**RESEARCH PROTOCOL APPLICATION**

|  |
| --- |
| **INSTRUCTIONS** |

* The application must be typed. Handwritten applications will not be accepted
* Spellcheck will not work on this application. Proofread before submitting.
* **SUBMIT COMPLETED APPLICATION AND ALL SUPPORTING DOCUMENTS TO:**
* The signature page must be signed by all applicable investigators and must be submitted to the IRB office via:
  + Email – [nobles.penny@navicenthealth.org](mailto:nobles.penny@navicenthealth.org) (as scanned .pdf file)
  + Campus Mail – Mail Stop 113
  + Mail – Medical Center of Central Georgia, Institutional Review Board, 777 Hemlock Street, MSC 113, Macon, Ga 31201

|  |  |
| --- | --- |
| **IRB OFFICE USE ONLY** | |
| Institutional Protocol ID#:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Received:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Approved:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Not Approved:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Withdrawn:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Expedited Category:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Exempt Category:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Informed Consent Document  □ Assent Document (studies involving minors)  □ Data Collection Instrument (survey/questionnaire/etc.)  □ Advertisement, Recruitment Materials, Scripts  □ IRB approval from applicant institution  □ Conflict of Interest Disclosure |

**TYPE OF REVIEW REQUESTED:**

*(Note: Only the IRB Chair, in consultation with committee members, if necessary can certify the appropriate level of review necessary.)*

Full Board Review

Expedited (Must include a completed Expedited Protocol Request)

Exempt (Must include a completed Exempt Protocol Request)

Note: *Any research involving human participants which does not qualify for exempt or expedited review must be submitted for full IRB board review. Research involving more than minimal risk requires full board review.*

**General Information**

Project Title: ****

Sponsor:  Sponsor or other Protocol #: 

Anticipated Start Date:  Anticipated End Date: 

**Type of Study:**  Drug  Device  Other: 

**Drug/Device FDA Status:**  FDA approved  NOT FDA approved

**Clinical Trial Phase:**  Phase II  Phase III  Phase IV (post marketing surveillance)  n/a

Has this study been reviewed and approved by another institutional review board?  YES  NO

If “YES”, attach a copy of the IRB approval letter as an appendix

**INVESTIGATOR INFORMATION**

**PRINCIPAL INVESTIGATOR (PI)** *(Refer to the IRB PI eligibility requirements. Students MUST list an eligible PI as a co-investigator)*

Name: 

Full Title: 

Navicent Health Employee  Navicent Credentialled Staff

Department:  Phone: 

Email: 

CITI Training Certificate Date: (Note: must be within last 3 years): 

**CO-INVESTIGATOR (CO-I)** *(Refer to the IRB PI eligibility requirements. Students MUST list an eligible PI as a co-investigator)*

Name: 

Full Title: 

Navicent Health Employee  Navicent Credentialled Staff

Mercer Resident/Fellow  Student  Graduate Student

Department:  Phone: 

Email: 

CITI Training Certificate Date: (Note: must be within last 3 years): 

Role and responsibility in this study:

****

**Do you have additional research personnel (Sub-investigators, key personnel, research assistant, etc.)?**

YES  NO If yes, Please least each person and their role.

****

**Conflicts of Interest Disclosure**

*(All local investigators must be listed)*

*The Investigators whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers’ bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, related to this research.*

****

Investigator Names (printed) Investigator Signature

****

Investigator Names (printed) Investigator Signature

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

*The investigators whose names are listed immediately below report the following details of affiliation or involvement in an organization or entity with a financial or non-financial interest related to this research project. Please specify the nature of the conflict.*

**Nature of Conflict:**



****

Investigator Names (printed) Investigator Signature

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

**Nature of Conflict:**



****

Investigator Names (printed) Investigator Signature

Each individual signing this Conflict of Interest Disclosure Statement confirms that the information provided on their behalf is complete and accurate to best of their knowledge.

1. **PURPOSE AND SIGNIFICANCE OF THIS STUDY**

In ONE sentence, state the OVERALL PURPOSE OF THIS STUDY:



In ONE paragraph, summarize previous work in this area and the **specific reasons this study is being undertaken.** Cite relevant references and **attach a reference list at the end of this application.**



1. **DESCRIPTION OF YOUR INTERACTION WITH PARTICIPANTS**

**Who will be interacting with the participants?** (check all that apply)

Principal Investigator

Co-Investigator

Research Assistant

Other: (Describe) 

**There will be NO interaction with participants. This is an analysis of pre-existing cleansed data.**

*(If you checked this choice, you may go the next section.)*

**What will your interaction with participants entail?** (Check all that apply)

Obtaining biometric data (List all types to be collected. Example: height/weight)



Obtaining biological specimens (List types to be collected. Examples: blood, urine, saliva)



Administering questionnaires/surveys or conducting interviews in person

Administering questionnaires/surveys using the internet.

* If you are conducting a survey using the internet, you must attach a copy of the email solicitation you will be sending to potential participants
* I certify that I have attached a copy of the email solicitation I will use as an appendix

Administering questionnaires/surveys using the U.S mail (USPS).

* If you are conducting a survey using USPS, you must attach a copy of the letter of solicitation you will be sending to potential participants along with the study materials. You must also provide participants with a pre-stamped, pre-addressed envelope for the return of your study materials.
* I certify that I have attached a copy of the letter of solicitation I will use as an appendix

Conducting a focus group.

* If you are conducting a focus group, you must attach a script as an appendix that describes your general interaction with the participants and include elements such as ensuring participants will only address each other by numbers/pseudonyms and the questions you will ask during the focus group.
* I certify that I have attached the script for conducting the focus group session as an appendix.

Other types of data collection interactions not listed above (describe):



**List and describe all EQUIPMENT you will use.** (Examples: “paper and pencil questionnaires; digital tape recorder; standard medical office standing scale manufactured by the Acme Scale Company, Model THX-1487; standardized sterilized venipuncture tubes, etc.”)



**Will you perform an experimental manipulation or an intervention on the participants?**

(An experimental manipulation or intervention is an activity your perform on participants designed to change a state or condition, such as teaching new knowledge or skills. Collecting data is NOT considered an intervention)

No, I am only collecting data from participants

Yes, and the experimental manipulation or intervention will consist of (describe):



(You must attach a complete description of all experimental manipulations or interventions you plan to perform as an appendix)

**What will be the length of participant involvement in study activities?** (Choose ONE option)

a ONE-TIME interaction consisting of  hours and  minutes of participant involvement.

MULTIPLE interactions consisting of  hours and  minutes of participant involvement.

If you checked “Multiple interactions”, please describe as clearly as possible the type of interactions and the time needed for each.



1. **TYPES OF DATA YOU INTEND TO COLLECT**

List and number EVERY TYPE OF DATA (each variable) you will measure, assess, or investigate, in your study interview guide you will use to do data collection for this data item.



1. **DESCRIPTION OF DATA COLLECTION TOOLS OR INTERVIEW GUIDES**

List and BRIEFLY describe EACH measurement/interview guide you have listed above. Do not exceed more than a few sentences for each measurement. You must state the author (e.g. “researcher developed” if you developed it) and the number of items (questions) on each item. Cite, reliability and validity, of available. You must attach a hard copy of ALL measurement tools or interview protocols to this application. Any materials you attach must be in the same format that you plan to give to participants.

**Title of Tool Description Appendix location**



1. **LOCATION OF DATA COLLECTION SITES**

(check all that apply) If you do not see an appropriate location of your data collection listed. Fill in at the bottom

In a specific location(s), such as a clinic, school, or community center:

If so, list complete address of location(s)



In participants’ homes or other public place where privacy can be maintained.

Via the internet, with participants clicking on a link to complete a survey or emailing you to receive an email survey.

* Will all potential participant identifiers (e.g. email, IP address) be excluded from the responses?  YES  NO

(If NO, explain here how confidentiality will be maintained:



By U.S. mail (USPS), with participants mailing back study materials in a pre-addressed, pre-stamped envelope with you provide.

Pre-collected data cleansed of all identifiers or secondary analysis.

If so, list the source of the data, including the name and institution affiliation of the researcher supplying the data OR the name of the facility providing the data here:



Other location not described above (describe fully):



1. **DESCRIPTION OF YOUR STUDY PARTICIPANTS**

TOTAL ESTIMATED NUMBER OF PARTICIPANTS: This Site:  Globally: 

(Check all that apply)

Inpatients

Outpatients

Staff / Employees

Students

Non-English speaking participants

Mentally challenged/incompetent participants

Adults age 18yrs or older

Children under age 18yrs

Males

Females Pregnant  YES  NO

Only members of a specific racial/ethnic group (specify): 

Only persons with a specific health need or characteristic (specify): (e.g. Persons age 50and over diagnosed w/ osteoporosis)

Only persons attending a specific school or working at a specific institution.

(specify): 

1. **DESCRIPTION OF HOW YOU WILL RECRUIT PARTICIPANTS**

There will be NO interaction with participants. This is an analysis of pre-existing cleansed data. (See Section II)

Check all that apply

Flyers will be posted in public places with researcher contact information

Flyers will be handed to potential participants with researcher contact information

Email will be sent soliciting participation with researcher contact information

An announcement will be made at a public gathering, meeting, or class, and the researcher will be onsite to recruit interested

Participants

Participants will be approached during medical clinic or office visits

You must attach a copy of the flyer, email text, or announcement you will be using to recruit participants as an appendix.

1. **DESCRIPTION OF HOW YOU WILL OBTAIN INFORMED CONSENT**

Choose ONE of the following:

There will be NO interaction with participants. No consent is necessary.

I will obtain informed consent from adult participants (> 18yrs) and document their consent with a signed consent form.

For participants under 18yrs of age, I will obtain informed consent from a parent or legal guardian AND obtain ASSENT from the minor.

I will obtain informed consent from participants but request a WAIVER of SIGNED consent as:

(check all that apply)

**1.**The only record linking the subject and the research would the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; OR

**2.** The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

**3.**I am requesting a waiver or alteration of the requirement to obtained consent. My project satisfies ALL four requirements of the four part test in 46.116(d): **(1)** The research involves no more than minimal risk to the subjects; **(2)** The waiver or alteration will not adversely affect the rights and welfare of the subjects; **(3)** The research could not practicably be carried out without the waiver or alteration; **(4)** Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**If you checked #3 above, please answer BOTH of the following:**

1. The waiver or alteration I am requesting is:



1. This research project meets the four-part test based on the following:



NOTE: You must attach a copy of ALL consent and/or assent forms, and completed Consent Form Check List as an appendix (only English versions are required)

1. **DESCRIPTION OF PROTECTION OF CONFIDENTIALITY**

* Will all data be coded using numbers or pseudonyms?  YES  NO
* Will all data collection tools be free of any names or identifiers such as patient medical record or billing numbers?

YES  NO

* Will all data be stored in a locked file cabinet or password-protected computer file? YES  NO
* Will only the researcher and his/her advisor (if applicable) have access to the data? YES  NO
* Will all data be kept a minimum of 5 years before being destroyed? YES  NO
* If you are conducting a focus group, will you take measurements to ensure confidentiality, such as instructing participants to address each other only by numbers or pseudonyms? YES  NO  N/A
* If you are retaining any personal identifiers following data collection, will you remove the identifiers as soon as possible?

YES  NO  N/A

If you answered “NO” to any item above, explain below.



1. **DESCRIPTION OF PARTICIPANT RISKS AND BENEFITS**

**RISKS**

**Does you study involve more than “Minimal Risk”, meaning that the risks involved are no greater than those encountered in everyday life.**

YES (Full Board review is required)  NO (only applicable for exempt and expedited review)

**Is there ANY possibility that the questions being asked in your survey or interview questions could result in negative or uncomfortable emotions, even mild/transient sadness or anxiety?**  (Any questions regarding mood or topics such as health status are considered a YES)

YES  NO

If you answered “YES”, it is strongly encouraged to include phone number to a LOCAL mental health resource on the consent form that participants can call, should they experience these emotions. Did you do this?  YES  NO

**Do you foresee any other risks form participation in this study?**  (Breach of confidentiality is not included in this section)

YES  NO

If yes, List the risks and plan for minimizing each risk.



**POTENTIAL BENEFITS TO PARTICIPANTS**

DIRECT BENEFITS:

**Will participants receive any reimbursement or incentive for participating?**

YES  NO

**If “YES”, answer the following:**

1. What is the reimbursement? 
2. Does the consent form contain language stating that all participants, regardless of whether they complete the entire questionnaire/interview or not, receive reimbursement? (Consent forms must contain this language)

YES  NO If “NO”, you must provide a rationale below.

INDIRECT BENEFITS:

**If your study includes no other direct benefits to participants, is there a potential benefit of an enhancement to the general knowledge of**

**this study area?**

YES  NO

If “NO”, CONSULT WITH AN IRB REPRESENTATIVE to discuss what value it provides. Such protocols are typically not approved.

1. **RESEARCH FUNDING SUPPORT**

How will this research be funded/supported?

Not funded  Industry Funded  Grant Support  In-house Support

Name of Agency or Sponsor: 

**COSTS TO BE BORNE BY PARTICIPANTS** (e.g. diagnostic and laboratory studies, drugs, devices, transportation, meals, professional fees, etc.)



**COSTS TO BE BORNE BY NAVICENT HEALTH**



**Principal Investigator Assurance and Acknowledgement**

*I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.*

*I agree to conduct the research involving human participants as presented in this protocol application as approved by the Navicent Health Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB/Office of Research Compliance of any adverse events that may occur during the study. I also assure that I will follow through with storage and destruction of data as outlined in the protocol. I understand that Navicent Health owns the research data. If I choose to transfer to another institution, I will notify the Navicent IRB immediately and will need Navicent Health approval to take the data with me.*

*I have reviewed the risks and benefits associated with this study and it is my professional opinion that the potential risks in this study are outweighed by the potential benefits*

*If I am a student investigator on this research application, I further agree to meet with my faculty advisor on a regular basis to discuss the progress of my study. I agree to meet with my faculty advisor to solve protocol issues as they arise.*

***I understand the data collection (including recruitment) is not permitted until final approval is granted by the IRB.***

****

**Principle Investigator Name (printed) Signature Date**

**Co-Investigator/Faculty Advisor Assurance and Acknowledgement**

*I certify that I have read this protocol application and that the information is complete and accurate. I ensure that the principal investigator is qualified to perform the procedures described. I understand that I will be included in all email correspondence related to the protocol application including questions from the IRB committee and approval notifications.*

*I further agree to meet with the principal investigator on a regular basis to monitor the progress of the study. I agree to be available and to personally supervise the student investigator in solving problems as they arise. I will arrange for an alternate Co-Investigator to assume responsibility if I become unavailable, as when on vacation or short business trips. I will arrange for an alternate Co-Investigator to assume responsibility if I go on extended sabbatical, leave, or transfer to another institution.*

****

**Co-Investigator Name (printed) Signature Date**