

Proposal Title:

Version Date:

Complete this template following the RED instructions, then delete the red font. There will be Recommended language is in BLUE and may be revised accordingly. If recommended language is used, change the font and color to match the rest of the draft.

Proposal Title:	
Short Proposal Title:	
Principal Investigator:	
Co-Investigators:	List all collaborators (indicate *mentor). Include institutional affiliation(s) and official titles.
Study Coordinator:	If a coordinator/research nurse/research assistant has been identified or not needed.
Number of Sites:	Single site / UA COMPHX is the lead site of multi-site study / Participating in a multi-center study
Study Duration:	State duration of study
Subject Duration:	State duration per subject ("As per medical records" for retrospective studies.
Funding:	Grant or Study Sponsor Information or indicate if unfunded.
Clinicaltrials.gov	Identify if the study requires clinicaltrials.gov registration and who is responsible for registering (i.e. sponsor, grantee, awardee, investigator). Provide NCT No. (if applicable).

PICO	
Patient Population/ Problem:	Who is the patient? Age, sex, race, diagnosis, primary problem, health status, past medical history etc.
Intervention/Exposure:	What type of screening, assessment, treatment, intervention, diagnostic test, exposure, etc. is being considered?
Comparison:	What is the alternative to the intervention/ exposure?
Outcome:	What is the accomplishment, measurement, improvement, etc. to the study?

Proposal Title:

Version Date:

REVISION HISTORY

Describe changes made to the protocol after initial approval.

Revision #	Version Date	Summary of Changes	Consent Change?

NOTE: Leave this section blank for the initial regulatory submission. The revision history should include documentation for modifications to approved studies.

Proposal Title:

Version Date:

Abbreviations/Acronyms: List all abbreviations and acronyms used within the protocol. Ensure alphabetical order.

Abbreviations/ Acronyms	Definition
CITI	Collaborative Institutional Training Initiative Program
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PHI	Protected Health Information

Proposal Title:

Version Date:

General Information/Lay Summary

A brief description of the research project. (3-4 sentences)

Introduction/Background (4-6 paragraphs)

[Statement of problem] 1 paragraph: Disease incidence or burden of disease in the specific population, and/or impact of morbidity on society which may include health care costs.

[Literature review] 1-2 paragraphs:

Summarize what is known in the literature on this topic. Describe past research, representing any consensus or disagreement in reports.

Summarize what is unknown in literature. Perhaps support this by how previous literature has fallen short, or what previous research has not addressed. This last paragraph should wrap up the previous two and give logical rise to the questions that remain unanswered, and thus, justifies the proposed study.

[Statement of deficiency based on literature review & proposed study to address it] 1 paragraph:

A succinct statement of the goal for the proposed study. A succinct statement of the innovation w/in the proposal (perhaps why and how the proposed study will help advance knowledge). Statement re: the significance of this study; for example, how it will advance knowledge or be used to direct future research including providing evidence to support a prospective study.

Purpose & Objectives (1 short paragraph)

Summarize the overall study purpose by describing the primary study endpoint or outcome to be evaluated. Indicate the study hypothesis (if hypothesis testing) or explain if this is a hypothesis-generating study or descriptive study.

List 1-2 aims/objectives to address the purpose and hypothesis. Aims should be well-focused, not too broad or specific. Tips: An aim can have sub-aims, no more than 3 aims.

Study Design & Methods

Study Design

(Elements to address in 1 paragraph)

- **Prospective vs retrospective methods:** Explain the type of study you plan to conduct.

Chart review, cohort, case series, randomized, case-control (if case-control, recommend an added subsection & controls), double-blind, observational, etc.

- **Data source and/or Study Interventions:** specify the information to be collected, and how it will be collected and stored. describe any study intervention (e.g., investigation agent, surveys, drug, device) to be evaluated. List any study-specific interactions/ medical chart review (e.g., blood draws, vitals, physical exam, etc.).

- **Patient population** (e.g. all patients w/ x, clinic or department, age x to x). Define Inclusion/ Exclusion criteria and cohort/sample size.

Explain how the project is representative/ inclusive of the demographic makeup for the study location.

Will non-English speakers be included? If not, explain.

Will any vulnerable population be targeted? i.e. newborns, neonates, children and pregnant women, Native Americans, etc. Include safeguards to protect the population and justification for including.

Proposal Title:

Version Date:

- **Timeframe** of case ascertainment/chart review (e.g. all eligible patients between x and x years)

Methods

Recruitment: (~~delete section if retrospective study~~) Explain when, where & how potential subjects will be recruited or identified (e.g.: email, face to face, flyers, screening EMR etc.). Provide examples of any patient-facing recruitment materials (such as Flyers). Indicate how patient privacy will be protected. Include if any screening will be done before consenting (such as a screening survey or medical charts review).

Example: The IRB-approved *Study Flyers* will be posted at Banner University Medical Center: Women's Institute (BUMCP-WI). Patients presenting at BUMCP-WI for their standard-of-care prenatal appointments can scan the QR code included in the *Study Flyers*. Patients will then be directed to complete the Eligibility Survey (via REDCAP). If the patient is eligible, they will be asked to include their contact information, and the research staff will contact them to discuss the study and review the *Informed Consent Form*.

Example: Patients presenting to Banner University Medical Center: Women's Institute (BUMCP-WI) for their standard-of-care appointment will be approached by IRB-approved staff. Patients' medical charts will be reviewed by research staff to ensure eligibility. Patients will be asked by BUMCP-WI clinic staff if they agree to be contacted by the research team to discuss research. If they agree, study staff will recruit the patient at the clinic during their appointment or by phone using [*Recruitment Script* OR the *Informed Consent form*] as a guide.

Example: "A clinician may present the study to eligible patients and if they are interested, a member of the study team will approach the patient during the clinic visit or by phone to review the informed consent form."

Consent: Include how/ if informed consent will be obtained and/or if a HIPAA/ consent waiver will be requested from the IRB.

If consenting participants: (Delete if retrospective chart review)

- Describes the consent process (when, where, by whom, and how). How will patient privacy be protected during the process?
- Attach the consent form in a separate document. Explain if the consent will be electronic/paper or both.
- Indicate where consent documentation will be stored.
- Written permission to access PHI will be obtained from the owner of the record before access to the record/ starting study procedures is permitted. (HIPAA)

Example: "Informed consent will be obtained before starting any study procedures by HIPAA-trained, IRB-approved study staff that ensure HIPAA compliance when discussing the study. The study will be explained, and patients will be assured that participation is voluntary, confirm patient understanding, and provide enough time for the patient to review the consent form and ask any questions. Once the patient confirms interest, the consent will be signed electronically via REDCap or on paper. A copy of the signed consent will be provided to the patient. Signed consents will be stored electronically in the study REDCap."

OR

If a waiver of consent is being sought:

- **For Retrospective chart review:** An *Appendix for Waiver or Alteration of Consent or PHI* will be submitted to the University of Arizona IRB or a designated Privacy Board or IRB to allow the

Proposal Title:

Version Date:

review and collecting of PHI for this Retrospective Chart Review. Indicate plans to protect the privacy of subjects under the waiver.

If pre-screening patients via the medical charts: An *Appendix for Waiver or Alteration of Consent or PHI* will be submitted to the UA IRB to allow the screening of medical records to determine potential eligibility before obtaining consent.

Study procedures: Provide a **detailed** description of the study workflow in paragraph form.

-Describe any measurement or assessment tools. Attach any surveys/questionnaires, scripted interviews, or patient-facing documents used for research.

-Indicate if patient procedures are standard of care diagnostic/treatment versus purpose research.

-Include a time commitment estimate for study participation

-NOTE: If conducting a retrospective chart review, data extracted from Cerner is only reliable from January 1, 2014, to present.

Example: This is a retrospective chart review. A patient list with patients meeting the XXXX criteria will be obtained using XXX codes. Identifiable information will/ will not be obtained due to [LIST REASON]. This information will be stored in the *Master Enrollment Log* stored in XXX. [Study Staff XXX] will have access to identifiable information. Further medical chart review will be done to obtain XXXX, as listed in the *Data Collection Document*.

Example: During their standard-of-care [Dept/Div] intakes, BUMCP [Dep] consenting individuals will be asked to complete the XXXX Survey and the *Weekly XXXX Survey* on paper or REDCAP. After their appointment, a 10mL blood draw will be done (in addition to any standard-of-care blood collections) at the clinic.

They will then be asked to complete the *Weekly XXXX Surveys* during their participation (90 days) via automatic REDCap invitation. The blood collections will be repeated during their monthly standard-of-care follow-up appointments for three months. [this example would require specimen (blood) processing and storage location. And what analysis will be done]

The information listed in the *Data Collection Document* will be extracted and inputted into the study REDCAP.

Total time commitment is less than 2 hours over 3 months, since each survey takes less than 10 minutes (100 minutes total), and blood draws take about 5 minutes (15 minutes total).

Schedule of Events: (remove if retrospective)

If Prospective: include a Schedule of Events or Schematic flow chart. Include allowable windows for each visit and all study procedures for each visit.

	Visit 1 (Day 0)	Visit 2: 1 month follow up (7±1 days)	Visit 3: 2-month follow-up (60±7 days)	Visit 3: 3-month follow-up (90 ±7 days)
Informed Consent	X			
Demographics Survey	X			
Weekly Stress Survey (±1 day)	X	X	X	
Blood Collection	X	X	X	

Proposal Title:

Version Date:

Medical Records Data collection: - Physical exam - Vitals	X	X	X	
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Interventional Device or Pharmaceutical(s) (remove if not applicable or retrospective)

If your study includes an interventional device or pharmaceutical, include your plan for record keeping, labeling, storage, handing, and administration. Note all investigational devices and pharmaceuticals must be labeled, “for Investigation only” and only handled and dispensed by authorized study team members.

Data Collection & Measurements: Describe how data will be collected and provide a separate data element list (*Data Collection Document*).

- State if educational or employment records are to be included.
- State if whether mental health/HIV/Other Confidential information will be collected.
- State if a Certificate of Confidentiality is required/will be obtained.

Describe the outcome measurements (in agreement with the aims) and how these are defined. If multiple outcomes, then designate as primary and secondary (and tertiary if necessary) outcomes. [For example, “The primary outcome is the presence of hypopituitarism at age 4 years. The secondary outcome is obesity defined as a BMI SDS >1.5.” Make sure the outcomes line up and match your primary and secondary aims.]

Describe the data elements and how these are defined. [If multiple exposures, then describe each. For example, “hypothyroidism will be classified based on initial hormone levels prior to x age and follow-up hormone levels at age x years”.

Data Analysis Plan: Describe the data analysis that is intended.

It is recommended that this paragraph start with restating the objectives; for example, the data will be analyzed to compare the initial x levels with the presence of hypopituitarism at age x years. Should include a description of how the outcomes will be examined by statistics.

Before submission, it’s recommended to schedule a consultation with the University of Arizona Biostatistician team, **see link: [Request for Statistical Assistance](#)**.

Resources

Describe the resources to be used to recruit, conduct study procedures, and analyze data (e.g. facilities, time, personnel, REDCap, UA Box Health, EMR, supplies, labs, imaging (research specific), software, etc.).

Regulatory Review & Ethics

State if IRB approval will be sought from University Human Subjects Protection Program or another IRB (under applicable Reciprocity Agreement). If waiver of consent or waiver of documentation, and/or HIPAA waiver will be sought.

Benefits/ Risks

Proposal Title:

Version Date:

Potential Benefit: Describe benefits individuals may experience from participating in research, indicating the probability, magnitude, and duration. Include any benefit to society at large. Payments or reimbursements for expenses are not considered a benefit.

Example: There will be no direct benefit to the patients included in this study.

Example: The knowledge gained by this study may help society by improving the treatment and outcomes of patients who undergo (XXXXXXX) Benefits may be educational, psychological, physical, and/or medical.

Potential Risks: List any reasonably foreseeable risk related to study participation. Note for each risk or set of risk below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

(This should be included in all studies that require access to PHI). There is minimal risk of loss of confidentiality if the patient's data or information is inadvertently disclosed outside of this study.

However, such risks would be minimized by ensuring compliance with UA-IRB and HIPPA guidelines to protect patient privacy.

(If retrospective) The study will be solely retrospective and therefore will not impact the standard of care treatment.

Subject compensation *(delete if retrospective study)*

Indicate the amount and timing of any compensation (monetary and/or non-monetary). Describe if compensation will be prorated. NOTE: If raffles are used, please refer to the State of Arizona specific laws governing raffles.

Medical care and compensation for injury *(delete if retrospective study)*

If the research involves more than minimal risk to subjects, describe the provisions for medical care and available compensation in the event of research-related injury. The information in this section should be reflected in the consenting instruments. If there is clinical trial agreement, this language should reflect what is stated in the agreement.

Withdrawal of subjects *(delete if retrospective study)*

Discuss how, when, and why subjects may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they are not put at increased risk. Include if data obtained up through withdrawal will be used. Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.

Monitoring for subject safety *(delete if retrospective study)*

State if adverse events are expected, if yes, describe how these events will be identified, assessed, and graded. If the Human Research involves more than minimal risk to subjects, provide a brief lay discussion of the plan to monitor for subject safety and reporting of adverse events. Describe how the data will be evaluated, include a timeline of the review with the who, what information and when the review (and reporting, if necessary) will occur.

Privacy & Data Confidentiality

Statement(s) re: steps to protect information obtained from subjects.

- All study staff will be GCP Trained, IRB approved, and following University of Arizona IRB and HIPAA regulations.

Proposal Title:

Version Date:

- State how the data will be linked to the subjects during the study (e.g., 3-digit #).
- State whether human subjects will be identifiable directly or through identifying information.
- Use of REDCap database or other secure system. Data security (e.g., file encryption, REDcap, secure log in

If using video or audio recording, indicate when, where, and how recording will take place. Storage and/or destruction plans.

The University of Arizona requires maintaining study records for 6 years following the closure of the study or if minors are included, 6 years after the youngest participant turns 18. Sponsored/externally funded studies may have longer requirements.

Data Handling & Record Keeping

Data Handling: State how and where the data will be recorded and stored. Specify which personnel and methods of access to medical record data, PHI, and/or source documents. If consent it obtained, describe where the originals will be stored. (e.g. Box UA Health, REDCap, etc.)

If UA REDCap is being used include the following boilerplate:

The REDCap electronic data management (EDM) system at the University of Arizona is housed on 2 virtual servers; one supporting database services and the other web services. Hardware is located in the University Of Arizona's Information Technology Services Center (UITs). The space is a temperature controlled and physically secured within a keyless entry area. Hardware management and support is provided by UITs. The database server is located behind a firewall and the web server is in a DMZ. REDCap software support is provided by the University Of Arizona Center for Biomedical Informatics and Biostatistics. All web-based information transmission is password protected and encrypted in transit. Administration of REDCap is managed through Virtual Servers located at the University Of Arizona College Of Medicine.

In REDCap, all incoming data is intentionally filtered, sanitized, and escaped. This includes all data submitted in an HTTP Post request and all query string data found in every URL while accessing REDCap, among other modes through which user-defined data is submitted in the application. Server environment variables that are vulnerable to forgery by users are also checked and sanitized. All user submitted data is properly filtered for any possibly harmful markup tags (e.g. <script>) and is then escaped before ever being displayed on a web page within the application. SQL queries sent to the database server from REDCap are all properly escaped before being sent. If any values used in an SQL query originated from user-defined values, they would have already been sanitized beforehand as well, as described above. User-defined data used within SQL queries also have their data type checked to prevent any mismatching of data types (e.g. making sure a number is really a number). These processes of sanitization, filtering, data type checking, and escaping all help to protect against methods of attack, such as Cross-Site Scripting (XSS) and SQL Injection. To specifically protect against Cross-Site Request Forgery (CSRF), which is another method of attack, REDCap utilizes a "nonce" (a secret, user-specific token) on every web form used in the application. The nonce is generated anew on each web page as the user navigates within REDCap during a session.

(For UA Only) REDCap was developed specifically around HIPAA-Security guidelines and is recommended to UA researchers by both our Privacy Office and Institutional Review Board. REDCap has been disseminated for local use at more than 2300 other academic/non-profit consortium partners in over 100 countries. Vanderbilt leads the REDCap Consortium, which currently supports more than 410,000

Proposal Title:

Version Date:

projects and 523,000 users. More information about the consortium and system security is available at <https://projectredcap.org/>.

Data Monitoring: Describe the data monitoring plan to ensure data entry completion, accuracy, and consistency. Indicate any third-party monitoring company. Include who will review the data, including quality assurance, safety data, untoward events, and efficacy data.

Future use, long-term storage and/or destruction of data or specimens: Indicate if data or specimens will be kept for future research, including unspecified future research and genetics. Indicate who holds the repository and what information will be sent to the repository. Explain if and how the data/specimens will be shared with collaborating entities or sold/shared with pharmaceutical companies. *NOTE: Include a separate section in the informed consent that reflects the future use and storage. See HSPP Guidance, Storing research data and/or specimens for future use.*

Budget *(delete if retrospective study)*

Indicate any anticipated costs for the study and who is responsible for the payments. If unfunded – consider plans for future funding (grants/sponsor) of the next stage of this research project. For research proposals a separate budget should be developed and available.

Name and address of the sponsor of the study *(delete if not sponsored or retrospective)*

Sharing Results with subjects

Discuss if study results will be shared with subjects, families, and/or the institution. If subjects or their insurance company will be billed for research procedures, discuss when and how procedure and billing information will be made available to the subject.

Publication Plan

Describe plans for publication of research results. State if results will be returned to research subjects. i.e. *Will the patient/subject be notified of any relevant findings of the study?* Note if data will be deidentified before publishing.

References