Study Title and Staff

All items marked with an orange asterisk ( ) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

1.0 * IRB Committee:

- (●) IRB-01
- ( ) IRB-02

Clear

Visit http://irb.ufl.edu/ for information on which committee to choose for review of your project.

* **1.1** Is this a multi-institutional research project where the UF IRB will be the single IRB of record for other participating sites OR are you ceding review to another IRB of record? (IAAs are required between UF and other institutions)

( ) **Yes** (●) **No** Clear

2.0 * Project Title:

How to Submit an Expedited Retrospective Data/Chart Review Using an AI Device

3.0 Short Title:

The "Short Title" is a simplified, short title for advertising on UFHealth.org or CTSI website.

4.0 Provide a summary description or abstract for this study:

max 500 char

This is a general guide for what a typical submission should look like for Expedited retrospective data/chart reviews using an FDA-regulated AI device. This guide focuses on the SmartForm pages related to this type of submission. Some pages and questions are left unanswered/not included in this guide as the answers will vary depending on the study.

5.0 * Principal Investigator:

Rebecca Simms ••• ⊗ | **COLLEGE-MEDICINE** | There are no items to display | **MD PhD**

Please review the policy on who can be a PI: *click here.*

UF Student*: Graduate Student and Resident PIs require a UF faculty member to serve as a mentor. Please include this mentor in the Study Staff listing* *vestigator with a* *lty mentor for* *ergraduate* *t serve as PIs.*

- [ ] Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects
- [x] Performs study related activities but does not interact directly with the study subjects
- [ ] Obtains informed consent
- [x] Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]
- [ ] Enters research related orders into EPIC for subsequent study physician or provider's electronic signature approval
- [x] Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations
- [ ] UF Student
- [ ] Volunteer (i.e. you are not staff, student or faculty at UF/Shands/VA)
- [ ] OneFlorida Site PI

Q 5.0 – Only select the MR function if the study team is going into the medical record for research purposes.

Requested Review Type

1.0 * Requested Review Type:

- ○ Non-Human
- ○ Data/Chart Review
- ○ Banking Only
- ○ Exempt
- ● Expedited
- ○ Full Board
- ○ Humanitarian Use Device [HUD]/ Humanitarian Device Exception [HDE]-Only

Clear

Choose One

Expedited Categories:
Exempt Categories:

Risk & Benefit Assessment

1.0 * Risk classification for this study.

- ● No more than Minimal Risk or No Risk
- ○ Greater than Minimal Risk

Clear

(select one)

***Minimal Risk**: A probability and magnitude of harm or discomfort (physical, psychological, or social) that are no greater, in and of themselves, than those in daily life or in a routine physical or psychological examination or test.*

1.1 If "Minimal Risk or No Risk", Justify:

This is a retrospective chart review testing a new AI model. The only risk is loss of confidentiality.

1.2 If "Greater than Minimal Risk", are you minimizing Risks to subjects by using procedures already being performed on the subjects for diagnostic or treatment purposes?

○ **Yes** ○ **No** Clear

1.2.1 If "Yes", Describe:

2.0 What plans are in place for medical emergency management?

- ☐ Public or community emergency services
- ☐ On-site medical expert with emergency medication and equipment
- ☑ Other

2.2 If "Other" specify:

This is a retrospective chart review. No emergency management is necessary as there is no subject interaction.

3.0 The study offers the prospect for direct benefit to: (choose from list)

- ○ all potential subjects
- ○ some potential subjects
- ● no subjects

Clear

Study Type

1.0 * Type of study:

(check all that apply)

HIPAA FAQ for Protected Health Information

☐	**Drug/biologic agent/non-food substance study**	
☑	**Device study**	**Investigational Device; FDA Approved Device; Humanitarian Use Device [HUD]**
☐	**Research-only procedure**	**Labs, surgical procedures, other experimental procedures; Tests & Procedures done solely for Research**
☐	**Use of radiographic procedures, radiation, or radioactive materials**	**Procedures that utilize ionizing radiation such as X-rays, CT-scans, SPECT scans, PET scans, etc.; radiation therapy including proton beam and gamma knife, etc.; radioactive materials such as radioactive iodine, technetium-99m, cobalt-60, etc. This does not include diagnostic MR or diagnostic ultrasound examinations.**
☐	**IBC Relevant Research**	**Gene therapy; viral vectors/virus based gene delivery; DNA vaccines; mRNA vaccines; use of mRNA or rDNA, synthetic nucleic acids, gentically modified immune cells/whitel blood cells; gene editing, gene silencing.**
☐	**Genetic Testing**	
☐	**Banking**	**non-local, off-site banking; collection and storage of tissue or data for unknown, future research; Local bank must be submitted as a separate study**
☐	**Deception**	**Deception is defined as purposely omitting information about the study to research participants**
☐	**Placebo**	
☐	**Behavioral / Social Research**	**Questionnaires, surveys, observational; behavioral/psychological; educational research; If your research is restricted to behavioral/psychological research, you may choose to use IRB-02 rather than IRB-01 if the following conditions are met: (1) you are not collecting Protected Health Information (see HIPAA FAQ), and (2) you are NOT a VA or Shands employee.**
☐	**Pharmacogenomic**	
☐	**Pharmacokinetic or pharmacodynamic research**	
☐	**Exercise or nutrition research**	
☐	**Record Review Arm**	**This option is if your study includes a population that is only a record review. This is not for studies that are only a record review. If your study is only a record review, please return to the Requested Review Type page and choose Data/Chart Review.**
☐	**Non-therapeutic research**	
☐	**Other**	

1.1 If "Non-Therapeutic research" or "Other", Describe:

Expedited Regulation Confirmation

1.0 * Indicate which Categories you believe the research can be approved under. *(check all that apply)*

- [x] 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 (1) an investigational device exemption application (21 CFR part 812) is not required, or (2) 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, non-pregnant 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 (defined in 45 CFR 46.402(a) as persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted), 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/kg over 8 weeks, and collection may not occur more frequently than 2 times per week.
- [ ] 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings, if collected in a non-disfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth, if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane before or during labor; 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; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 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 generally not eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: 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 subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate to the age, weight and health of the individual.
- [x] 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 regulations for the protection of human subjects as noted in 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.
- [ ] 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 behaviors) 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 regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Devices

1.0 * Please indicate the type of device(s) that will be used on this project:

Choose all that apply

- [x] Exempt from IDE
- [ ] Abbreviated IDE
- [ ] FDA Approved IDE Required
- [ ] Humanitarian Use Device

Exempt: *Either approved device used consistently with its approval/clearance or device qualified for an exemption under FDA regulations*
Abbreviated IDE: *The device must be non-significant risk (NSR) (documentation to this effect from sponsor and/or FDA required)*
FDA Approved IDE Required: *Typically includes significant risk (SR) devices. The PI must include the IDE number on the detail smartform.*
Please refer to the FDA guidance on SR and NSR Device studies, including common examples:
https://www.fda.gov/media/75459/download
Humanitarian Use Device: *Research use only*

Device: Exempt from the IDE Regulations - Detail

1.0 * What is the name of the device?

Name of AI model

2.0 Who is the manufacturer of the device?

Manufacturer of AI model

3.0 Describe briefly the use of this device in this study:

Describe the intended use of the AI model.

4.0 * Please select the correct exempt category for the device you are using:

- ○ Approved/Cleared Devices
- ○ Substantial Equivalence (510(k) Clearance)
- ● Diagnostic Device
- ○ Modifications, Consumer Preference Testing and Combination Devices
- ○ Custom Device

Clear

5.0 * Is training required to use the devices(s)?

○ Yes ● No Clear

6.0 Describe how the device(s) will be kept secure so that unauthorized use is prevented:

Describe your storage plan for the AI model. What protections are in place to ensure no unauthorized access occurs?

7.0 * Who will pay for the device(s)?

- ○ Subject/Insurance
- ● Sponsor/Other

Clear

* **7.2** Provide details:

State who is paying for it. Likely sponsor or study team.

This page and the next describe 2 different ways to answer the pregnancy questions.

Females, Child-Bearing Potential v2024

Q 1.0 – Only select 'Yes' if you are recording information regarding pregnancy status.

1.0 * Are pregnant women eligible to participate in the study?

◯ Yes ● No Clear

1.1 If no, what method will be used to determine participant is not pregnant?

◯ Pregnancy test required

● Self Report

Clear

Females, Child-Bearing Potential - Self Report

1.0 The following statement must be true. Affirm by checking the box, otherwise a pregnancy test is required.

- ☐ there are no risks to pregnancy, embryo, or fetus
- ☑ Not collecting data on pregnancy status with any of the study instruments (pregnancy status not relevant to the study and no risk to fetus)
- ☐ Population too young, old, surgically sterilized
- ☐ other

Females, Child-Bearing Potential v2024

1.0 * Are pregnant women eligible to participate in the study?

● Yes ○ No Clear

Pregnant Women or Human Fetus - Protections

7.0 * BENEFIT & CONSENTING: The study offers the prospect for: *Select one*

- ○ direct benefit to the pregnant woman. Obtain consent from the woman only
- ○ direct benefit to both to the pregnant woman and the fetus. Obtain consent from the woman only.
- ● no benefit to the woman or fetus, but the risk to the fetus is minimal (not greater than minimal) AND the purpose of the research is to develop important biomedical knowledge that cannot be obtained by any other means. Obtain consent from the woman only. SEEK GENERAL COUNSEL ADVISEMENT IF AN ABORTED FETUS OR ABORTED PREMATURE INFANT ARE EXTRACTED ALIVE.
- ○ direct benefit to the fetus only (no benefit to the woman). Obtain consent from the pregnant woman AND the father. Consent of the woman is adequate IF you document that the father is unable to consent because of unavailability (such as death, or if you document that several attempts to reach him failed, etc), incompetence, temporary incapacity, or the pregnancy resulted from rape or incest.

Clear

7.1 Provide protocol specific information to justify the benefit/consenting answer you selected above in Q7.0:

This is a retrospective chart review with no participant interaction.

Q 7.0 – If you choose “Yes” select the 3rd option on this page.

Type of Subjects - Expedited/Full Board/Banking: Detail

1.0 * Description:

Describe the patient population. Each population needs to be a new entry using "+Add."

(e.g. People with Diabetes)
If more than one type of subject or subject information, please use the "OK and Add Another" feature and describe only one type at a time.

2.0 * Indicate the age range of subjects (for each group, if applicable) to be studied :

2.1 Minimum Age: Units

2.2 Maximum Age: Units

Each group listed should have a specific age range identified.

List ages in years, months, or weeks.

3.0 Will this group of potential subjects need to undergo screening that is not part of their routine care in order to determine if they are eligible for this project?

○ Yes ● No Clear

3.1 If "Yes", Describe what screening procedures are needed for this group:

NOTE: *subjects must be consented to the study before undergoing any screening procedures that are not part of their routine care.*

If your project has different groups of subjects, list each group separately.

4.0 What is the expected length of time that each individual subject in this group will participate in this project?

Until the study is closed

Indicates years, months, weeks, days, or hours

Vulnerable Subjects (Expedited/Full Board/Banking Only Studies)

1.0 * Will vulnerable subjects be considered for participation in this project?

○ Yes ● No Clear

this includes tissue/data from vulnerable subjects

NOTE: The definition of Human Fetus is one that is extracted alive by abortion.

1.1 If "YES", indicate which of the following vulnerable populations will be considered for this project:

☐ **Human Fetus**	
☐ **Neonates**	
☐ **Children**	
☐ **Prisoners**	
☐ **Decisionally Impaired/Comatose Individuals**	
☐ **Terminally Ill Patients**	**Only select if you are targeting this group. Do not check if they may be included as part of the general population.**
☐ **Staff at the Institution**	**Only select if you are targeting this group. Do not check if they may be included as part of the general population.**
☐ **Students at the Institution**	**Only select if you are targeting this group. Do not check if they may be included as part of the general population.**
☐ **Economically/Educationally Disadvantaged**	**Only select if you are targeting this group. Do not check if they may be included as part of the general population.**
☐ **UF Student Athletes**	**Only select if you are targeting this group. Do not check if they may be included as part of the general population.**

Q 1.1 – Only select the populations you record information about

Enrollment Details

1.0 * Local enrollment information:

1.1 Will your study include procedures (clinical tests, surveys, etc) being done solely for research purposes in order to determine whether or not the subject meets eligibility requirements (i.e. screening for research purposes)

◯ **Yes** ● **No** Clear

	# of Subjects
* a. How many subjects do you need to complete the study?	
* b. How many additional subjects will be enrolled/included in this project but might discontinue participation in the study before completing all study interventions/interactions (either due to adverse event, withdrawal, etc.)?	0
* c. If 1.1 (above) is "Yes", how many additional subjects do you believe will need undergo these screening procedures and will not count toward the numbers listed in questions a and b above (these subjects would be screen failures)?	0
TOTAL (a+b+c) =	**0**

If your response to 1.1 is "No", then enter 0 (zero) for c.

NOTE: For **OneFlorida** projects, enter the total number for all sites.

Recruitment Methods

1.0 How do you have access to the subject population? Do you have a prior professional relationship with these subjects?

- ☐ General population via advertisements (no clinical relationship)
- ☐ As a part of normal clinical care
- ☐ Instructor / Faculty
- ☐ Other

1.1 If "Other", specify:

2.0 Describe who will identify and recruit subjects for this research:

(e.g. position, title, classification, type of employee, student, etc)

State who is identifying the subject population.

3.0 How will the individual(s), listed above, identify and recruit subjects for this research?

Describe in detail.

State how the subject population will be identified.

Written Informed Consent Determination

1.0 * Are you going to seek **written Informed Consent** from any subjects in order to enroll them?

- (●) No — written informed consent will not be obtained
- ( ) Yes

Clear

Written Informed Consent *means that participants are documenting, with their signature, that they have been informed about the study and agree to participate.*

Waivers or Alterations of Informed Consent Determination

1.0 * Are you seeking a Full Waiver of Informed Consent, Partial Waiver, Waiver of Documentation, or Alteration of Informed Consent?

(●) **Yes** ( ) **No** Clear

Types of Waivers/Alterations

1.0 * What type of Waiver or Modification of Informed Consent are you requesting for ENROLLING subjects?

check any or all that apply

☐	**Waiver of Documentation of Informed Consent**	**The researcher will still inform the potential subject about the research and seek to obtain consent, sometimes by including an IRB approved written statement that includes the mandatory elements of consent. However, consent of the subject is not documented by having the subject sign an Informed Consent form.**
☐	**Partial Waiver of Informed Consent**	**The waiver criteria are to be evaluated with respect to the portion of the research to which the waiver applies**
☑	**Full Waiver of Informed Consent**	**Subjects will not be informed nor will consent be sought or obtained prior to their involvement in the research (including collection of data from identifiable records or tissue)**
☐	**Alteration of Informed Consent**	**The researcher still obtains informed consent but one or more of the required elements of the consent is not present due to the nature of the study**

2.0 * Does this study involve the development, collection, use, or sharing of protected health information (PHI)?

- ( ) **No**
- (●) **Yes**

Clear

Full Waiver of Informed Consent

1.0 * Is this research project subject to FDA regulations?

(●) **Yes** ( ) **No** Clear

Examples include but are not limited to: the use of investigational drugs, devices, or other biological substances subject to FDA regulations; collecting post-treatment data on subjects who previously received an investigational drug or device; collecting data on off-label use of a marketed drug in order to support use of the drug for a new indication. Contact our office if you have any questions or review the FDA's regulation on scope

2.0 * Describe and Justify why the research could not practicably be carried out without the waiver.

Describe and justify.

Information Sources and Identifiers

1.0 Identify the sources where you will get your information/data that is being collected:

Check all that apply

- [ ] Subject
- [ ] Questionnaires or Interviews
- [ ] Mental Health Records
- [x] Hospital or Medical Records
- [ ] Data Previously Collected for Research Purposes
- [ ] Biological Samples
- [ ] DNA Samples
- [ ] Research Database
- [ ] Clinical Database
- [x] Other

Q 1.0/1.1 – An example of common responses

1.1 If "Other", specify:

IDR

2.0 Please review the list of forms and/or questionnaire(s) you have already provided:

There are no items to display

Also include information sheets, letters, handouts

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

You must save this page to save your attachments

+ Add

Name	Description
Data Collection Sheet.docx(0.01)	•••

Q 2.0 – Attach all data points

2.1 Please describe the method of data collection (ex. paper and pencil, interview, electronic, etc) and storage plan (ex. hard copies kept, servers, etc) for all forms of data collection listed.

Q 3.0 (not shown) – Select all identifiers that will be used. Must be consistent with Q 2.0 above and Q 1.0 of the HIPAA Waiver of Authorization page.

HIPAA Waiver Determination

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

- [x] to enroll subjects in the study
- [ ] to identify, for the purpose of recruiting, potential subjects for the study
- [ ] Not Applicable

NOTE: In chart review studies, collecting the data for your study from a medical record is considered enrolling a study subject.

Choose one.

Anyone you collect identifiable information on is considered enrolled: HIPAA FAQ

HIPAA Waiver of Authorization

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

List all identifiers and a summary of the health variables you will collect. This must match your data collection sheet (Q 2.0) and Q 3.0 on the Information Sources and Identifiers page.

NOTE 1: Do not list the information that you are collecting, using, disclosing under an authorization signed by the subject. This section is just for information collected/used/disclosed under this waiver.

NOTE 2: *(click for suggested language)*

*If you are collecting Social Security Numbers for reasons other than compensation, you must complete the **SSN Exception Form** Attach form to this application on the **Miscellaneous Attachments** page in the Supplements section.*

2.0 * **I certify** that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least the following elements:

a. An adequate plan is in place to protect the identifiers from improper use and disclosure.
Add each type of storage used and describe how identifiers will be protected for each type:

+ Add

Storage type	Protection Plan Description

There are no items to display

b. Approval of a HIPAA waiver requires that an adequate plan is in place to de-identify (destroy the identifiers) at the earliest opportunity consistent with conduct of the research *(no later than the completion of data analysis, sooner if appropriate)*, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
Indicate which methods you will use to de-identify the data that you have collected/used under this waiver. *(check all that apply)*

- [ ] **Hardcopy of identifiers/key code shredded**
- [ ] **Electronic copies de-identified and are now anonymous**
- [ ] **Redacting identifiers as you record information**
- [ ] **Research conducted at the VA, therefore all research records including identifiers must be retained in accordance with the VHA Record Control Schedule or a minimum of 6 years, whichever is longer.**
- [ ] **Other**

Q 2a/b– Must be consistent with the protocol

b.1 If "Other", Specify:

c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by HIPAA regulations.

You must save this page to save your attachments