

Research Proposal for Retrospective Data Analysis

Expedited or Exempt Review Retrospective Analysis

Note: IRB may approve retrospective studies as an exempt or expedited study.

Appendices: APPENDIX I for Exempt Regulation Confirmation (categories)

APPENDIX II for Expedited Category Definitions

APPENDIX III for other useful information for questions in myIRB

Please note that most of the information requested in this template is the same as the information requested in the myIRB. Therefore, completing this document before attempting to enter information in myIRB will enable you to have all the necessary information in one place. Once this protocol template is completed, then one can just “copy and paste” information in myIRB.

All highlighted text should be replaced with appropriate study-specific text.

All instructional language (yellow highlighted text, including this box, should be deleted before submission to the IRB.

Project Title:

Full Title

Short title:

..... (4 to 6 words)

Study Abstract (brief description):

A paragraph describing the objectives of the project.

Study Staff/role and function:

Name	Role	Conflict of Interest	Affiliation

Protocol Title: Brief title

Background:

Provide brief description.

Objectives:

Primary

- To review the
-

Secondary

- None

Study Design

- This is chart/data review study

Inclusion Criteria

- Age greater than 18
- Males
-

Exclusion Criteria

- Patient under the age of 18
- Prisoners
-

Treatment groups

- Specifics

Study Endpoints

- Primary:
 -
- Secondary:
 -
- Safety
 -

Definitions:

-

Data extraction:

Protocol Title: Brief title

- The PI is a UF faculty member in the Department of

Will any part of this project include the use of VA personnel, facilities, and/or resources? (including, but not limited to, review of medical records or use of tissue specimens)

- Yes/No

If “Yes,” specify how and where the research will involve VA:

When you extract data and record it for research purposes, will you collect/record any identifiable information in your data collection forms/records?

- Yes/No
- Number of records to review: ??

Do you need to examine multiple sources for each subject where one of the sources is specimens /tissue?

- Yes/No

Indicate which Categories below you believe the research can be approved under.

Use appropriate Exempt Category Definitions:

- See Appendix I and II at the end of this document

Are you collecting any information that could:

- Yes/No

(e.g., sexual behavior, HIV status, illicit drug use, alcohol use/abuse, illegal activities, or any other information that the subject might not want publicly known for any reason)

(a) be sensitive and possibly affect the reputation, status, or insurability of the research subjects,

(b) place the subject at risk of criminal or civil liability, or

(c) be damaging to the subject’s financial standing or employability?

If Yes, describe and describe how you will ensure the confidentiality of this information - describe the storage and eventual de-identification of this data.

Will subjects of a specific race or ethnicity (as defined by NIH) be studied?

- Yes/No

Gender?

- Yes/No

Protocol Title: Brief title

Approximately how many subjects' records will you study?

-

Will vulnerable subjects be considered for participation in this study?

- Yes/No

List where/how you will obtain your data (e.g., where you will give your survey, all sources to be studied, such as medical records, pathology, or directly from subjects themselves, if applicable). Be very specific:

- EPIC IT Team

Attach a copy of data collection form(s) or questionnaire(s) that will be used for the study

Attach MS Excel File.

Please describe data points or variables that you have not attached or additional information that is not included in your attachments (Data Collection methods):

- Need list of Data elements (list all data elements that you wish to collect. (Excel file can be useful)

Will you review any medical records or collect any medical record information from UF and/or UF Health facilities or the VA:

- Yes/No

Will you review any medical records or collect any medical record information from any facilities other than UF, UF Health, or the VA?

- Yes/No

This is a request to waive a patients' HIPAA authorization:

- **In myIRB Choose: To enroll subjects in the study**
- **If UF/Shands/OneFlorida institution, and if this request is to identify and/or contact potential subjects, Will you disclose identifiable information to anyone outside your covered entity?**

What protected health information will you collect, create, use, or disclose (disclose = outside the covered entity), under this waiver?

- MRN
- Name
- Date of Birth
- List only those data elements that are considered PHI

CTSI ancillary info- REDCAP:

- If using REDCap

Protocol Title: Brief title

References:

1.

===== DELETE THESE APPENDICES BEFORE SUBMISSION TO THE IRB =====

APPENDIX I

Exempt Regulation Confirmation (categories)

1.0

* Indicate which Categories below you believe the research can be approved under.



1. Research, conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction



2. Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of 3 criteria are met: (i) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR (iii) the information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination required by 45 CFR 46.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality) AND the research is not subject to subpart D.



3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human

subjects cannot readily be ascertained directly or through identifiers linked to the subjects; (ii) Any disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)

4.i. Secondary Research Use of Identifiable Private Information and Identifiable Biospecimens for which Consent is Not Required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available

4.ii. Secondary Research Use of Identifiable Private Information and Identifiable Biospecimens for which Consent is Not Required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (ii) The information is recorded by the investigator in such a way that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact subjects, and the investigator will not re-identify subjects

4.iii. Secondary Research Use of Identifiable Private Information and Identifiable Biospecimens for which Consent is Not Required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., the use is regulated for purposes of "health care operations" or "research" or for "public health activities and purposes" as those terms are defined at 45 CFR part 164)

4.iv. Secondary Research Use of Identifiable Private Information and Identifiable Biospecimens for which Consent is Not Required. Secondary research uses of identifiable private information or identifiable biospecimens,

if at least one of the following criteria is met: (iv) The research is conducted by or on behalf of a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with certain federal statutes

5. Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency. Applies to research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads. Applies to activities that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, but not limited to: procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and Food Quality Evaluation and Consumer Acceptance Studies. This exemption applies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe by FDA or approved by the EPA or the USDA's Food Safety and Inspection Service.

7. Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (and Storage or Maintenance for such Secondary Research Use) for which Broad Consent is Required. Exemption Category 7 applies to storing and maintaining identifiable private information/specimens for secondary research use.

8. Applies to secondary research studies that involve use of identifiable private information/specimens, provided the following criteria are met: (i) Broad consent for storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1)-(4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; (iii) An IRB conducts a

limited IRB review to make the determination required by 45 CFR 46.111(a)(7), and to make the determination that the research to be conducted is within the scope of the broad consent; AND (iv) The investigator does not include returning individual research results to subjects as part of the study plan. However, it is permissible under the exemption to return individual research results when required by law regardless of whether or not such return is described in the study plan.

APPENDIX II

Expedited Category Definitions

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. Note: Research on a marketed drug is not eligible if the research significantly increases the risks or decreases the acceptability of the risks associated with the use of the drug.
 - b. Research on medical devices for which
 - i. an investigational device exemption application (21 CFR Part 812) is not required; or
 - ii. the medical device is both cleared/approved for marketing and being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. Subjects are healthy, nonpregnant adults who weigh at least 110 pounds; amount drawn may not exceed 550 ml over 8 weeks; and collection may not occur more frequently than 2 times per week. OR
 - b. Subjects are other adults and children*, considering the age, weight, and health of the subjects; the collection procedure; the amount of blood to be collected; and the frequency with which it will be collected. For these subjects, the amount collected may not exceed the lesser of 50 ml or 3 ml per kg over 8 weeks, and collection may not occur more frequently than 2 times per week.

*Children are defined in the HHS regulations as *who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted: 45 CFR 46.402(a).*
3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples:
 - a. hair and nail clippings, if collected in a non-disfiguring manner;
 - b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - c. permanent teeth, if routine patient care indicates a need for extraction;
 - d. excreta and external secretions (including sweat);

- e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
 - f. placenta removed at delivery;
 - g. amniotic fluid obtained at the time of rupture of the membrane before or during labor;
 - h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - j. sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples:
- a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the privacy;
 - b. weighing or testing sensory acuity;
 - c. magnetic resonance imaging;
 - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate to the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101[b][4]. This listing refers only to research that is not exempt.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Protocol Title: Brief title

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

APPENDIX III

Requested review type:

- Expedited: Data/Chart Review – retrospective and prospective

Which CTSI resources will be used (For example, use of REDCap)?

- No

Will information gained from this project result in publication in an ICMJE member Journal?

- Yes

Is research considered classified?

- No

Does this study require that patients have a known diagnosis (current or previous) or suspected diagnosis of cancer as part of the eligibility criteria?

- Suspected biliary stricture

Is this study looking at cancer-relevant aims, endpoints or outcomes (including any studies involving tobacco use, cessation or prevention) (i.e. related to cancer treatment, supportive care, control, diagnosis, screening, prevention, risk factors or other cancer-specific research)?

- Yes/No

Do you plan to exclusively enroll patients with a known diagnosis (current or previous) or suspected diagnosis of cancer?

- Yes/No

Conflict of interest of the research team?

- Yes/None

Where will this research be conducted?

- UF and/or UF Health Jacksonville

Are you getting any data or tissue from international locations?

- Yes/No

Indicate appropriate funding types for this project: detail-funding sources if appropriate

- No funding required or provide details of the funding source (may need PeopleSoft Project number)

Does the institution (University of Florida, Shands, or NF/SG VHS) hold a patent or license for any material, object, or process used in this project?

- Yes/No

Protocol Title: Brief title

Is a patent or license pending or under consideration, or is there any intention to file a patent application at a later date?

- Yes/No

Does the institution (University of Florida, Shands, NF/SG VHS) own stock in the company sponsoring the project?

- Yes/No

Are you accessing or using any tissue (e.g., blood) as part of this research?

- Yes/No

Are you accessing records or data?

- Yes – Provide date (e.g., From January 2018 to December 2021 (monthly report))