



UTSD CLINICAL RESEARCH GUIDE

2023

**The University of Texas Health Science
Center at Houston (UTHealth) School of Dentistry**

**Section for Clinical and Translational Research -
Office of Research**

Version April 3, 2023



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Introduction

The Section for Clinical and Translational Research (CTR) in the Office of Research (OR) provides support and guidance to UTSD students, staff, trainees and faculty on initiating and managing all aspects of clinical research and clinical trials. The purpose of the Clinical Research Guide is to help researchers navigate the clinical research process from START to FINISH. BEFORE beginning any research involving human subjects, human derived data or specimens, researchers should contact the UTSD Office of Research and Section for Clinical and Translational Research for guidance.

Guide Aims/Purpose/Mission

- Protocol development and study guidance
- UTSD approval and UTHHealth institutional approval process
- Regulatory compliance requirements
- Coverage analysis
- Ongoing study resources
- Study close out procedures

Section for Clinical and Translational Research (CTR) - Office of Research

Dr. Mary “Cindy” Farach-Carson – Director of Clinical and Translation Research

Office of Research (OR)

Dr. Mary C. (Cindy) Farach-Carson – Associate Dean for Research

Dr. Dharini van der Hoeven – Director of Pre-/Post-Doctoral Research

Sandra Jung – Administrative Manager

Dr. Nat Holland – Data Scientist

Position Open – Senior Grants & Contracts Specialist

Augustus Gerald Bellot – Research Coordinator II

Arminda Martinez- Research Coordinator I

Mary Kim- Support Assistant

Office of Research Directory <https://dentistry.uth.edu/directory/research.htm>

Office of Research Website <https://dentistry.uth.edu/research/>

Definitions and Acronyms

Clinical Research is a branch of healthcare science that focuses on obtaining information about individuals, groups and populations about specific clinical conditions. This includes but is not limited to: review of electronic health records for defining the natural history of a condition/ determining efficacy of medications/procedures and treatments, tissue collection, interventional studies and controlled drug, method or device trials.

Clinical Trial is a clinical research study in which one or more patients are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related clinical or behavioral outcomes.

Quality Improvement in health care focuses on implementing knowledge/programs/processes to improve patient care and assessing the impact/outcomes of these processes/programs. This includes but is not limited to: workflow, treatment outcomes, satisfaction survey and new sterilization protocol.

Research is a systematic investigation, including research development, testing and evaluation, that uses the scientific method to develop or contribute to the healthcare knowledge base.

Human subjects research is defined as research involving human subjects, human derived materials, or human derived data. The data may be obtained through intervention or interaction, whether identifiable or not, and may include private information.

Human Subject is a living individual about whom research is being conducted.

Acronym	Definition
CA	Coverage Analysis
COHQS	Center for Oral Healthcare Quality and Safety
CPHS	Committee for Protection of Human Subjects
CRU	Clinical Research Unit
CTR	Clinical and Translational Research
CTRC	Clinical Trials Resources Center
DUA	Data Use Agreement
IRB	Institutional Review Board
iRIS	Internet Research Information System
MTA	Materials Transfer Agreement
NB	Non-Billable
OR	Office of Research
QI	Quality Improvement
SOC	Standard of Care
SPA	Sponsored Projects Administration
UTSD	University of Texas School of Dentistry at Houston

Distinguishing Clinical Research and Quality Improvement

Before beginning a project, it should be determined if the proposed work is clinical research or quality improvement using the definitions above. The Office of Research can help with making this decision.

Examples of clinical research: tissue collection from patients, some reviews of medical records, interventional studies, controlled drug, method or device trials, genetics research with blood or tissue collection.

At UTSD, clinical research is overseen by the Section for Clinical and Translational Research (CTR) in the Office of Research under the direction of the Associate Dean for Research. IRB approval is required.

Examples of quality improvement projects: new treatment workflow, satisfaction survey, new sterilization protocol.

Quality improvement projects are overseen by the Associate Dean for Technology Services & Informatics in the Center for Oral Healthcare Quality and Safety (COHQC) in the Office of Technology Services & Informatics. IRB approval is not required.

All studies in the UTSD clinics must receive administrative approval prior to initiation of work, regardless of whether it is clinical research or quality improvement. The form for this is in Appendix E.

Clinical Trials

A clinical trial is a study in which patients are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Examples of clinical trials:

- Test ways to detect a disease/syndrome early, sometimes before their symptoms appear (Early detection trial).
- Test ways to prevent a health problem such as a new vaccine or lifestyle intervention (Prevention trial).
- Examine whether a new device, drug, or treatment improves quality of life for people living with a life-threatening disease or a chronic health problem (Treatment trial).
- Study the role of caregivers or support groups, including outcomes measurements of effectiveness (Clinical support trial).

Clinical trials advance through four phases to test a new treatment. They may be observational or interventional.

- **Phase 1** trial tests an experimental treatment on a small group of often healthy people (20-80) to judge its safety and side effects and to find the correct conditions for treatment (i.e. drug dosage, duration of treatment, route of administration, etc.).

- **Phase 2** trial enrolls a larger sample, typically 100-300 individuals with a specific condition to obtain preliminary data on whether the treatment outcomes are attained (eg. works in the specific condition). Phase 2 trials continue to study safety, including short-term side effects.
- **Phase 3** trial enrolls a larger number of subjects to obtain more complete information about safety, efficacy and effectiveness, in different populations. It may also compare different treatment regimens, as well as evaluate different drug combinations.
- There are many evolving study designs for phase 3 trials including classical new treatment versus standard-of-care, adaptive trials in which patients can switch among cohorts depending on pre-determined criteria to study responses, and crossover trials when patients try one treatment then switch to the other after a rest period. Data from phase 3 trials provide the information that is the basis of an application for FDA approval.
- **Phase 4** trial takes place after the FDA approves the use for drugs or devices. A device or drug's effectiveness and safety are monitored in large, diverse populations. Sometimes, the side effects of a drug may not become obvious until a larger number of people have taken a drug for a longer time period. This often continues through the post-marketing period. Failure in this period can result in a new product being taken off the market.

Phases of Clinical Trials

Phase 0: Preclinical: From concept/discovery to being ready for first-in-human	Phase 0 Does the preclinical evidence indicate that the concept is correct and likely to serve the desired function?
Phase 1: Healthy Subjects Optimization in humans: delivery, dosing, safety, clearance, prototype design compatibility, etc.	Phase 1: Healthy Subjects Do modifications need to be made before testing on target population?
Phase 2: Small Target Population Sample Does the treatment work? Usually tens of subjects with target condition; safety in this population, side effects?	Phase 2: Small Target Population Sample Do modifications need to be made before larger scale, controlled trial begins with more subjects?
Phase 3: Larger Target Population Study Is the treatment better than the existing standard of care? Controlled study with hundreds or thousands of subjects and clear outcome measures	Phase 3: Larger Target Population Study Does the trial provide evidence that the new treatment is better than the existing treatment?
Phase 4: Post-marketing surveillance- thousands to millions of patients- do long term safety issues emerge?	

The **Clinical Trials Resource Center** (CTRC) at UTHealth provides a single portal of resources, expertise, training resources and best practices for investigators and research staff to facilitate efficient, compliant and ethical study conduct and management: <https://www.uth.edu/ctrc/>

UTSD Approvals

Clinical Research Approval Mechanism

Before study initiation, all clinical research studies enrolling patients from any UTSD clinic must have administrative approval from both the UTSD Office of Research and the Office of Patient Care.

The following steps (in order) are required so that you can start your clinical research study:

1. All faculty who are named investigators for the study will complete the following training/compliances:
 - UT Start Link: <https://www.uth.edu/sponsored-projects-administration/tools-resources/uthstart>.
 - Investigator Briefing: <https://www.uth.edu/evpara/investigator-briefing.htm>.
 - Financial Disclosure: <https://inside.uth.edu/coi/financial-disclosures.htm>.
 - Information on CITI Training: <https://www.uth.edu/cphs/for-researchers/training.htm>.
 - Committee for the Protection of Human Subject: <https://www.uth.edu/cphs/index.htm>
2. Consult the Office of Research at SOD-IRB@uth.tmc.edu to determine if this is a clinical study and for information concerning potential 3rd party sponsors and budgets.
3. If it is determined to be a clinical study, please visit this [link](#) to fill out the Request for Clinical Research Form (see Appendix E) to initiate the workflow (see Appendix F)
4. PI submits the form to the Office of Patient Care (email address provided on the form) who will review and provide feedback on the clinical research workflow, billing compliance, clinical IT and supplies/equipment needs.
5. The Office of Patient Care notifies the PI and the Office of Research of approval. The Office of Research will review the application and the collection of study documents for PI to submit for IRB approval.
6. After the IRB is approved, PI notifies the Office of Patient Care, who will provide the PI will a unique investigator code (Q code) in axiUm for project tracking (if applicable) and any additional services in Clinical IT, equipment/supplies/space. For any equipment purchase to be utilized clinically, items will need to be properly declared to the Office of Patient Care.
7. PI can start the clinical research study

Note: It is recommended that all who conduct research visit HOOP 95 – **PI Responsibilities on Research Training** <https://www.uth.edu/hoop/policy.htm?id=1448038>.

Quality Improvement (QI) Approval Mechanism

- QI projects do NOT require IRB review but must be submitted and approved by the QI Registry: <https://www.uth.edu/cphs/qi-projects/qi-projects.htm>.
- Contact: Emily.W.Sedlock@uth.tmc.edu, UTSD Quality Improvement Coordinator II for questions

Funded Research Approval Mechanism

- If the study is to be funded by any external funding source (foundations, federal/state agencies [NIH, NSF, HRSA, CPRIT], private industry, drug and pharmaceutical manufacturers, etc.), APPROVAL MUST be obtained from OR and SPA before study initiation, and before a budget is submitted to the potential funder. Contact: SOD-Grants@uth.tmc.edu
- Working with Industry Partners
 - UTHealth has an Office of Technology Management: <https://www.uth.edu/otm/>. This office can provide advice on developing any intellectual property you produce including patents. They also can advise on developing a best practices relationship with our industry partners.
 - The CTR can connect you with this office. Please contact Dr. Farach-Carson: Mary.C.Farachcarson@uth.tmc.edu BEFORE you start if you will be working with industry.
 - Industry trials are DIFFERENT from Investigator-Initiated Trials! **Please consult with the CTR before you make commitments to or discuss budgets with potential industry sponsors.**

Institutional Review Board (IRB) Approval

The [Committee for the Protection of Human Subjects \(CPHS\)](#) serves as the IRB for UTHealth. All studies, funded and unfunded, must be reviewed and approved by the UTHealth CPHS before it is initiated if it falls in one of the following categories:

- Conducted by any UTHealth employee (faculty, staff, administrative and professional), student, or resident in any facility/location (e.g. Memorial Hermann Healthcare System, Harris County Psychiatric Hospital, Thomas Street Clinic or LBJ General Hospital, etc.)
- Conducted by non-UTHealth investigators that involves subjects/patients from any UTHealth facility (including Harris County Psychiatric Hospital). In such cases, a University faculty member must be identified who will agree to assume co-responsibility for the conduct of the research.
- Conducted by non-UTHealth investigators in Memorial Hermann Healthcare System facilities.

CPHS policies are found at <https://www.uth.edu/cphs/policies/requires-review.htm>.

CPHS oversight includes:

- Authority to approve, require modifications to secure approval, and withhold approval of all human subjects research.
- Annual continuing reviews to maintain active IRB status.
- Review and approval of changes to research protocol, personnel, site additions, study document changes, protocol deviations, adverse events and study closures.
- CPHS Policies <https://www.uth.edu/cphs/policies/requires-review.htm>

IRB Review Categories

Exempt Review

- Please review the following exemption categories: <https://www.uth.edu/cphs/policies/exemptions.htm>
- Exempt human subjects research does not require ongoing IRB oversight as long as it meets at least one of the federal exempt categories criteria. Research may qualify for an exemption if it is no more than minimal risk.
- Exemption applications should be submitted to the CPHS/IRB office for review before starting research. Reviews generally take 2 weeks for decision.

Expedited Review

- Please review the following expedited categories: <https://www.uth.edu/cphs/policies/expedited.htm>
- Expedited human subjects research is research that qualifies as having minimal risk and is reviewed by a convened meeting of IRB/CPHS.

- Reviews generally take 2 weeks for decision.

Full Board Review

- All human subject research proposals must be reviewed at a convened full board meeting unless the study is determined to be exempt or qualify for expedited review. CPHS must receive and review adequate information to determine whether the criteria for approval have been met. Examples of research involving human subjects are clinical trials and clinical research.
- Review times vary depending on the complexity of the study.

Special note about research subject to Exemption 4.

- Human subjects research that meets the criteria for Exemption 4 is not considered clinical research as defined by NIH, although it remains human subjects research. Therefore, NIH policies for reporting inclusion of women, minorities and children do not apply to research that is determined to meet the criteria for Exemption 4.
- Research meeting criteria for Exemption 4 involve the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- See <https://grants.nih.gov/sites/default/files/human-subjects-exemption-infographic.pdf> and <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html> for more details.

IRB Application Process

The Section for CTR and/or Office of Research staff are available to assist with the application process including guidance on the online application, required study documents, and additional reviews and approvals BEFORE submission to the IRB.

- Contact SOD-IRB@uth.tmc.edu for any questions about Exempt and Expedited studies and for Full Board clinical research and clinical trials study guidance.
 - The CTR and OR will guide you on required training and provide a checklist of required documents specific to your study.
 - **Basic iRIS instructions:** <https://www.uth.edu/cphs/for-researchers/basic-iris.htm>
 - **UT research templates:** <https://www.uth.edu/cphs/templates-and-forms/>
 - **CPHS Tips for for Successful Submissions** <https://www.uth.edu/cphs/for-researchers/Summary%20Tips%20from%20CPHS.pdf>
 - Complete iRIS, CITI, GCP, FDS training (See Trainings and Resources Section Below)
 - List the CTR Director as a collaborator on all IRIS submissions so they can be seen in the system.
 - Please upload an updated copy of your current CV or NIH style biosketch into your profile in iRIS: My Assistant>My Account Information> Biosketch, CVs, Pubs

External IRB Review

Commercial IRBs

UTHealth researchers may choose to use an independent or commercial IRB with which UTHealth has signed an IRB reliance agreement with the permission of UTHealth IRB. This option is available for industry sponsored multi-center clinical trials. Researchers may also request to use an independent or commercial IRB as the sIRB under the NIH sIRB mandate. <https://www.uth.edu/cphs/irb-reciprocity/commercialirbs.htm>

Reciprocity Agreements

UTHealth may use an IRB review of another organization or may serve as the IRB for another organization under a written IRB authorization agreement. These agreements are also called IRB reciprocity agreement or IRB reliance agreements.

<https://www.uth.edu/cphs/irb-reciprocity/reciprocity.htm>

SMART IRB Agreements

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). The SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status. More than 350 institutions have signed the SMART IRB reliance agreement. UTHealth and Memorial Hermann Health System are participating institutions. 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 SMART IRB platform by visiting the SMART IRB [website](#)

Contact for guidance for external IRB reviews.

Fees

IRB Fees

IRB Fees may apply for studies with funding from private industry/drug and device manufacturers.

- Fee of \$2,600+ for initial review and \$650 for each annual continuing review. Studies with industry funding below \$5,000 may be subject to a waiver with the IRB director. See <https://www.uth.edu/cphs/for-researchers/irb-fees.htm>.
- Fee of \$1300 for use of an external commercial IRB such as WIRB, Chesapeake.
- Federal, Non-profit foundations and investigator-funded studies will not be charged any fees for IRB review.
- Contact SOD-IRB@uth.tmc.edu for guidance.

Clinical Research Administrative/Startup Processing Fees: UTSD will require a non-refundable administrative start-up fee of 15% prior to enrolling research subjects and continued maintenance fee of 3% subsequent years for all externally funded clinical research. This fee covers the cost of reviewing the protocol and determining study feasibility at our site, preparing and submitting regulatory documents and required documentation to the IRB, preparing the coverage analysis and

budget, and attending the site initiation visit. This fee is due upon contract execution and receipt of invoice.

Cost Analysis: In the cost analysis, all procedures being paid for by research must be budgeted for. For each procedure at each visit you will need to provide how much will be expensed to the project account. These values can be obtained from the charge master documents provided by the healthcare provider (typically UT Physicians, Memorial Hermann Hospital, and Harris Health). Additionally, pricing fluctuates each year for procedures, so we suggest that you increase your pricing by 5-10% to ensure that there are enough funds in the account to pay for these procedures. **Remember that all charges expensed to the account will incur a 30% indirect cost if the study is a clinical trial and 56% indirect cost if the study is clinical research.** You will need to plan your budget to include these costs accordingly.

New for 2022: All procedures, regardless of the clinic where they are performed, should use the approved set of fees for Clinical Research. These are listed in axiUm and can be accessed from the clinics once a clinical researcher has been provided a Q provider number.

Resources and Training

Statistical Support

For projects needing statistical support, please contact Dr. Nat Holland, Data Scientist at Julian.N.Holland@uth.tmc.edu. Dr. Holland can provide input in study design, power analysis, data analysis plan. Contact him **BEFORE** you start your project.

Review guide and request form for support request.

- [UTSD Consultation Guidelines for Research Design and Statistical Analyses](#)
- [Request for Statistical Services Form](#)

UTHealth START Training

- Required System Training for researchers: <https://www.uth.edu/sponsored-projects-administration/tools-resources/system-access-guides/uthealth-start>
- Contact SOD-Grants@uth.tmc.edu to inquire about upcoming courses.
- In UTHealth START, click SPIN on the homepage to search for potential funding sources by keywords. SPIN is a searchable database that provides real-time access to current research funding opportunities. All data in SPIN is obtained directly from the sponsoring agencies to ensure authenticity.

iRIS Training

- iRIS is the online application system for ALL IRB and AWC applications for UTHealth
- Class dates and registration: <https://www.uth.edu/cphs/for-researchers/reg-iris-training.htm>

CITI Human Subjects Education Training

- **REQUIRED** for all human subject's research studies.
- Registration instructions: <http://www.uth.edu/cphs/for-researchers/training.htm>
- CITI website: <https://about.citiprogram.org/en/homepage/>
- Complete the free registration and your school affiliation will be "University of Texas Health Science Center Houston. Then add your course to your learning profile from menu shown.
- Modules needed to be completed:
 - Human Subjects Research (HSR) - two options – 1) Biomedical Researcher and 2) Social and Behavioral Educational. Choose the option that is most suitable to your research area.
 - Good Clinical Practice Training (GCP) – REQUIRED IF CONDUCTING CLINICAL RESEARCH
- Once you have completed the certificate, please e-mail the certificate to: SOD-IRB@uth.tmc.edu
- The training is valid for 3 years from the completion date.

Please make your selection below appropriate to your research activities.

This question is required. Choose all that apply

- Human Subjects Research (HSR)
- Good Clinical Practice (GCP)
- Conflicts of Interest (COI)
- Data Acquisition and Management
- Responsible Authorship and Publication
- Animal Care and Use (IACUC)
- Clinical Research Coordinator (CRC)
- Clinical Trial Billing Compliance (CTBC)
- Responsible Conduct of Research (RCR)

Annual Financial Disclosure Statement (FDS)

ALL research study personnel - PIs, co-investigators, research associates, and others - must complete an annual financial disclosure statement.

- Form is found at: <https://inside.uth.edu/coi/financial-disclosures.htm>

Grants 101/102

- The New Investigator Development Program (NIDP) helps junior faculty members develop effective research proposals in a two-phase process. Grants 101 teaches about UTHealth research policies and procedures Grants 102 refines skills for writing competitive grant applications. The New Investigator Development Program is led by the Office of the Executive Vice President for Academic & Research Affairs.

- If you are a new faculty and plan to do research, you should take Grants 101/102.

Informed Consent Training

- Part 1: Complete **one** of the following activities:
 - Watch [OHRP video on General Informed Consent Requirements](#).
 - If your research involves working with participants who have mental health issues, watch the [NIMH video, Elements of Successful Informed Consent](#).
 - Attend the in-person [Clinical Research Education course](#) conducted by the Research Compliance office.
 - Read the [AHRQ Informed Consent And Authorization Toolkit for Minimal Risk Research](#)
- Part 2: Completing the [UTHealth Consent Training Exam](#) with a passing score of 80% or higher.
- A certification will be emailed to the researcher after successful completion of the training.

Coverage Analysis (CA) for Clinical Research and Clinical Trials

The coverage analysis is an itemized list of every procedure included in the study protocol. This includes both effort based and patient care based procedures. The coverage analysis details which visit each procedure will be done at and whether or not it will generate a bill in the clinic billing system. If an item generates a bill, the study team must designate whether that charge will be standard of care (SOC) or research. All SOC items must have a justification provided to detail how that conclusion was made. Adequate justifications include peer reviewed journal articles, nationally published guidelines from professional medical organizations, or national coverage determinations from the Centers for Medicare and Medicaid.

- Is a service or procedure required billable?
- Where will this service or procedure occur?
- Is this service a standard of care which can be paid for by the patient/patient insurance, or a research charge that will be paid for by the sponsor?

New in 2021: UTHealth has contracted an outside party to oversee coverage analysis for clinical trials. Contact the Section for Clinical and Translational Research if you plan to conduct a sponsored clinical trial and do this **before** you create your budget.

Coverage Analysis is to determine who will be responsible for any service.

Notes to remember when completing the form:

- **NB (non-billable)** account for them in the effort tab
- **NB cost of research** will not generate a bill, but can be used when you can invoice for a certain charge (i.e. Room charges or etc)
- **SOC (standard of care)** billable to the insurance or will be picked up by the patient
- **Research** billable, but will be paid by a sponsor

Contact SOD-Grants@uth.tmc.edu if you have any questions about coverage analysis.

******DO NOT CONTACT SPA (Sponsored Projects Administration) DIRECTLY!!! ******

Compliance Considerations for Clinical Research and Clinical Trials

As a clinical investigator, the PI accepts certain responsibilities. These can be found at the website: https://www.uth.edu/cphs/policies/investigator_responsibilities.htm

Many clinical studies/trials involve procedures that require additional actions beyond obtaining IRB approval to be in compliance with federal standards. UTHHealth Clinical Trials Resource Center (<https://www.uth.edu/ctrc/>) offers an online resource to answer questions about how an investigator can determine what is needed (trial registration/IND/IDE etc) for a particular study.

Clinical Trials Resource Center

Clinical Trials Resource Center

Home

About Us

Ongoing Clinical Trials

▶ Clinical Trial Resources

▼ **Regulatory Services**

IND / IDE Submissions

Clinicaltrials.gov

Regulatory Services

FDA Inspections

Validation & Compliance
with 21CFR11

GCP Policies

▶ Training

ClinicalTrials.gov Support

The Clinical Trials Resource Center (CTRC) supports UHealth study teams in complying with the regulations and policies for registration and results reporting at ClinicalTrials.gov.

UHealth's ClinicalTrials.gov Policy and Procedures document is [at this link](#).

Contact CTRC at clinicaltrials@uth.tmc.edu for help with:

- Determining whether registration and/or results submission are required, and determining which party is responsible
- ClinicalTrials.gov account setup
- Initial registration
- Record updates (guidance document [at this link](#))
- Results reporting and protocol upload
- Informed consent form (ICF) upload per the Revised Common Rule (guidance document [at this link](#))
- Determining due dates for registration, updates, results entry, protocol upload, and ICF upload (guidance document [at this link](#))

ClinicalTrials.gov FAQs

Another resource for educational materials and conferences for those new to clinical research is found at SOCRA's website. <https://www.socra.org/>.

Research Agreements: Data Use Agreements and Material Transfer Agreements

Material Transfer / Data Use Agreement

A Material Transfer Agreement (MTA) or Data Use Agreement (DUA) is a contract that establishes terms and conditions governing the transfer of research-related materials or data between the University and another institution or company. An MTA or DUA between a providing entity and a receiving entity should be fully-executed before any materials or data are sent or received.

"**DATA**" is defined as recorded and/or retained information regardless of the form or the media on which they may be recorded or retained. The term includes laboratory notebooks and worksheets, memoranda, original notes or exact copies of notes that are the result of original observation, video recordings, clinical protocols, spectra, computer files and digital data (including software source code), print-outs, images or any other records necessary for reconstruction and evaluation of the results of a study. See this website for more information: <https://www.uth.edu/sponsored-projects-administration/set-up/contracts-agreements/data-use-agreement>

"**MATERIALS**" is defined as unique tangible research resources such as synthetic or natural compounds, organisms, cell lines, viruses, cell products, recombinant DNA, antibodies, mapping data, spectroscopic or x-ray data, software developed in the course of research, and such new tangible resources that emerge as science and technology progress. See this website for more information: <https://www.uth.edu/sponsored-projects-administration/plan-propose/contracts-agreements/material-transfer-agreement>

UTHealth Policy - <https://www.uth.edu/hoop/policy.htm?id=1448032>

Contact SOD-Grants@uth.tmc.edu

Study Close Out

You may close your study when the following are met: a) all subject enrollment, procedures/interventions, and follow up and final visits are complete, b) data analysis or manuscript preparation does not involve personal identifying information and c) you have received permission from the study sponsor to close the study with the IRB (if applicable)

- If funded, contact the Office of Research SOD-Grants@uth.tmc.edu for guidance on financial close out process.
- Submit the Study Closure Form in iRIS. Contact SOD-IRB@uth.tmc.edu for questions.
- Prepare all study files for storage and review investigator responsibilities for guidance on records management https://www.uth.edu/cphs/policies/investigator_responsibilities.htm

Statistics and Research Design

The Office of Research provides support for faculty, fellows and students in study/trial design and statistical analysis to aid in clinical research.

Services include:

- Formulating questions and hypotheses
- Developing research plan
- Study design
- Data management
- Applying statistics
- Power analysis
- Data analysis
- Communicating results and findings

You are strongly encouraged to meet with us during the planning phases and before IRB submission.

To submit a service request email the pdf request form to Dr. Nat Holland at Julian.N.Holland@uth.tmc.edu

Your request should include each of the following and is found on our website at the link below

1. Name
2. Title/Affiliation/Department
3. Email
4. Phone
5. Advisor/Mentor (if applicable)
6. Date Needed
7. Statistical Service Request
8. Intended Use

https://dentistry.uth.edu/research/docs/request_for_statistical_service_form_062018.pdf

Appendix A

PROTOCOL

Protocol Template Version Jan 2018

Adapted from NIH protocol template and ICH Guidelines

Protocol Title:

Principal

Investigator:

Co-Investigators: List all collaborators

Study Coordinator: If a coordinator / research nurse / research assistant has been identified

Population: Include sample size, gender, age, general health status, geographic location

Number of Sites: Single site / UT Houston is lead site of multi-site study / Participating in multi-center study / Data coordinating center

Study Duration: State duration of study

Subject Duration: State duration per subject

General Information

- A brief description of the research project.

Background Information

- Include study hypothesis, summary of findings from studies that have potential significance to proposed study and a discussion of important literature and data that are relevant to the study and that provide background for the study.
- Applicable clinical, epidemiological, or public health background or context of the study.

Objectives

- Primary and secondary objectives.
- Include statement of purpose e.g., to assess, to determine, to compare, to evaluate and method of assessing how the objective is met, i.e., the study outcome measure.

Study Design

- A description of the design of the study to be conducted (e.g. chart review, case cohort, non-interventional etc.).
- Expected duration of study and subject participation.
- A specific statement of the primary and secondary outcomes to be measured during the study (must be consistent with Study Objectives, as stated in Section).
- Assessment of efficacy.
- Assessment of safety.

Study Population

- The study population and inclusion/exclusion criteria should be clearly defined in this section of the protocol.
- This section should include a discussion of selection of the study population and inclusion/exclusion criteria.
- Describe the recruitment and screening strategy.

Study Procedures and Informed Consent

- For research involving interaction with participants, describe the number of study visits, what procedures will occur at each visit, and how long each visit will take. Indicate the total amount of time required of each subject to participate in the project.
- Specify the type of information the PI will gather, along with the means for collecting and recording it.
- Methods for collecting specimens and data. List all laboratory evaluations, if applicable. Include specific test components and estimated volume and type of specimens needed for each test.
- If biological specimen are going to be stored, describe the plans for storage, duration of storage and procedure to maintain confidentiality.
- Describe when and by whom informed consent will be obtained (see Appendix B).

Data and Safety Monitoring

- State if adverse events are expected, if yes, describe how these events will be identified, assessed and graded.
- Describe plans for reporting unanticipated problems (including adverse events, protocol deviations, and/or other problems).
- Describe the safety-monitoring plan (periodic review by research team, external review, formal data, and safety monitoring board).

Statistics

- A description of the statistical methods to be employed, including timing of any planned interim analysis.
- The number of subjects planned to be enrolled. In multicenter trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
- The level of significance to be used.
- For clinical trials, list criteria for the termination of the trial.
- The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

Ethics

- If IRB approval will be sought from another IRB, indicate which institution in this section.
- Describe the consent process. If waiver of consent or waiver of documentation will be sought, describe the plan to protect privacy of subjects.

Data handling and record keeping

- Access to source documents.
- Procedures for maintaining subject confidentiality, any special data security requirements, and record retention per the sponsor's requirements.
- State whether human subjects will be identifiable directly or through identifying information.
- State how the data will be linked to the subjects during the study.

- State how and where the data will be stored, and how it will be protected.

Quality control and assurance

- Describe steps to be taken to assure that the data collected are accurate, consistent, complete, and reliable. (source data verification, audits or self – assessment)
- Describe whether there are plans to have ongoing third party monitoring.

Publication Plan

- Describe plans for publication of research results.
- State if results will be returned to research subjects.

Appendix B

CONSENT TO TAKE PART IN RESEARCH

Consent Template Version: January 2019.

This is a template – please replace all the text in blue with study specific information.

Simple Study Title: <use www.clinicaltrials.gov title, if the study not registered use iRIS study alias>

Full Study Title: <use the full protocol title>

Study Sponsor: <if the study is not sponsored, delete this line>

Principal Investigator: <PI name, credentials; e.g. John Smith, MD, Professor, Internal Medicine, UTHealth>

Study Contact: <include the name and phone number; e.g., Jane Doe, RN, Research Nurse, XXX-XXX-XXXX>

The purpose of this study is to <briefly state the purpose of the study>. If you choose to participate in this study, you will be asked to <please briefly describe the study procedures in a sentence or two>. The total amount of time you will be in this study is <briefly describe the time commitment>.

There are potential risks involved with this study that are described in this document. Some known risks include <briefly describe the most common risks>. There may be potential benefits to you such as <please add potential direct benefits to the subject here>.

There are alternatives <procedures or courses of treatments> to participating in this research study, such as <briefly describe alternatives procedures or courses of treatments>.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth), Memorial Hermann Healthcare System, or Harris Health System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of this study is to see how well <name the study intervention> works at treating people with <name the study condition>. This study will test the safety of the <name the study intervention>. This <name the study intervention has/ has not been> approved by the Food and Drug Administration (FDA); therefore it is called an investigational drug/device.

<Include only if the study has funding:

<State the name of the sponsor or funding agency> is paying UTHealth for their work on this study.

<Include only if any of the study personnel has a financial conflict of interest related to this study:

The <state the name of the individual with the conflict> <state the conflict – e.g. owns equity, receives payment for consulting or other services, is an inventor of the drug/compound/device> <state the name of the company> which is paying for this research. You may ask <state the name of the PI> for more information about this financial interest.

Include only if the trial will be registered:

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?

You are being asked to take part in this research study because you have <XXXX>. This study is being conducted at <state the number of sites, if only UTHealth, state UTHealth>. About <XXXX> people will take part in the study <worldwide/in this country/in this city> including approximately <state local enrollment target> at UTHealth, Memorial Health System, and/or Harris Health System.

What will happen if I take part in this study?

Explain what will be done as part of study procedures. State the information in simple short sentences. State the study disease/condition in lay terms: e.g. heart attack instead of myocardial infarction. Clearly state the use of experimental drugs, devices, treatment, etc. If this is a registry where clinical information is taken from the medical record, please describe the type of information that will be collected.

If randomized to a treatment:

If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive <study drug> or placebo (a tablet that contains no active ingredient). It is not known whether <study drug> will be of benefit. For this reason, some study participants must receive a placebo. This will allow a careful comparison to study the benefits and side effects of the investigational drug. There is a 50% chance you will receive <study drug> and a 50% chance that you will receive placebo. Neither you nor your doctor will know if you are receiving <study drug> or placebo, as both will look the same.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects. <A patient study calendar is attached at the end of this document. It shows how often these <insert appropriate words, e.g., exams, tests, and/or procedures> will be done.>

For venipunctures for blood samples –

You will have about <state in tsp., tbsp. or oz.> of blood drawn from a vein in your arm (state frequency). The total amount of blood withdrawn during your participation will be about <state in tsp., tbsp. or oz.>.

How long will you be in the study?

If you agree to take part, your participation will last for <state duration in days, weeks, months, or years> and will involve <state the number of visits>.

What choices do you have other than this study?

You may select other options than being in this research study. <Discuss the usual approaches for treatment of patients with this condition in a few sentences. If the study intervention is available outside of the study, please state.>

What are the risks of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this study, there is a risk that the <study intervention> may not be as good as <the usual approach> in treating your condition.

There is also a risk that you could have side effects from the <study intervention>. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most common side effects that the study doctors know about are:

In a bulleted list, identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the study intervention will make them, but with a particular emphasis on how those risks are changed by participating in the study. This should be a brief list (generally around 5 although more may be necessary), including the most important reasonably foreseeable risks and discomforts.

Some of the less common side effects that the study doctors know about are:

In a bulleted list, identify the less frequent risks. This should be a brief list including the most important reasonably foreseeable risks and discomforts.

There may be some risks that the study doctors do not yet know about.

Use and adapt the following text when the study intervention may pose risks to fetus. Include additional detail as required:

Female:

If you are a woman able to become pregnant, a blood or urine pregnancy test will be done, and it must be negative before you can take part in this study. The <specify intervention> used in this study could be harmful to an unborn baby. The <specify intervention> may hurt an unborn baby in ways we do not currently know. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for <specify time> months afterward. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for <insert time in months/years> after you have completed the study. If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

Male:

If you are a man, taking part in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. If you are sexually active, it is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for <specify time> months afterward. If your partner becomes pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

What are the benefits to taking part in this study?

There is some evidence in people with <state name of condition> that the <study intervention> can <list potential benefits>. However, we do not know if this will happen in everyone with <state name of condition>. This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact <PI Name> at <XXX-XXX-XXXX>.

Your doctor or the sponsor can stop the study at any time. Your doctor or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, the study drug is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?

When the study has no provision for treatment, Option A:

If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any such injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

When the study has no provision for treatment, Option B:

If you are injured or have any harmful effects during the course of the research study, treatment will be available to you. You or your insurance company will be billed for any treatment. You should report any such injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

When the study is **sponsor initiated**, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols) Option A:

If you suffer any injury as a result of taking part in this research study the sponsor of this study, <insert sponsor's name>, will pay for reasonable and necessary medical expenses if the injury is a direct result of taking the study medicine or undergoing study procedures, and not due to the natural course of any underlying disease or treatment process. You should report any such injury to <insert PI name and phone number> and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

When the study is **sponsor initiated**, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols), Option B:

If you are injured or have any harmful effects during the course of the research study, treatment will be available to you. You will not have to pay any charges for treatment for injuries resulting due direct result of study medicine or device or study procedures that would not have otherwise been done as part of your regular care. You or your insurance will be billed for all treatment for injuries due to the natural course of the disease or due to treatments; you may have received even if you were not part of the research study.

Add if either **sponsor initiated** Option A or Option B is used add:

If you are treated for a research injury that is paid for by <Study Sponsor>, <Study Sponsor> or its representative will collect your name, date of birth, gender, and Medicare Health Insurance Claim

Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, <Study Sponsor> will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services, in accordance with CMS reporting requirements. <Study Sponsor> will not use this information for any other purpose.

What are the costs of taking part in this study?

The sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care.

Include if study also involves standard of care procedures:

However, many of the tests, procedures, and exams you will receive are believed to be part of standard medical care, and may or may not be covered by your medical insurance. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.

If you receive a bill that you believe is related to your taking part in this research study, please contact <PI Name>, or research staff at <XXX-XXX-XXXX> with any questions.

You will receive \$XXXX for each study visits, with payment at each visit even if you do not complete the entire study. You will be issued gift card (if applicable), following completion of each visit. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

Include if compensation will exceed \$600 in a calendar year:

If you receive payment for taking part in this study, please be informed that you will be asked to complete a copy W-9 form that will be forwarded to the accounting department as a requirement by the Internal Revenue Service. You will also be issued a 1099-Misc form from this study for tax reporting purposes.

How will privacy and confidentiality be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth, Memorial Hermann Healthcare System, or Harris Health System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes <Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition>. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Use for Investigator Initiated Studies:

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Use for Industry Sponsored Studies:

Please understand that research study data will be sent to the sponsor of this research study, <Study Sponsor>. The data that will be sent to the sponsor will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures.

Use for Collaborative Research Studies:

Please understand that research study data will be sent to the research collaborators at other Universities. The data that will be shared will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System and/or Harris Health System
- [Representatives from the U.S. Food and Drug Administration \(FDA\)](#)
- [Representatives of the sponsor of this research including contract research organizations](#)
- [Members of Data and Safety Monitoring Boards \(an independent group of experts that reviews this study's data to make sure participants are safe and the research data is reliable\)](#)
- [Companies engaged with the UTHealth for the commercialization of the results of the research study](#)

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System or Harris Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact <PI Name> in writing at <PI campus mailing address>.

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact the <insert the PI or study coordinator name> at <insert 24 hour phone number>, as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

<Checkboxes for options may be included here. See the document "Additional Informed Consent Elements" for suggested language.>

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject

Signature of Subject

Date

Time

Printed Name of Legally
Authorized Representative

Signature of Legally
Authorized Representative

Date

Time

Printed Name of Person
Obtaining Informed
Consent

Signature of Person
Obtaining Informed Consent

Date

Time

Appendix C

Data Collection Form Example

The image shows a Microsoft Excel spreadsheet titled "Data Collection Log - Excel". The ribbon is set to the "Home" tab, showing options for Clipboard, Font, Alignment, Number, Styles, Cells, and Editing. The spreadsheet contains a data collection form with the following structure:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	C
1	Study ID	Patient Age	Height	Weight	BMI	Gender	I1	I2	C	P1	P2	M1	M2	Dental Maturity Score	Expecte
2	1														
3	2														
4	3														
5	4														
6	5														
7	6														
8	7														
9	8														
10	9														
11	10														
12	11														
13	12														
14	13														
15	14														
16	15														
17	16														
18	17														
19	18														
20	19														
21	20														

Appendix D

Linking Log Example

The screenshot shows an Excel spreadsheet with the following data:

	A	B	C	D	E	F	G	H	I	J	K	L
1	EHR Number	De-identified Patient ID Number										
282		281										
283		282										
284		283										
285		284										
286		285										
287		286										
288		287										
289		288										
290		289										
291		290										
292		291										
293		292										
294		293										
295		294										
296		295										
297		296										
298		297										
299		298										
300		299										
301		300										

Appendix E

Request for Research in UTSD Clinics

The link to the fillable form to request to use the UTSD Clinics for clinical research can be found at the following link:

<https://inside.uth.edu/dentistry/docs/request-for-clinical-research.pdf>

Pre-Approval Request for Clinical Research

Please complete the form to request pre-approval for your clinical research project.

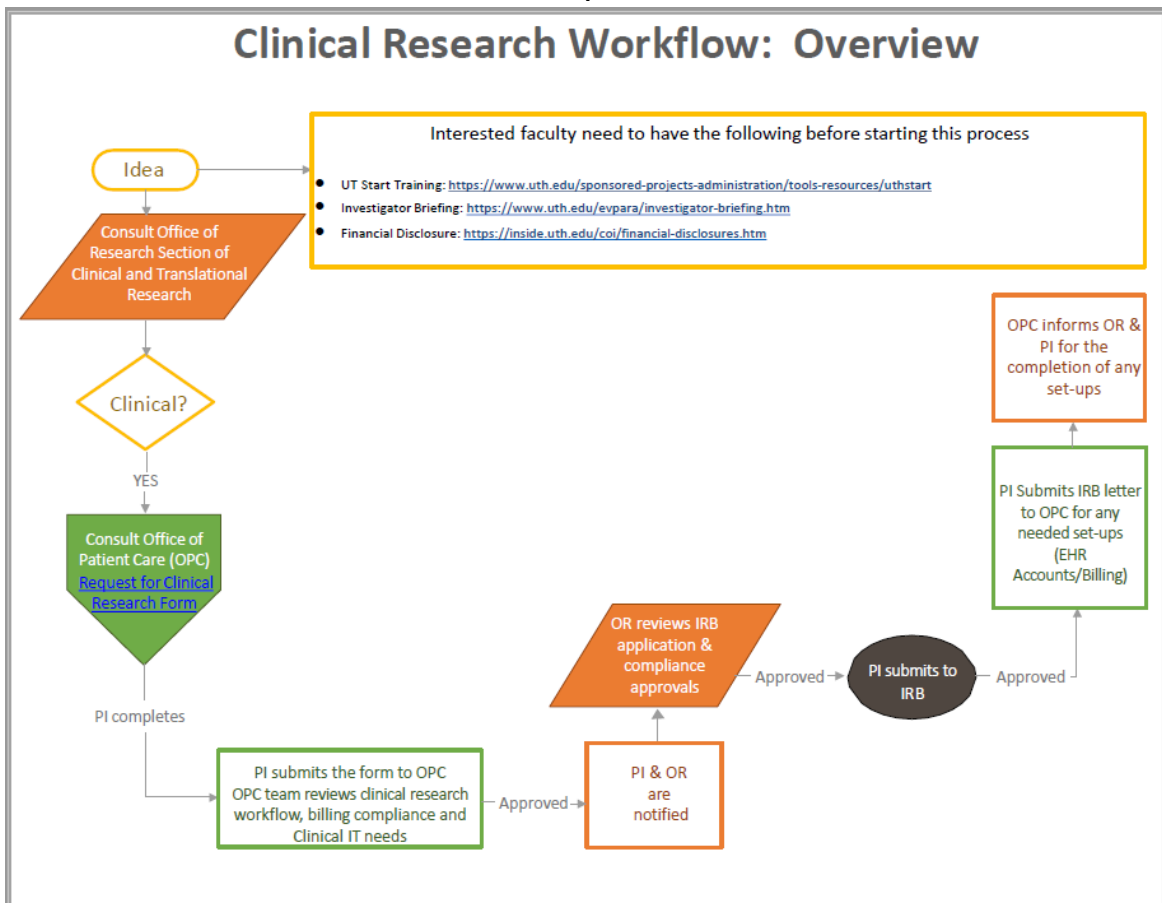
Investigator Information	
<i>Please provide your information.</i>	
Primary Investigator Name:	
Department Name:	Phone#:
Co-Investigator Name:	Phone#:
Research Information	
<i>Please provide details about the research you are requesting to perform in clinic.</i>	
Project Title:	
Anticipated Start/Enroll Date:	Anticipated End Date:
A. Clinic: <i>Select all that you anticipate the research will occur.</i>	
<input type="checkbox"/> Dental Clinical Research Unit	<input type="checkbox"/> University Dental Center (AEGD/GPR)
<input type="checkbox"/> Endodontics	<input type="checkbox"/> UTHealth Pediatric Dentistry (HMC)
<input type="checkbox"/> Periodontics	<input type="checkbox"/> UT Dentists
<input type="checkbox"/> Prosthodontics	<input type="checkbox"/> UT Oral & Maxillofacial Surgery
<input type="checkbox"/> Pre-doctoral Clinics	<input type="checkbox"/> Other:
B. Brief Description of Study: <i>Provide a brief description of what the research project entails, goals/aims and the benefit(s) to patients.</i>	
C. Description of Patient Recruitment Plan: <i>Provide a brief description of how patients will be recruited.</i>	

Appendix F

To view the full workflow, please enroll at this [link](#) for the Office of Patient Care Canvas course under the Clinical Research tab.

UTSD: Office of Patient Care

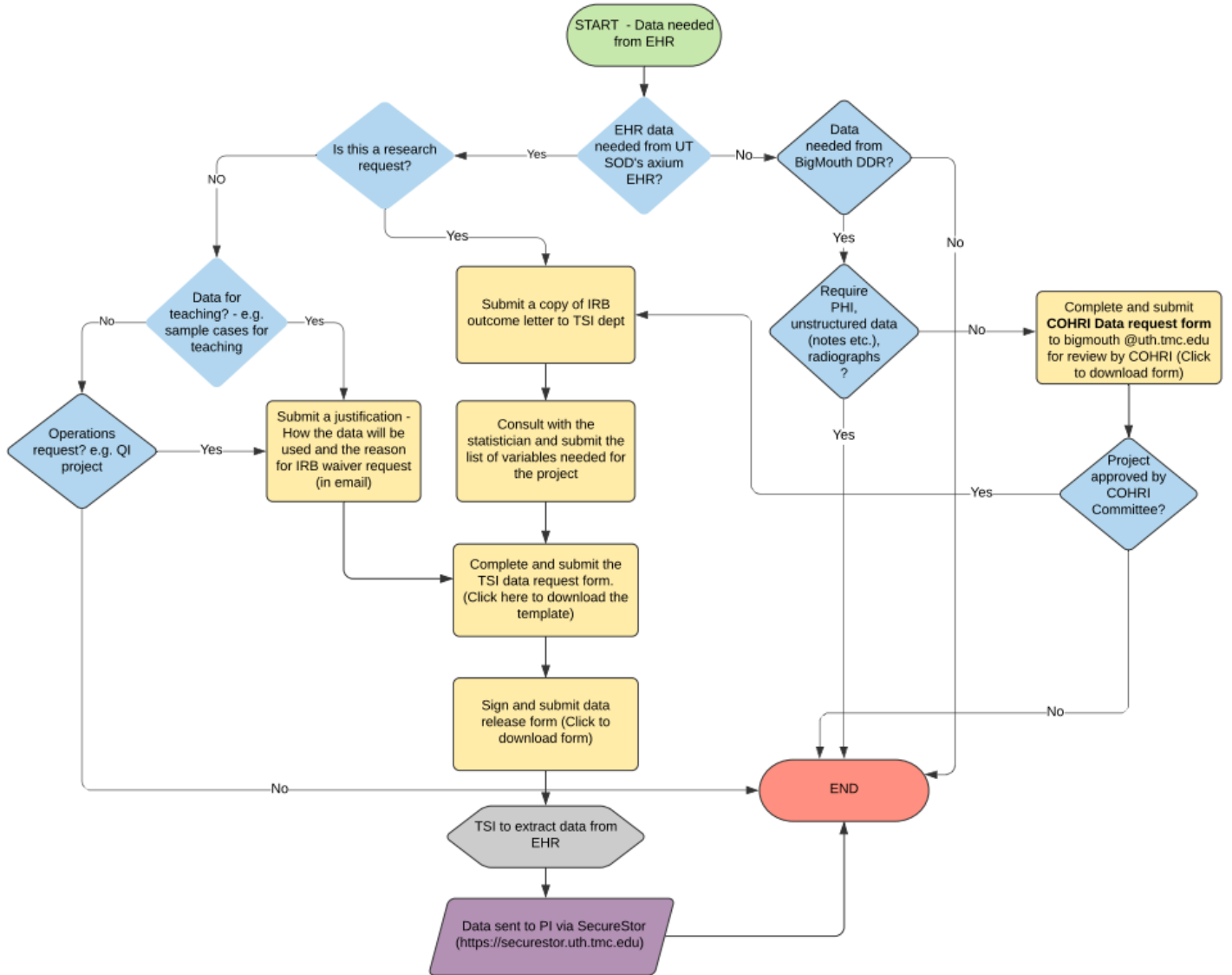
Home



Appendix G

UTHealth SOD - EHR Data Request Process

krishnakumar.kookal | April 30, 2021



UTHealth SOD - EHR Data Sharing Policy

krishnakumar.kookal | April 30, 2021

