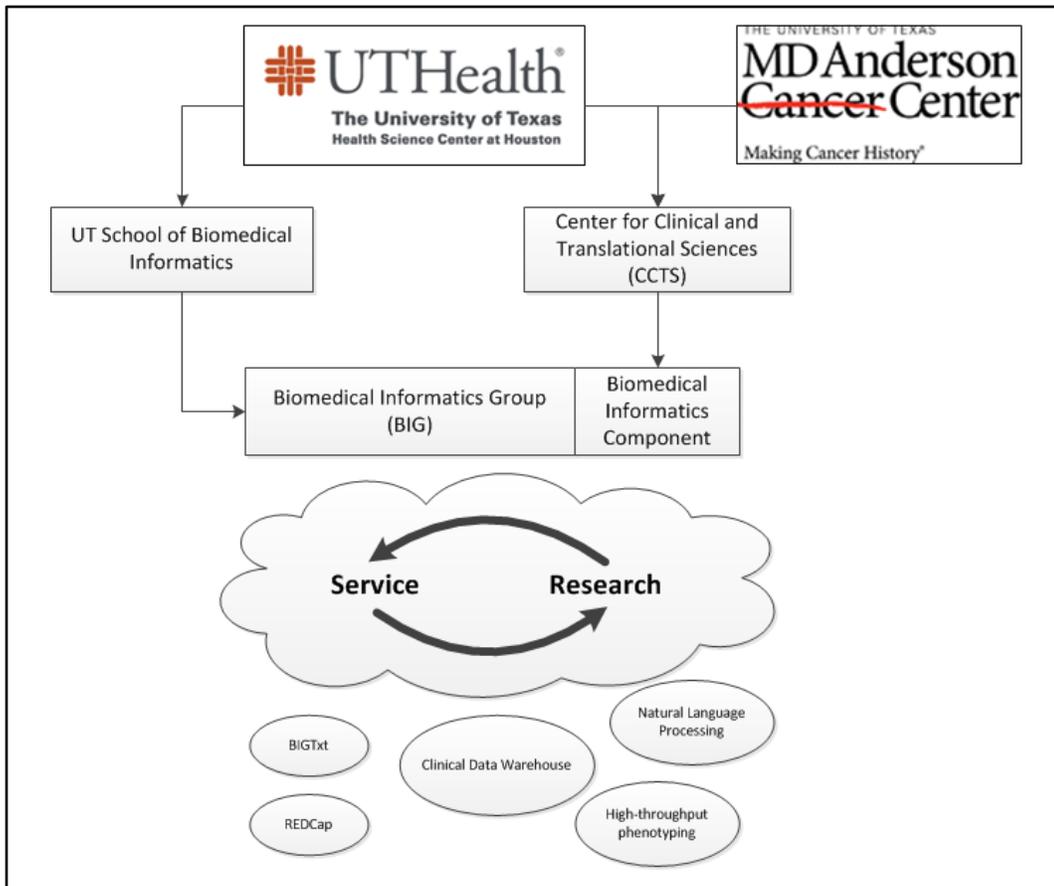
We were delighted to have Susan Guerrero speak at the September 2019 Study Coordinator Forum about services offered by UTHealth's Biomedical Informatics Group (BIG). Services are outlined below and include direct access to clinical data, enhanced subject recruiting, PHI data management, and customized support for research projects.

Data Requests: UT Physicians' patient data is stored in the Clinical Data Warehouse. UTHealth BIG can provide two types of data extracts: identified or de-identified. Identified data requests must be accompanied by an IRB approval letter that clearly indicates the data elements for which access is allowed. De-identified data and aggregate record counts of specific diagnosis can be requested for grant hypotheses development. This service is also useful for Chart Reviews and Quality improvement (QI) projects. Requests can be submitted at:

https://redcap.uth.tmc.edu/surveys/?s=79RDHRDPLH

Enhanced Subject Recruitment: Custom scripts can be developed to identify subjects within the UT system who meet study inclusion and exclusion criteria. These scripts can be scheduled to run on a frequency basis that meets the need of the research team. This service allows for the focusing of recruitment efforts on qualified individuals. Use the same link as data requests and indicate this is a subject recruitment request Requests can be submitted at the same link used for data requests (but indicate it is a subject recruitment request): https://redcap.uth.tmc.edu/surveys/?s=79RDHRDPLH

REDCap: REDCap is a web-based data repository that can capture subject information and associated study data. Data can be extracted for import into the

most popular statistical packages (SPSS, SAS, R, Stata). Link for access: https://redcap.uth.tmc.edu

BIGTxt: BIGTxt is a low-cost, text-messaging system for university studies that can be used to deliver non-medical text messages and promote subject retention. Link for access: https://bigtxt.uth.tmc.edu

ACT Network: The ACT network provides access to local UT Physicians' patient data, as well as to over 60 participating members' patient data, for cohort identification. Login is via UTHealth user id and password. All data is de-identified. Query construction is via drag and drop and can be stored for future reuse. Link: https://www.actnetwork.us/national

Audit and Risk Assessment: UTHealth BIG can also provide support for remediation and compliance issues. Upon request.

For More Information, contact Susan Guerrero, PMP, CISSP, Director of the BigARC Service Center at Susan.C.Guerrero@uth.tmc.edu or 713-500-3926. UTHealth BIG's website is at https://sbmi.uth.edu/uth-big/index.htm.

Test Your Good Clinical Practice Knowledge

1. TRUE or FALSE: Phase 1 studies involve the initial introduction of an investigational drug to humans.

2. The purpose of a phase 1 study is to assess _____ and determine _____.

3. A phase _____ study involves randomized and blinded testing of an investigational drug in several hundred to thousand patients.

4. Phase 4 studies are also known as _____.

5. Phase _____ studies assess the efficacy of a drug.

6. TRUE or FALSE: The term "phase" may be used to describe both drug and device studies.

7. The terms "early feasibility study," "traditional feasibility study," and "pivotal study" are used to describe different types of _____ studies.

Answers:
1. true, 2. safety, dosage, 3. three, 4. post-marketing studies, 5. two, three, and four, 6. false, FDA only uses "phase" in reference to drug studies, 7. device

FDA's definitions of drug study phases are found at:
https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

FDA's definitions device study types are found on page 6 in the guidance at:
https://www.fda.gov/media/81784/download

Upcoming Training

iRIS Training
Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth's CPHS and AWC.
Date and Time: 10/29/19 (1:30 pm - 4:00 pm); 11/20/19 (9:30 am – 12:00 pm)
Location: UCT 1155 (parking will be validated)
Registration is required. [Register here](#).

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management. More information [here](#).
Date: No forum in November or December 2019; next forum will be January 22, 2020
Time: 11:30 am – 1:00 pm
Topic: TBD
Location: MSB B.645
Lunch will be provided for the first 40 participants.
Registration is not required.

TMC – SoCRA METS
Objective: Monthly training and educational event for clinical research professionals.
Date: November 6, 2019
Time: 3:30 pm – 4:30 pm
Topic: Consolidating Your Research Framework into the 21st Century by Dennisse Galdamez, Director of Clinical Research, Gadolin Research, LLC
Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue
Registration is required. [Register here](#).

IRB Office Hours
If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.
MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640
SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room).
An appointment is not necessary

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT suite 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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We would love to hear from you.
Please send your comments and suggestions to clinicaltrials@uth.tmc.edu.