



This is a sample protocol and should be used for reference purposes only. However, please see the directions in red and include the areas highlighted in yellow as they are a mandatory part of your IRB submission for the CRDW Data Extraction.

Section 2.1 Project Team

- The person making the Honest Broker request must be listed in this section
- Adding team members is a quick administrative update to the protocol, no committee approval needed

Section 3.4 Minimal Risk Activities

- Check "Records collected for non-research proposed" since the CRDW is populated with EHR and billing data
- This will open up Section 3F

Section 3F - Records Research

- 3F.2 & 3F.3 define the date for the earliest records you will access?
- 3F.4 Screen and Use – the screen total should be an overestimate and the use total should be some reasonable fraction of the screen number. It's okay for the screen total to be double or triple the use total.

Sections 19 Protocol Summary (The text in this Section is an example. This text should be replaced with text that is relevant to your unique study proposal.)

- 19.7 Include the language about how the project will utilize the CRDW and the query tools (i2b2 or TriNetX) and the Honest Broker Process.
- If needed, additional template language can be found at <https://ctri.mcw.edu/cda/crdw/>

Section 26 Connection with a Bank - accessing data

- 26.1 & 26.2 Link to the CRDW Banking Protocol PRO00013874

Section 52 Supporting Documents

- 52.1.2 Upload your specific data fields that you will be looking at for your study/IRB. This is usually a listing of data fields in Excel or Word.



1. Project Identification

1.1 * Short Title:

Implanted Device Measured Physical Activity in COVID-19 pandemic

1.2 * Full Title of Project:

Impact of COVID-19 Pandemic on Physical Activity and Arrhythmias in Patients with Implanted Cardiac Devices

1.3 * Principal Investigator (PI):

Enter PI Name

1.3.1 * Does the Principal Investigator, their immediate family members (spouse and dependent children) or their significant other have a "Significant Financial Interest" with the sponsors of this research or that might affect the result of this research?

Yes No

1.3.2 * Does the Principal Investigator need to access Epic for this project? Yes No

1.3.3 * Will the Principal Investigator be involved with any of the following:

Screening subjects for entry into a magnetic environment for MRI

Entry into a magnetic environment for MRI

None of the above


1.4 * Will there be other project team members in addition to the Principal Investigator?

Yes No

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2. Project Team

2.1 Project Team Members Other Than PI: (Check Training Status)

For projects relying on another IRB for review: add only MCW/Froedtert Hospital/Versiti, Inc. project team members. 

Make sure to add the CAI Data Analyst to your Project Team

	Last Name	First Name	Primary Organization	Department	Position	Is Primary Contact	Can Edit	Receives Emails	Role on Project	Consenting Subjects	MRI Involvement?	Epic?	Human Material?	SFI
View	Knezevich	Michelle	Medical College of Wisconsin	Medicine	Data Analyst II	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Sample1	Susie	Medical College of Wisconsin	Medicine	Professor	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Key Personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View	Sample2	Susie	Medical College of Wisconsin	Medicine	Nurse Practitioner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			Medical College of Wisconsin	Medicine	Clinical Research Coordinator I	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			Medical College of Wisconsin	Medicine	Associate Professor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			Medical College of Wisconsin	Medicine	Associate Professor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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3. Project Category

3.1 * Which category best describes the type of project you are submitting for review?

- Case Report[†]** – Involves a description of routine medical care for three patients or less
- Quality Improvement[†]** – The entire project is initiated, overseen, and analyzed by an official Froedtert Health Entity Quality Assurance committee
- Research Project[†] - Including clinical trials, record reviews, specimen reviews, surveys, etc.**
- Research Project plus distant bank[†]** - No banking at a local project site
- Research Project plus creating a new local bank[†]** - At least one at a local project site *Note: see 3.1.1 below
- Research Project requesting reliance on another IRB[†]** - An IRB other than the MCW IRB will serve as the IRB of record for this project.
- Creating a new local bank[†]** - No research project being proposed in this submission
- Treatment Use[†]** - Use of investigational drugs, medical devices, biologics or Humanitarian Use Devices (HUDs) solely for clinical purposes with no elements of research or research data collection
- Emergency Use[†]** - Use of an investigational drug, medical device, biologic or Humanitarian Use Device (HUD) – after-the-fact report to the IRB
- Not Human Subjects Research[†]** – The project will not interact/intervene with living human beings

3.2 * Does the proposed project involve any of the following features?

(check all that apply)

- Deception projects
- Direct contact with subjects
- Human Source Material (human blood, tissues, cell lines)
- None of the above**

3. Project Elements

3.3 * Does this project involve any of the following elements?

(check all that apply)

- 100% of subjects are known to be deceased, e.g., work with cadavers or biospecimens of deceased persons; record reviews where all subjects are demonstrably deceased
- In-vitro or laboratory diagnostic tests in the absence of FDA approval and/or CLIA certification: chemistry, drug monitoring, immunological/hematologic, tumor marker, genetic disorder, infectious disease, microorganism, bio-threat tests
- Dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus from any source, commercial or otherwise
- More than one site. Project activity will take place at other institutions or locations that are not under the supervision of the PI listed on this IRB application.
- Any part of the project takes place in another country. Check here if the PI is the lead PI for a multi-site project where one or more sites are in another country or if any project related work or oversight work is being done in another country.
- Application to waive informed consent requirements for certain types of planned emergency medicine research [(21 CFR 50.24 or 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research) or (FR doc. 96.24968)]
- Research using the internet as a source of information or a survey tool
- None of the above**


3.4 * Does this project involve ONLY one or more of the following minimal risk activities?

(check all that apply)

- Biospecimens collected for non-research purposes
- Blood draws with collection limited to finger, heel or ear stick, or venipuncture
- Educational
- Non-invasive collection of biospecimens
- Non-invasive Procedures
- Psychosocial Interventions
- Records collected for non-research purposes**
- Surveys, questionnaires, interviews, focus groups, or observation of behavior
- Voice, Image or digital recording for research purposes
- No, my project involves activities which are not minimal risk, or the identified activity no longer qualifies as minimal risk

Make sure this box is checked

3.5 Use of Identifiers - indicate the level of "subject identification" you require to BEGIN this work.

- If any element of your records, data files, or administrative records contains an identifier, you should select Identified Data.
- If you plan to de-identify data at any time other than the first day you access the information, you should select Identified Data.
- If different levels apply, choose the "most identified" one, e.g., if level A and level B apply, choose level A. 

- A - IDENTIFIED DATA: Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule but not using a "limited data set." See help text for complete listing.**
- B - CODED DATA, KEY held by project team:** Data is coded; and key code held by any person at MCW, Froedtert Hospital, Children's Hospital of Wisconsin, or Versiti, Inc. whether or not they are part of the project team.

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- C - CODED DATA, KEY not held by project team:** Data is coded; key code not held by any MCW/Froedtert faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** the key code will never be accessible to any member of the project team.

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- D - LIMITED DATA SET:** The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB "limited data set" data use agreement has been executed by the PI; and is uploaded into this IRB application.

-
- E - DE-IDENTIFICATION PROCESS:** The IRB application describes how the project team will de-identify data in one of two approvable methods: 1) reliance on an MCW/FH IRB-sanctioned "honest broker" or 2) receiving coded data/specimens without identifiers and without a key code. For details see "*Two ways to de-identify data or biospecimens for IRB purposes.*" To use these options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables must be uploaded in Section 52.

-
- F - ANONYMIZED:** The investigator receives data in anonymized form and no other party has the potential to re-identify data (i.e. no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarizes all the information that will be recorded, must be included in Section 52 Attached Documents.

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3F. Records Research - Part I

You received this section because in Section 3. Project Elements, Question 3.4, you checked "Records collected for non-research purposes"

3F.1 * For what purpose were the records originally created?

(check all that apply)

Clinical Care

* Identify the Sources:

Medical College of Wisconsin

Froedtert Hospital Campus (including all speciality clinics, the Cancer Center and the Eye Institute)

Versiti, Inc. and Blood Research Institute

Other

* If Other,
Community Physicians Sites (FHMF, FHWB, and Moorland Reserve)

Quality assurance

School or teaching records

Billing or insurance

Program administration

Hospital or community surveillance

Different research project

Other

Sample Protocol for CAI
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3F. Records Research - Part II

3F.2 * Do you plan to use/analyze records created before the date of IRB approval (retrospective records)? (i.e., NO additional cases created after that date, and NO opportunity to include follow-up information created after that date)

Yes No

If Yes,

* 3F.2.1 What is the date for the earliest records you will access?

1/1/2019

3F.3 * Do you plan to access records created after the date of IRB approval (prospective records)?

Yes No

If Yes,

* 3F.3.1 How will you get permission to access these records?

(check all that apply)

Using informed consent

From an IRB approved bank

Other

* 3F.3.1.1 Specify other:

IRB review & approval along with a request to waive HIPAA authorization

3F.4 * Estimate the total number of subject records that you intend to:

(The IRB expects the investigator to provide meaningful estimates and to adhere reasonably to these estimates. It is often better to make a slight over-estimate of numbers.)

Screen, whether you use the record for this project or not.

1000

Use for this project.

900

Use total should be some reasonable fraction of the screen number.

3F.5 * Explain how you determined the number of records to include in the project at this site.

The numbers are based on the number of individuals who had their implanted devices interrogated in person or remotely in April 2020 through April 28th 2020 and extrapolating that number through to May 15, 2020.


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Enter your desired date

Screen total should be an overestimate

4. Safety and Research Review Committees

4.1 * Does this project include any of the following regulated items or resources?


Selections will determine if there are additional review requirements prior to IRB review process beginning, per MCW policy: 

(check all that apply)

- Biological Toxins
- Project with a cancer focus (including healthy subjects)
- CTSI Adult Translational Research Unit (facility or resources)
- Human Gene Transfer
- Human stem cells
- Human/Non Human Primate (NHP) Cell Lines, Tissues, or Blood Products
- Microorganisms
- Magnetic Resonance Imaging (MRI) (that is not Standard of Care)
- Radiation therapy, radioactive materials/brachytherapy, CT, X-ray, fluroscopy
- Recombinant DNA (non-Viral vectors)
- Viral Vectors
- None of the above**

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6. Project Locations

6.1 * Under the direction/supervision of this Principal Investigator, project activities will take place at the following locations: 

(check all that apply)

Froedtert & the Medical College of Wisconsin Hospitals and Health Partners

Cardiothoracic Surgery Clinic

Drexel Town Square Health Center

Endocrinology Clinic (Oconomowoc)

Endocrinology Clinic (Waukesha)

Fitness Center (Sports Medicine)

Froedtert Hospital (including all specialty clinics, the Cancer Center and the Eye Institute)

Froedtert Menomonee Falls Hospital

Froedtert West Bend Hospital

Germantown Health Center

Greendale Medical Clinic

Greenfield Highlands Health Center

Hartford Health Center

Jackson Health Center

Jackson Rehabilitation and Sports Medicine Center

Kewaskum Health Center

Lincoln Avenue Health Center

Menomonee Falls Behavior Health Center

Moorland Reserve Health Center

North Hills Health Center (previously Community Memorial Medical Commons – CMMC)

Orthopaedic, Sports and Spine Center

Sargeant Health Center

SpineCare Clinic (Oconomowoc)

Springdale Health Center

St. Joseph's Health Center (attached to SJH)

Sunnyslope Health Center

Sussex Health Center

Tosa Health Center

Town Hall Health Center

West Bend Health Center

Westbrook Health Center

Medical College of Wisconsin - Milwaukee Campus

Medical College of Wisconsin - Green Bay Campus

Medical College of Wisconsin - Central Wisconsin Campus

Center for AIDS Intervention Research (CAIR)

Adult Translational Research Unit (TRU)

Versiti, Inc.

Children's Hospital of Wisconsin[†]

Clement J. Zablocki Veteran's Affairs Medical Center[†]

UW-Milwaukee[†]

Marquette University[†]

Milwaukee School of Engineering[†]

Other

* 6.1.1 For all locations other than MCW, Froedtert Hospital, or Versiti, Inc. list the lead collaborator at each institution, their role at each institution, and the name of the institution.

6.2 * Will any subject recruitment activities or research procedures under the responsibility of this Principal Investigator take place outside of Wisconsin but within the US? 


Yes No

8. National Cancer Institute (NCI) Cooperative Groups

8.1 * Is this project part of a NCI cooperative group? 

Yes No

10. Intervention Evaluation

10.1 * Is this research project designed to evaluate the safety or effectiveness of a research treatment/intervention? 

Yes

No

10.2 * Does the research involve: 

(check all that apply)

Drug: FDA-approved, investigational, or other

Device: FDA-approved, 510(k), investigational, HUD, or other

Biologic: FDA-approved, investigational, or other

Botanical, medical food, or dietary supplement

None of the above

11. Funding Source

11.1 * Do you have funding to support any of the activities for this project:

Yes No

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12. Project Subject Types

12.0 * Does this project involve any minor subjects, or use of records or biospecimens related to minors? (Minor status is defined by the legal age of consent for the state or country where the research activity takes place; e.g., under 18 years of age in Wisconsin.)

- All minors
- Some adults and some minors
- All adults of legal age

12.1 * Enter the disease/affliction that is the focus of this project (e.g. pancreatic cancer):
Cardiovascular Disease

12.2 * Identify all categories of subject populations that will be included in this project:
(check all that apply)

- Cancer patients
- Inpatients
- Outpatients
- Healthy Subjects (i.e. subjects NOT selected because they have a particular medical condition or history)
- Elderly - age 70 and over
- Employees including faculty, staff, residents or fellows
- Fetuses
- Issues of cognitive or decisional impairment
- Limited or non-reader
- MCW students
- Neonates
- Non-English speaking
- Nursing home residents
- Persons with alcohol or drug use disorders
- Persons with developmental disabilities - neurologic or psychiatric
- Persons with mental illness
- Poor and/or uninsured
- Pregnant women
- Prisoners - see help text
- Terminally ill patients
- Traumatized, sedated, or comatose patients
- Visually / hearing impaired

12.3 * Are the exclusion criteria for this project likely to exclude groups or categories of subjects based on race, socioeconomic status, or insurance coverage?

Yes No

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17. Recruitment Strategies

17.1 * Will potential subjects be identified or screened by searching records of any source outside MCW/FH/CHW/Versiti, Inc.? (e.g., motor vehicle records, military service records, state registries, Medicare files, other hospitals including International hospitals)

Yes No

17.2 * To recruit potential subjects, will you use any of the following:

- Print advertisements (e.g. newspapers, magazines, flyers, posters, brochures)**
IRB SOP: [Recruitment Methods and Compensation](#)
IRB SOP: [Advertisements](#)
- Letters/emails**
- Radio or television advertisements**
- Web solicitations**
Examples of web solicitations include posting on craigslist.org, use of Researchmatch.org, sponsor website, advertisements on internet search engines and social media websites.
- Telephone**
- Recruiting company**
- Physician referrals (includes in-house and/or outside referrals)**
- Approach subjects in-person** (Example: a public place or knocking door-to-door)
- EPIC Tools:**
- Other strategies (not already covered) to identify, screen, or recruit subjects** (Other professional referral sources (PhD clinicians, nurses, other investigators) should be classified as "other".)
- No recruitment activities**

Instruction: Upload all recruitment materials in Section 52.

19. Protocol Summary

You received this section because the responses you provided in Sections 3, 6, 11, and 12 qualify this project to be a minimal risk project that could be Registered.

Introduction

19.1 * Briefly summarize the background and the history of the proposed project.

Regular physical activity is known to reduce the risk of cardiovascular events and atrial fibrillation. Our prior work has shown that reduce physical activity as measured by implanted cardiac devices is strongly associated with an increased risk of death. Our clinical observations have been that during the "safer at home" order in Wisconsin due to COVID-19, the activity levels of our patients with implanted devices appears to have decreased which might be associated with an increased risk of cardiovascular events.

Rationale/Purpose

19.2 * Describe the reason this project is being proposed. Include why is it significant or important to conduct this project.

Our prior work has demonstrated that the activity data readily obtainable from implanted cardiac pacemakers is a powerful predictor of adverse outcomes. (Tyagi S et al, *J Am Coll Cardiol*, 2015) Additional studies have demonstrated that cross-sectional data obtained from a wide variety of types of implanted cardiac devices that report out quantifiable physical activity demonstrate correlations between lower activity levels and cardiovascular outcomes (Rosman et al, *J Am Heart Assoc*. 2018 doi/10.1161/JAHA.118.008663). However, only limited data exist showing that changes in physical activity as reported by an implanted cardiac device are associated with changes in cardiac status. (Kelly J et al, *JACC: Heart Failure* 2020. 8(4). 280-288). However, no data to date report on the impact of changes in physical activity and subsequent arrhythmia events or are able to discern if a subsequent heart failure admission were a cause or a result of reduced physical activity. Wisconsin's "safer at home" order that went into effect on March 17, 2020 provides an opportunity to determine the directionality of this relationship as stable outpatients with cardiac devices may have reduced their activity levels due to limited activity opportunities during the safer at home period.

Objectives or Hypothesis

19.3 * Describe the Aims and Objectives of this project.

(1) To determine whether the "safer at home" order required to protect public health during the COVID-19 pandemic in Wisconsin was associated with reduced levels of physical activity based on activity data readily obtainable from cardiac device interrogation reports.

(2) To determine whether changes in activity level during the "safer at home" order required to protect public health during the COVID-19 pandemic were associated with an increase in atrial and ventricular arrhythmia

(3) To determine whether changes in activity level during the "safer at home" order required to protect public health during the COVID-19 pandemic were associated with an increase in chest impedance (also reported in the interrogation reports)

19.4 * Describe goals which are empirically measurable.

(1) Determination in the changes in activity levels by pacemaker measurements between time periods 1 year apart and time periods prior to and following Wisconsin's safer at home order

(2) The amount of time in an atrial or ventricular arrhythmia during the period of time between interrogations as well as the number of each of these events is discretely recorded and reported directly by the implanted devices on interrogation reports. These can be used to determine changes in events between time periods 1 year apart as well as in the time periods prior to and following Wisconsin's safer at home order through June 30, 2022 given the length of the pandemic.

Inclusion/Exclusion Criteria

19.5 * Identify subject selection criteria in inclusion criteria

(1) Individuals ages 21 and over with an implanted cardiac device (pacemaker, implanted defibrillator) who have had device interrogations between Jan 1 and May 15, 2020

19.6 * Identify subject selection criteria in exclusion criteria

(1) Individuals ages 21 and over without implanted cardiac devices implanted prior to Oct. 1, 2019

(2) Individuals who tested positive for COVID-19 prior to May 15, 2020

Please note, for all of Section 19 the text you see is an example. This text should be replaced with text that is relevant to your unique study proposal.

Project Design

Make sure to add text

regarding MCW

CRDW and

Honest Broker

19.7 * Provide details of how the project will be performed including a description of what will happen during each visit/activity.

This study is a chart review only. Data will be obtained by searching for eligible participants by querying a cohort discovery tool (i2b2 and/or TriNetX) from the MCW CRDW (PRO00013874) with inclusion/exclusion criteria listed in Section 19.5/19.6 and extracting the clinical information for each identified participant using Honest Broker.

Financial Implications

19.8 * Explain which procedures are research-related.

All procedures are research related

19.9 * Will there be any costs to the subjects? If yes, then list each item being charged.

There are no costs to the subjects

Subject Compensation

19.10 * Will subjects be offered stipends, gifts or compensation for their participation, or reimbursement for project-related expenses?

Yes

No

Statistical justification for number of subjects

19.11 * Provide detail as to how the number of subjects was chosen. Include a number or range that will give you statistical viability or make your results meaningful. The number of cardiac device interrogations fitting the inclusion criteria over a three week period is approximately 500. With this pace of interrogations, we expect there to be at least 1000 individuals with device interrogations during the selected time period who would be eligible for data abstraction. Assuming activity levels drop by an average of 30 minutes per day following the safer at home order, we will have 90% power to detect this difference with 337 subjects at an alpha level of 0.05 and sigma= 2 hours. Because this is an exploratory analyses and we do not know what the magnitude of the changes we will see in activity time, we are asking to analyze up to 1000 subjects's data.

Statistical Methods and Data Analysis

19.12 * Provide a simple overview of potential statistical tests for analysis.

Categorical outcomes (e.g. numbers of arrhythmia events and chest impedance measured by ICD) will be compared using Chi-Square or Fisher's Exact tests as appropriate. Continuous variable outcomes measures at all time points will be compared using repeated-measures ANOVA. Stratified analyses will be performed with stratification based on the type of device implanted (pacemaker only, ICD, monitoring device only).

In addition, generalized linear models will be constructed to whether the changes in physical activity between the period immediately prior to and following the safer at home order independently predicted adverse cardiovascular outcomes (e.g. changes in arrhythmia episodes, changes in chest impedance as measured by the ICD lead).

Risks/Safety

19.13 * Identify the risks associated with project including physical, psychosocial, confidentiality, and privacy risks.

1) Loss of confidentiality- collection of data that includes patient identifiers raises the risk of potential loss of confidentiality due to lost or stolen data.

19.14 * Identify efforts to minimize the identified risks and how confidentiality will be protected.

1) All paper records will be stored in a locked drawer in a locked room under the primary investigator's supervision. All electronic records will be stored on MCW's password-protected, encrypted server. Any laptop computers or thumb drives used to carry data related to the study will be encrypted according to MCW's current policies for encryption.

Benefits

19.15 * Identify any potential benefits to subjects.

There are no known benefits to subjects

19.16 * Identify any potential benefits to science and society.

These data provide a unique opportunity to both quantify reductions in physical activity and determine the impact that reduced physical activity has on the development of arrhythmias and heart failure

References

19.17 * Briefly summarize findings from previously published data or pilot projects that substantiate the soundness of protocol being proposed; or describe formulation of research questions:


Please see section 19.2 for a summary of the findings and our prior work that substantiate the soundness of the protocol being proposed.

- 1) Tyagi S...Widlansky ME, *J Am Coll Cardiol* 2015 Aug 11;66(6):754-5
- 2) Rosman et al, *J Am Heart Assoc.* 2018 doi/10.1161/JAHA.118.008663
- 3) Kelly J et al, *JACC: Heart Failure* 2020. 8(4). 280-288

26. Connecting with a Bank


26.1 * Will this project contribute data, records, or biospecimens to a local bank?

Yes No

26.2 * Will this project access data, records, or biospecimens from a local bank? 

Yes No


**Link to the
CRDW
Banking
Protocol**

*** 26.2.1 Cite the PRO for the local bank from which you will access data (records or biospecimens) for this project:** 

Bank ID	Bank Title	Principal Investigator	Bank State	Accessing Records	Accessing Biospecimens
View PRO00013874	Clinical Research Data Warehouse	Reza Shaker	Approved	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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38. Informed Consent

38.1 * Indicate your approach to the informed consent process requirement for this project: 

(check all that apply)

-
- Subjects or parents of minor subjects participate in an informed consent process and sign an informed consent document
-
- Waiver or Alteration of the Informed Consent Process is granted by the IRB. This option is not permitted for most FDA regulated research.
-
- Subjects participate in an informed consent process, but a Waiver of Documentation of Informed Consent is granted by the IRB
-
- None of the above**


38.1.1 Please identify which pathways are applicable to this project.

(check all that apply)

-
- Project will not have direct contact with subjects, and a consent form or process is not required per MCW institutional policy**
-
- Project will have direct contact with subjects, and an informational letter will be provided
-
- Project qualifies for Approval without the Requirements of Informed Consent under the 2006 FDA guidance regarding In-vitro diagnostic evaluation using de-identified, discard clinical specimens
-
- Informed consent has already been obtained (i.e. previously IRB approved bank, incoming data form another institution, etc.)

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42. HIPAA: Protected Health Information

42.1 * Will potential subjects be identified or screened by searching any kind of pre-existing MEDICAL records before consent is obtained? (e.g., medical records, hospital census or procedure logs, emergency room visit rosters) 

Yes No


* 42.1.1 Does this research team request permission to screen existing medical records for potentially eligible subjects before consent is obtained? Do not check "Yes" unless you intend to obtain informed consent for subjects who decide to enroll in the project

Yes No

If No, only the physician or nurses caring directly for the patient are allowed to review the patient's records.

* 42.1.2 Does this research team request permission to retain screening logs as part of the investigator files?

Yes No

42.2 * Indicate the HIPAA authorization pathway applicable to this project. Generally, the Health Insurance Portability and Accountability Act (HIPAA) prohibits collecting, accessing, using or disclosing a person's protected health information (PHI) for research without valid authorization. Under some circumstances, a waiver of authorization may be granted by the IRB: 

(check all that apply)

- No Protected Health Information (PHI) will be Accessed or Used For This Project
- An IRB-Approved Consent Process and Document will be Used that incorporates the required HIPAA authorization
- Waiver of HIPAA Authorization Is Requested. Generally, this request should accompany the "Waiver of the Informed Consent Process" at 38.1.
- Research using only information on deceased persons
- Limited Data Set, as defined by HIPAA regulations (download "Data Use Agreement" form located on InfoScope HIPAA website, complete it or an equivalent, and upload in Section 52)
- De-identification of data subject to the IRB's definition and verification of de-identification
- None of the above

48. Waiver of HIPAA Authorization: Justification

Note: Here "practicable" refers to the size of the burden and/or cost of obtaining authorization from subjects, on a scale from "difficult" to "impossible". Explain how difficult it would be. It is not acceptable to argue that obtaining authorization would be "inconvenient".


48.1 * Is it practicable for the investigator to conduct this project without a waiver of HIPAA authorization? 

Yes No

* If No,

48.1.1 Explain:

Obtaining consent from 1000 patients in a reasonable time window would be virtually impossible. We would not be able to perform this study without access to these records. In addition, we have found in our experience that an electronic consent process that could speed up consenting is very challenging to implement with any effectiveness in this primarily older and less computer literate patient population.

48.2 * Is it practicable for the investigator to conduct this project without access to and use of the identified health information? 


Yes No

* If No,

48.2.1 Specify:

We would not be able to perform this project without review of the charts and their interrogation printouts

49. Waiver of HIPAA Authorization: Safeguards

49.1 * How will subjects' rights and welfare be protected to assure that use or disclosure poses no more than minimal risk? 

All data will be in password-protected files. The files will be on MCW's 256-bit encrypted server. All paper files will remain in a locked drawer in a locked office. Any data on laptops or thumb drives will conform to MCW's current encryption practices.

49.2 * What is the plan to ensure that the identified health information will NOT ever be removed from the institution? 

All data will be in password-protected files. The files will be on MCW's 256-bit encrypted server. All paper files will remain in a locked drawer in a locked office in the PI's office and will not be removed from the institution. Any data on laptops or thumb drives will conform to MCW's current encryption practices.

50. Waiver of HIPAA Authorization: Procedures

50.1 * Who will have access to the identifiers? (List by name, class or organization)

List names of all people needing access and organization (e.g. Medical College of Wisconsin/Froedtert Health)

50.2 * How will the identifiers be protected from improper use and disclosure? 

All data will be in password-protected files. The files will be on MCW's 256-bit encrypted server. All paper files will remain in a locked drawer in a locked office in the PI's office and will not be removed from the institution.

52. Supporting Documents

52.1 * Select all items that will be included for IRB review:

(select all that apply and upload documents in Section 52.1.2, using the prefix in the title of the document. For example, ICF-PRO1234 (document name), IB-PRO1234(document name))

DA - Data agreements or contracts

DCF - Data Collection forms/tools

ADV - Advertisement

ICF - Informed Consent form

INF - Informational material for subjects

SUR - Surveys / Questionnaires

Other(s) (SPECIFY)

52.1.2 Upload each item specified from 52.1 and 52.1.1 in the section below:

Name

Last
Modified Date Version

 DataCaptureSheet_PPM_Activity_AFProject_3_16_20.xlsx(0.01) 3/16/2021 8:15 AM 0.01

Here is where you upload your specific data fields that you will be looking at. (e.g. an excel or word document showing all fields of interest for your study/IRB)

Sample Protocol for CAI
CRDW Data Extraction

Final Check

(a) Submission Instructions:

- The Principal Investigator must click the "Submit Application" activity in the workspace to submit this Project for Departmental, Ancillary and/or Safety Committee(s) review. **Once these reviews have been completed, the submission will automatically get routed to the IRB for review.**
 - Clicking "Go to Workspace" does NOT submit this Project for review.
 - Clicking "Go to Workspace" saves your work and exits the SmartForm, taking you back to the Workspace.

(b) Spelling and Grammar:

IRB will not accept any application that has not been checked by the submitter for spelling and grammatical errors. Spell checking capability is not available within the eBridge system at this time.

(c) Attached Documents:

Make sure all documents have been uploaded before submission.

(d) Copy and Pasting from Word or PDF:

If the format of your text is altered when it is pasted into eBridge, please refer to the "[How to Cut & Paste from a Word Document](#)" directions.

Sample Protocol for CAI
CRDW Data Extraction