UF | myIRB

Date: Monday, September 12, 2022 10:33:45 AM

Print Close

ID: IRB201903477

View: Study Title and Staff

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

* **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**

2.0 * Project Title:

A multi-domain machine learning approach to predicting patient mortality and outcomes

3.0 Short Title:

Machine Learning to Predict Mortality

4.0 Provide a summary description or abstract for this study:

Proactively identifying patients at-risk for in-hospital and 30-day mortality remains a persistent clinical conundrum. While traditional predictive models reveal obvious risk factors, there are still unexpected patients deaths. We propose a multi-domain machine learning approach to better identify patients at-risk for death so that care can be adjusted accordingly.

* **4.1** Is this a OneFlorida study?

○ **Yes** ● **No**

* **4.2** Is this project a SUS Reciprocity study?

○ **Yes** ● **No**

5.0 * Principal Investigator:

Jennifer Fishe	**JX-EMERGENCY MEDICINE-JAX**	UF	**MD, Assistant Professor of Emergency Medicine**

- [ ] 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

6.0 Study Staff:

(HDE-ONLY: SEE IMPORTANT HELPTEXT)

Name	Role	Function	Affiliations	Degree/Title
Brian Celso	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**	**PhD Associate Professor**
Salvatore Dacunto	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects** ▪ **Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]**	**UF**	**Data Management Analyst II, MBA, M.Eng. - Biomedical Engineering, MS - Electrical Engineering, BS - Electrical Engineering**

Name	Role	Function	Affiliations	Degree/Title
Christina Guerrier	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects	UF	MBA, SSBBP, Data Management Analyst II
Guillaume Labilloy	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	ME, MBA, Data Management Analyst II
Leigh Neumayer	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects	UF	MD, MS, MBA, Professor and Chair
Rui Wang	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects	UF	PhD, Database Management II
Cassandra White	Co-Investigator	▪ Performs study related activities but does not interact directly	UF	MD

Name	Role	Function	Affiliations	Degree/Title
		with the study subjects		
Jason Widrich	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects	UF	MD MS MBA

7.0 * Is this study a NIH funded clinical trial?

○ **Yes** ● **No**

8.0 * Is this study related to COVID-19/Coronavirus?

○ **Yes** ● **No**

Date Page Modified:1/31/2020

ID: IRB201903477 View: Researcher Training Summary

Researcher Training Summary

1.0 Researcher Training Summary

1.1 PI Training:
Jennifer Fishe:

Course ID	Name	Completed	Course Due
NIH	**NIH Extramural Education**	**7/5/2017**	**6/28/2047**
GCP200	**Good Clinical Practice: Biomedical Research**	**8/29/2022**	**8/28/2025**
IRB803	**IRB Training**	**7/6/2020**	**7/6/2023**
GCP200	**Good Clinical Practice: Biomedical Research**	**10/14/2019**	**10/13/2022**

1.2 Study Staff Training:
Brian Gerard Celso

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	12/4/2021	11/27/2051
H70	CITI Mandatory IRB Trng-Biomed	1/1/2019	12/24/2048
H70	CITI Mandatory IRB Trng-Biomed	2/3/2016	1/26/2046
H64	NSF Responsible Conduct of Res.	4/15/2013	4/8/2043
CITI	CITI Mandatory IRB Trng-Spec Mods	4/2/2013	3/26/2043
IRB803	IRB Training	7/30/2021	7/29/2024

Salvatore Joseph Dacunto

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	7/13/2020	7/13/2023
IRB803	IRB Training	7/13/2020	7/13/2023

Christina Guerrier

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	12/31/2019	12/23/2049
NIH	NIH Extramural Education	5/16/2018	5/8/2048
IRB803	IRB Training	6/3/2021	6/2/2024

GCP200	Good Clinical Practice: Biomedical Research	8/5/2020	8/5/2023
GCP200	Good Clinical Practice: Biomedical Research	12/31/2019	12/30/2022

Guillaume Patrick Ludovic Labilloy

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	1/22/2020	1/21/2023
IRB803	IRB Training	9/26/2019	9/25/2022

Leigh Anne Neumayer

Course ID	Name	Completed	Course Due
IRB803	IRB Training	10/6/2020	10/6/2023

Rui Wang

Course ID	Name	Completed	Course Due
IRB803	IRB Training	12/27/2021	12/26/2024
GCP200	Good Clinical Practice: Biomedical Research	12/21/2021	12/20/2024

Cassandra Quiana White

Course ID	Name	Completed	Course Due
IRB803	IRB Training	10/2/2021	10/1/2024

Jason Brian Widrich

Course ID	Name	Completed	Course Due
IRB803	IRB Training	5/14/2022	5/13/2025

Date Page Modified:

ID: IRB201903477

View: Requested Review Type

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

2.0 * Will you be using Clinical and Translational Science Institute [CTSI] resources (including, but not limited to RedCap, CTSI Biorepository, Healthstreet)? Please see link provided in the help text for a complete list.

● **Yes** ○ **No**

3.0 Full Board Agenda Group: *(choose one, if applicable)*
Indicate if submissions related to study should be reviewed in a Full Board group category

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

● **Yes** ○ **No**

5.0 * Is this research considered "classified"?

○ **Yes** ● **No**

Date Page Modified:

ID: IRB201903477 View: Oncology SRMC Determination

Oncology SRMC Determination

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

○ **Yes** ● **No**

2.0 * 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**

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

○ **Yes** ● **No**

For more information on studies that require SRMC review, click here

NOTE: If you answered yes to any of the questions above, the UFHCC Scientific Review and Monitoring Committee (SRMC) will need to review this study to determine if SRMC review is required. To submit for SRMC review and determination, please complete the new

submission request form found at: https://sharepoint.ahc.ufl.edu/research/cro/Intake/SitePages/Home.aspx

If SRMC review is required, please ensure that the IRB application requests collection of all SRMC required datapoints based on the SRMC level of review assigned. More information can be found at: https://cancer.ufl.edu/wordpress/files/2019/05/ADM-004-V3-2019-02-20.pdf

Date Page Modified:

ID: IRB201903477 View: Individual COI and Affiliation Summary

Individual Conflict of Interest [COI] and Affiliation Summary

This page is to show you whether or not all Study Staff have "Agreed to Participate" on the project (as indicated in the "Agreed" column below).

It will also provide you with information as to whether or not the study staff have a conflict of interest [COI] or are considered an unaffiliated investigator [Affiliations/UIA].

Be sure that you send an email to your study staff to notify them to execute the "Agree to Participate" activity. Use the **Send Email to Study Team** activity to notify them.

1.0 Individual Conflict of Interest [COI] and Affiliation Summary

Name	Role	Agreed	COI Doc	Compliance Doc	Affiliation	UIA Doc
Brian Celso	Co-Investigator	yes	no		UF	
Salvatore Dacunto	Co-Investigator	yes	no		UF	
Christina Guerrier	Co-Investigator	yes	no		UF	
Guillaume Labilloy	Co-Investigator	yes	no		UF	
Leigh Neumayer	Co-Investigator	yes	no		UF	
Rui Wang	Co-Investigator	yes	no		UF	
Cassandra White	Co-Investigator	yes	no		UF	
Jason Widrich	Co-Investigator	yes	no		UF	

2.0 PI Conflict of Interest and Affiliation Summary

	PI Name	Agreed	COI Doc	Compliance Doc	Affiliation	UIA Doc
View	**Jennifer Fishe**	**yes**	**no**		**UF**	

Date Page Modified:

ID: IRB201903477 View: EHS Determination

EHS Determination

1.0 Will you **send shipments** of tissues/specimens/samples **known or suspected to contain a human disease agent**

* **1.1** To others inside UF:
  ○ **Yes** ● **No**

* **1.2** To others outside UF but within the US:
  ○ **Yes** ● **No**

* **1.3** To others outside the US:
  ○ **Yes** ● **No**

2.0 Will you **receive shipments** of tissues/specimens/samples **known or suspected to contain a human disease agent**

* **2.1** From inside UF:
  ○ **Yes** ● **No**

* **2.2** From outside UF but within the US:
  ○ **Yes** ● **No**

* **2.3** From outside the US:
  ○ **Yes** ● **No**

3.0 Will you **hand carry shipments** of **ANY** tissues/specimens/samples

* **3.1** To or from others outside UF but within the US:
  ○ **Yes** ● **No**

* **3.2** To or from others outside the US:
  ○ **Yes** ● **No**

Date Page Modified:

ID: IRB201903477 View: Study Locations

Study Locations

1.0 * Where are you going to conduct this project? *(choose all that apply)*

- [x] **UF and/or UF Health**
- [x] **UF and/or UF Health Jacksonville**
- [ ] VA
- [ ] Baptist/Wolfson
- [ ] Sacred Heart
- [ ] Nemours
- [ ] Florida Department of Health
- [ ] Halifax
- [ ] Community Health Northwest Florida (Escambia Clinic)
- [ ] Other sites in the USA
- [ ] Other sites outside the USA

2.0 Are you getting any data or tissue from international locations?

○ **Yes** ● **No**

3.0 Name a lead site investigator if any of the following is true:

More than one (1) UF location is selected
OR
One (1) UF location is selected in combination with a non-UF location and the PI for the study is not at both locations

Date Page Modified:

ID: IRB201903477 View: Study Funding

Study Funding

1.0 * Indicate appropriate **funding types** for this project:

- [ ] DHHS, including NIH and NCI or NSF
- [ ] Federal Grant (other than DHHS or VA)
- [ ] Veteran Affairs (VA)
- [ ] State or Local Government
- [ ] Non-Profit Organization
- [ ] Industry
- [ ] Internally Funded, CTSI
- [ ] Internally Funded, Other
- [x] **No Funding required to initiate or complete this study**

NOTE: Industry authored/sponsored, multisite, FDA regulated research in the College of Medicine is required to be submitted to WIRB. If you wish to submit to IRB-01 and your study is required to be submitted to WIRB, per the above criterion, you must receive written approval from Michael Mahoney**.**

DO NOT proceed with your submission until approval is received. If Michael Mahoney approves IRB-01 review, attach a copy of the approval to the 'Miscellaneous Attachments' page of this mylRB submission.

Date Page Modified:

ID: IRB201903477 View: Funding Summary

Funding Summary

1.0 **Funding Sources:**

Government Funding Sources:

ID	Source Name	Other	Grant Number	UFIRST Project	Deadline

There are no items to display

External Funding Sources:

ID	Source Name	Other	UFIRST Project	Deadline

There are no items to display

Internal Funding Sources:

ID	College	Dept	Unit	UFIRST Project	Deadline

There are no items to display

1.1 Upload Additional Funding documentation/attachments here:

Document	Description

There are no items to display

Date Page Modified:

ID: IRB201903477 View: Conflict of Interest - Institutional

Conflict of Interest - Institutional

1.0 * 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**

2.0 * 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**

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

○ **Yes** ● **No**

NOTE: **If the answers to any of these questions change from "No" to "Yes" you must inform the IRB IMMEDIATELY.**

This includes any new investigators who are added to the study at a later date.

Date Page Modified:

ID: IRB201903477 View: Tissue / Data Access

Tissue / Data Access

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

○ **Yes** ● **No**

2.0 Are you accessing records or data?

● **Yes** ○ **No**

Date Page Modified:

ID: IRB201903477 View: Study Description (v2019)

Study Description

1.0 * Explain the **purpose** of the study:

In-hospital mortality and post-hospitalization and post-surgical 30-day mortality remain a significant healthcare problem in the United States. Annually between 700,000-750,000 patients die in the hospital (CDC - https://www.cdc.gov/nchs/products /databriefs/db118.htm), and nearly 200,000 patients die in the 30-day postoperative period (Surgery. 2012 Feb;151(2):171-82). Traditional statistical models perform adequately for predicting mortality from single conditions such as coronary artery disease (Circulation. 2008; 117(6):743–53.), but underperform in predicting death in complex medical and surgical patients with multiple comorbidities (PLoS ONE 14(3): e0214365). Accurate prediction of mortality for hospitalized and surgical patients represents an important opportunity to optimize and preemptively change medical/surgical management to decrease mortality. Therefore, we propose a multi-domain machine learning approach first using retrospective data to better predict in-hospital and 30-day post hospital and post surgical mortality in patients at UF Health Jacksonville and UF Health Gainesville. Our multi-domain approach (Journal of Asthma. July 2019:1-14.) takes a 360-degree view of the patient, incorporating demographics, geospatial characteristics, socioeconomic factors, individual patient clinical factors and unit/hospital-level factors to comprehensively simulate the many inputs into a patient's outcomes.

2.0 Describe the **steps involved** in conducting this study.
If applicable, provide details for each of the following:

- the inclusion/exclusion criteria,
- How you will obtain the list of records/tissue you intend to review
- How data will coded in the analysis phase of the research
- and a data analysis plan

Inclusion: All patients greater than or equal to 18 years admitted to UF Health Jacksonville and UF Health Gainesville hospital from January 1 2014 - December 31 2024. We will work with the IDR to continually refresh the data throughout 2024.

Exclusion: Less than 18 years of age.

Data Source: We will obtain the data through the UF Integrated Data Repository (a CTSI resource).

Data Coding: We will assign each patient a unique Study ID number that is not linked to any identifiable data. Some of the data we are requesting is PHI. For example, we are requesting patient address in order to geocode their census tract and 9-digit zip code in order to assign them their area deprivation index. After use of that address information, we will scrub (delete) the address from the dataset. We also request dates of encounters (to assess temporal trends). We will use both to compute a numeric patient age in years using birthdate if IDR cannot provide patient age at time of ecah encounter.

We will report ADI according to the categories laid out in its dataset, available at https://www.neighborhoodatlas.medicine.wisc.edu/mapping. The ADIs on this website are provided in national percentile rankings at the block group level from 1 to 100. A block group with a ranking of 1 indicates the lowest level of "disadvantage" within the nation and an ADI with a ranking of 100 indicates the highest level of "disadvantage". We therefore will not report a patient's zip code or census tract, but rather their ADI ranking. As for geocoding, we will map ADI percentile (average/median) at the census tract level.

Data Analysis Plan: In order to aggregate potential predictive features from raw data variables, we will first split the large

dataset into two datasets (a training and a validation dataset). We will keep 2020 data separate as that will be the dataset we use to test our model after validation. We will employ a supervised approach wherein we build a machine learning algorithm (neural network) with the training set where patients with in-hospital or 30-day post hospital/post surgical mortality is known. The end product of this will be a classifier model to distinguish mortality vs no mortality. We will then test and refine the model on the validation dataset. We will also employ more traditional analyses such as univariate and multivariable logistic regressions to compare model predictive power with our machine learning algorithm. We will consider all variables abstracted for inclusion in the machine learning model.

3.0

Describe your storage plan, de-identification plan if applicable, and security plan for the data/tissue. Please state when and how data/tissue will be de-identified if applicable.

Once all data elements are abstracted (via IDR), we will perform geocoding and calculate patient ages, after which patient addresses and birthddates will be deleted/scrubbed from the dataset.

All data, including that in Excel or other files, will be handled only on secure, password-protected computers physically located at UF Jacksonville in locked offices. Data can only be accessed by those listed on this IRB. We will perform statistical analysis in R and Python.

4.0

* By what authority does the Principal Investigator and Co-Investigator(s) have access to the data/tissue? If accessing medical records please state who is part of the covered entity.

Covered Entity is defined as:

1. UF Health Science Center + Shands, or
2. NF/SG VHS

Contact the IRB office if you have questions.

Dr. Jennifer Fishe (Principal Investigator) has authority to access the data as part of (employee, Assistant Professor) the UF Health Science Center.

5.0 * 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**

5.1 If "Yes", specify **how** and **where** the research will involve VA:

Date Page Modified:1/29/2020

ID: IRB201903477 View: Exempt / Multiple Sources Determination

Exempt / Multiple Sources Determination

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

- ○ No (All information will be collected without any identifiers, codes, links or other means of linking the research data to the subjects identity) NOTE: you are certifying you will never record identifiable information or coded information even for a temporary period.
- ○ Yes identifiable information from a publicly available source
- ● **Yes (you will either collect identifiable information or you will have a code key/link that associates your data collection tools/research records with the identity of the subjects**

2.0 * Do you need to examine **multiple sources** for each subject where one of the sources is specimens /tissue? (Usually in order to correlate information between multiple sources)

- ● **No None of the sources for this research include specimens or tissue**
- ○ Yes you will examine multiple sources for each subject including specimens or tissue

2.1 If yes, Can you access all the sources and extract your research data at the **same time** on a per subject basis?

- ○ No you will need to look at the sources at different times and have a link or record identifiable information
- ○ No you certify all sources are publicly available and that you do not link the public data to a non-public data source
- ○ Yes you certify that you can assemble all of your sources including specimens for each subject and extract your research data from them at the same time and you will never have a link or use a code.

Date Page Modified:

ID: IRB201903477 View: Exempt Regulation Confirmation

Exempt Regulation Confirmation

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

(4)(iii) Secondary research 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 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b)

2.0 * Are you collecting any information that could
(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?

○ **Yes** ● **No**

2.1 If "Yes", describe:

2.2 Describe how you will insure the confidentiality of this information:

Date Page Modified:1/29/2020

ID: IRB201903477 View: Study Population, Overview

Study Population, Overview

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

- ○ Yes
- ● No

1.1 Indicate if you will target any of the following ethnic groups:

- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Will not target a specific ethnic group

1.2 Indicate if you will target any of the following racial groups?

- ☐ Native American/Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Black or African American
- ☐ White
- ☐ Will not target any specific racial groups

1.3 If any racial or ethnic group has been selected, the justification is:

- ☐ The condition being studied only occurs in the selected group(s)
- ☐ Other

1.3.1 If "Other", Provide rationale for selection of specific groups

2.0 * Gender:

- ○ Male
- ○ Female
- ● **Both**

2.1 Provide the rationale for studying a single gender:

Date Page Modified:

ID: IRB201903477 View: Subject Numbers (Record/Data Review)

Subject Numbers (Record/Data Review)

1.0 * Approximately how many subjects records will you study?

3000000

2.0 * Will vulnerable subjects be considered for participation in this study?

○ **Yes** ● **No**

2.1 If "YES", Specify:

- ☐ Pregnant Women
- ☐ Human Fetus
- ☐ Neonates
- ☐ Children
- ☐ Prisoners
- ☐ Decisionally Impaired/Comatose Individuals

Date Page Modified:1/29/2020

ID: IRB201903477 View: Study Population Complete

Study Population Complete

You have completed the Subject Population section.

Please continue to the next section.

Date Page Modified:

ID: IRB201903477 View: Data Collection

Data Collection

1.0 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:

We will obtain our data from the UF Health Jacksonville and UF Health Gainesville electronic medical record, which is EPIC. The way we will obtain this data is through an honest broker data analyst in the UF Integrated Data Repository who will pull the data.

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

	Document	Description
View	Data Variables v4(0.04)	

3.0 Please describe data points or variables that you have not attached or additional information that is not included in your attachments.

Date Page Modified:

ID: IRB201903477 View: UF VA UF Health Data Collection - Medical Records Access

Data Collection - Medical Records Access

1.0 * Will you review any medical records or collect any medical record information from UF and/or UF Health facilities, or the VA?

● **Yes** ○ **No**

2.0 * 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**

2.1 If "Yes", list all facilities from which you intend to obtain medical records and upload letter of permission from facility, FWA Information, etc.:

Outside Facility Name	Permission Letter, FWA, etc.	If No Letter

There are no items to display

Date Page Modified:

ID: IRB201903477 View: HIPAA Waiver Determination

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.

1.1 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? *(e.g. release initials, names, birthdates, etc. of people who do not meet eligibility criteria to the study sponsor)*

○ **Yes** ● **No**

If VA is involved, a HIPAA Waiver of Authorization must be completed. If VA is not involved, a HIPAA Waiver of Authorization to Identify or Recruit only needs to be completed if you are disclosing identifiable information outside of the covered entity.

Date Page Modified:

ID: IRB201903477 View: HIPAA Waiver of Authorization

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**?

We will collect patient address. This is for the purposes of geocoding to the patient's census tract / 9 digit zip code so that we may abstract the patient's area deprivation index (ADI). After getting the patient's ADI, we can scrub the dataset of the patient's address.
We will collect patient birthdate only if IDR cannot provide patient age at time of health care encounter.
We will collect date of healthcare encounter to assess temporal trends.

Other health information we will collect includes:
Included variables are:
Date of Encounter
Location of Encounter (ambulatory, inpatient, ED, surgical)
Patient Age at encounter or birthdate if IDR cannot provide age at encounter
Patient Race
Patient Ethnicity
Patient Gender
Patient Insurance at time of encounter
LOS (length of stay – for inpatient / ED encounters)
ICD 9 / 10 codes from encounter
Outpatient medications at each encounter
Medications and time administered for each encounter
CPT codes / Procedures performed and times for each encounter
Status for medication and procedure orders (cancelled or completed)
Death during encounter yes/no
Death 30 days after hospitalization yes/no/not applicable no hospitalization
Death 30 days after surgery yes/no/not applicable no surgery
Tobacco User yes/no
BMI
All vital signs during encounter
Referral orders / consult orders during encounter
Patient 9 digit Zip Code (or address) -> for geocoding to census tract to obtain area deprivation index/ ADI, after which data will be de identified
Family History Data
Social History Data
For hospitalizations / ED visits -> any readmission within 30 days, any ED visit within 30 days

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)*

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:

Storage type	Protection Plan Description
Data is stored on an institutional server that is encrypted, password protected, and backed up	**Data will be stored in an institutional common drive that is password protected and encrypted**

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**
- [x] **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**

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.

3.0 * **I certify** that this research could not practicably be conducted without access to and use of the protected health information.

a. Explain why it is impractical to conduct the research without the waiver of authorization:
(check all that apply)

- [ ] **It would be inappropriate to contact people who do not qualify for the study**
- [x] **No direct subject contact to obtain authorization**
- [ ] **Unreliable/inaccurate contact information for subjects**
- [x] **Subjects may be deceased**
- [ ] **Other**

If "Other", describe:

4.0 * **I certify** that I will only access PHI under this waiver until the end of the study.

Date Page Modified:1/31/2020

ID: IRB201903477 View: Privacy Confidentiality Complete

Privacy & Confidentiality Complete

You have completed the Privacy & Confidentiality section.

Please continue to the next section.

Date Page Modified:

ID: IRB201903477 View: Ancillary Reviews

Ancillary Reviews

1.0 Ancillary Reviews Required:

CTSI

Date Page Modified:

ID: IRB201903477 View: CTSI Ancillary

CTSI Ancillary

CTSI Protocol Number: **IRB201903477**

Protocol Category:

UFIRST Number:

Project Title: **A multi-domain machine learning approach to predicting patient mortality and outcomes**

Funding Sources: No Funding required to initiate or complete this study

1.0 eRA Commons ID:

2.0 You have indicated that you are using CTSI resources (tools, funding, space) throughout the submission. Please check all that apply to this study proposal:

- ☐ UF Clinical Research Center
- ☐ BERD (Biostatistics, Epidemiology, and Research Design)
- ☐ Research Electronic Data Capture (REDCap)

- [ ] Research IT
- [ ] Regulatory Assistance includes assistance with IRB, RAC, and/or ClinicalTrials.gov
- [ ] IDE, IND submission assistance
- [ ] Research Subject Advocate, Ethics consultation
- [ ] Quality Assurance
- [ ] Biorepository
- [ ] South East Center for Integrated Metabolomics (SECIM)
- [ ] CTSI Human Imaging Core
- [x] **Integrated Data Repository (IDR)**
- [ ] Genotyping Core
- [ ] HealthStreet
- [ ] Biobehavioral Core
- [ ] Recruitment Assistance

Date Page Modified:

ID: IRB201903477 View: Miscellaneous Attachments

Miscellaneous

1.0 Certificate of Decedent Information Form:

2.0 Approved Social Security Exception Form:

3.0 Upload miscellaneous study attachments below:

Name	Modified	Version

There are no items to display

4.0 List any specific information that needs to be included in the IRB approval letter:

NOTE: **YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS**

Date Page Modified:

ID: IRB201903477 View: Legacy Paper Determination

Legacy Paper Determination

1.0 * **Is this a conversion from a paper study**?

○ **Yes** ● **No**

2.0 * Is this paper study in the state of Expired Non-renew?

○ **Yes** ● **No**

2.1 If Yes, please state why you want to regenerate this study and your plan for the previously collected data:

Date Page Modified:

ID: IRB201903477 View: Study: Final Page

Study: Final Page

Completion Instructions:

1. Select "Finish", to access the Study Workspace.
2. From the Study Workspace, execute the "Submit Study" activity to initiate the approval process.
   This activity is only available to the Principal Investigator.

NOTE: Prior to submitting the study, the PI and all Study Staff must perform the **"Agree To Participate"** activity, located in the My Activities area for this Study.

NOTE: *Please click on the **"Hide/Show Errors"** option. This will open a split screen which will show you any errors that may have occurred during the process of completing the forms. Once you have fixed all of the errors identified by myIRB, you will need to click on the **"Hide/Show Errors"** link again to return the screen to normal size.*

Important Note! If you plan to publish in an ICMJE member journal, you may be required to register your study in ClinicalTrials.gov PRIOR to enrolling the first subject into the study. For assistance with ClinicalTrials.gov questions, please contact 352-273-5946 or email UFCT-gov@ufl.edu .

Date Page Modified:

ID: IRB201903477 View: Data Entry View

HIPAA Authorization Determination

* Specify the type of storage/data transmission to be used:	Describe your protection plan for type of media you selected.
Data is stored on an institutional server that is encrypted, password protected, and backed up	**Data will be stored in an institutional common drive that is password protected and encrypted**