

**HRP-591 - Protocol for**

**Human Subject Research**

**Protocol Title:**

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS IRB (<http://irb.psu.edu>).

Understanding bipolar disorder symptom-related spending behaviors and the acceptability of banking data-based interventions to support financial wellbeing and decision-making

**Principal Investigator:**

Name: Johnna Blair

Department: Information Sciences and Technology

Telephone: 814-706-8412

E-mail Address: jlb883@psu.edu

**Version Date:**

Provide a version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

10-8-24

**Clinicaltrials.gov Registration #:**

Provide the registration number for this study, if applicable. See “HRP-103- Investigator Manual”, under “ClinicalTrials.gov” for more information.

n/a

**Important Instructions for Using This Protocol Template:**

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

* + 1. **GENERAL INSTRUCTIONS:** 
       - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
       - Do not change the protocol template version date located in the footer of this document.
       - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
       - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
* **Do NOT delete the instructional boxes from the final version of the protocol.**
* Add the completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the “Basic Information” page.
  + 1. **CATS IRB LIBRARY:**
* Documents referenced in this protocol template (e.g. SOP’s, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
  + 1. **PROTOCOL REVISIONS:**
* When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.
* Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

**If you need help…**

**All locations:**

**Human Research Protection Program**

Office for Research Protections

The 330 Building, Suite 205  
University Park, PA 16802-7014  
Phone: 814-865-1775  
Fax: 814-863-8699  
Email: [irb-orp@psu.edu](mailto:ORProtections@psu.edu)

[**https://www.research.psu.edu/irb**](https://www.research.psu.edu/irb)

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# Objectives

## Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

Study Goals:

* Build out a library of symptomatic spending behaviors associated with bipolar disorder mood episodes for use in future intervention design
* Understand user acceptance and privacy concerns of financial data use for the purpose of curbing unwanted spending and promoting financial wellbeing
* Understand current self-imposed intervention behaviors (especially in relation to technology use) and receive feedback on proposed intervention ideas
* Explore the role of technology and its effect on current spending, as well as users’ future wants to curb spending

The following research questions will be use to guide this work:

Financial behaviors

* What spending categories are common when in a.) a depressive mood episode and b.) a manic mood episode?
* What are the temporal characteristics of symptomatic spending when in a.) a depressive mood episode and b.) a manic mood episode?
* Temporal -- time of day/year/month, timing of purchases (burst of many, one large purchase)

Tech-Use (positive and negative effects)

* What strategies do individuals use to (attempt to) control their own spending?
* What aspects of technology do individuals perceive enable their problematic spending?
* How do individuals believe technology could help curb spending?

## Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

## The primary outcomes of this study will be a better understanding of the types of spending behaviors that exist in relation to bipolar mood episodes, including the types and patterns of spending, as well as the perceived motivations behind different purchases.

## We also mean to gather insight on their technology-use related to spending—both what exacerbates problematic spending and how new technologies could intervene to support decision-making processes.

## Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Additionally will address the feasibility and acceptability of using online banking/financial data as the basis of a future behavioral intervention system aimed to help curb problematic spending and promote better financial wellbeing. This will involve presenting different example scenarios of data use (e.g., how much and what types of data) and data sharing (e.g., with care partners) for respondents to rate their level of comfort or potential privacy concerns.

We will also ask questions about their current banking situation—e.g., Do you currently have a bank account? With which banking institution?—to better understand the technical feasibility of developing a future intervention system built on online banking data and available open banking APIs. *No actual banking data will be collected from respondents at any point during the survey.*

# Background

## 

## Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

## 

The relationship between mental health and financial difficulties is complex. Those living with mental illnesses are at increased risk of financial hardships and debt-related stress [6]. This can be further complicated by a range of problematic financial behaviors related to specific mental health symptoms, such as impulsive purchasing or missing deadlines [3-5]. Previous studies show insight on how mental health symptoms may manifest in financial behaviors [4]. However, additional knowledge is needed about people’s own experiences with spending during mood episodes and their first-hand insights on using banking data as a means of intervening on problematic spending behavior and to help support better financial wellbeing to develop a system to support these goals.

## Previous Data

Describe any relevant preliminary data.

We do not have any preliminary data for this study.

## Study Rationale

Provide the scientific rationale for the research.

Through this large-scale survey, we mean to assess the range of attitudes toward using banking and purchasing behavior information to develop a real-time intervention meant to assist with financial decisions and curb impulsive spending associated with bipolar disorder. This will be distributed online in the US, UK, and Ireland (among potential countries) to understand potential differences that exist due to banking data access and relevant financial concerns (e.g., medical debt), as well as different purchasing behaviors that may be culturally bound. This survey will also further document the relevant financial concerns and most common problematic spending behaviors for those living with bipolar disorder, from first-hand accounts. This information, along with potential privacy concerns, will be crucial in prioritizing system features in the future development of a financial wellbeing intervention.

# Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

**Vulnerable Populations:**

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

* **Children –**Review “HRP-416- Checklist - Children”
* **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
* **Cognitively Impaired Adults-** Review “HRP-417- Checklist - Cognitively Impaired Adults”
* **Prisoners-** Review “HRP-415- Checklist - Prisoners”
* **Neonates of uncertain viability or non-viable neonates-** Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

[Do not type here]

## Inclusion Criteria

### Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

Age 18 or older

English-speaking

From the US or the EU

Self-described as having bipolar disorder (any form)---no medical/diagnostic verification to be collected

## Exclusion Criteria

### Create a numbered list of the exclusion criteria that define who will be excluded in your study.

## Minors, under age 18 Non-English speaking respondents Those who do not have bipolar disorder Those unable to provide informed consent at the time of the survey

## Early Withdrawal of Subjects

### Criteria for removal from study

### Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

At the beginning of the survey, respondents will be told that their participation in the study is voluntary. Therefore, should respondents feel uncomfortable with the questions asked or no longer wish to continue with the survey they can choose to stop at any time.

### Follow-up for withdrawn subjects

### Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

n/a

# Recruitment Methods

* + - Upload recruitment materials for your study in CATS IRB (<http://irb.psu.edu>). **DO NOT** include the actual recruitment wording in this protocol.
    - StudyFinder: If StudyFinder (<http://studyfinder.psu.edu>) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
    - Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (<http://irb.psu.edu>).

[Do not type here]

## Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

* + If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, include this method in this section.
  + Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (<http://irb.psu.edu>). See “HRP-103- Investigator Manual, What is appropriate for study recruitment?” for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Potential subjects will be identified with the help of several mental health clinics and organizations, such as Active Minds, International Bipolar Foundation, and Crest BD. Recruiting information will also be shared via social media using the accounts of these organizations and the study team.

## Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

[Do not type here]

### How potential subjects will be recruited.

Research informational materials will be shared with the organizations noted above to then share with their contacts who may be eligible, via their organization pages and social media accounts. Our study team will NOT be provided with lists of potential subjects that meet the eligibility requirement of a bipolar diagnosis to contact directly. All personal contact information (e.g., name, email, phone number, etc.) for subjects recruited with help of external organizations will remain with that organization and will not be shared with the study team.

### Where potential subjects will be recruited.

This recruitment process will be conducted online.

### When potential subjects will be recruited.

Upon the approval of the survey study protocol, recruitment materials will be made available online and shared with related organizations, including a link to complete the survey online.

* + - 1. Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

At the beginning of the survey, following informed consent, respondents will be asked questions to determine study eligibility (i.e., bipolar diagnosis, age). Should respondents provide ineligible answers, they will not be invited to complete the main survey.

# Consent Process and Documentation

Refer to the following materials:

* The “HRP-090- SOP - Informed Consent Process for Research” outlines the process for obtaining informed consent.
* The “HRP-091– SOP - Written Documentation of Consent” describes how the consent process will be documented.
* The “HRP-314- Worksheet - Criteria for Approval” section 7 lists the required elements of consent.
* The “HRP-312- Worksheet - Exemption Determination” includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
* The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
* Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>). Links to Penn State’s consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

## Consent Process:

**Check all applicable boxes below:**

**Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

**Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

**Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

**Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

**The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:**

**Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in “HRP-312- Worksheet- Exemption Determination.” Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in “HRP-590- Consent Guidance for Exempt Research”):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

**If the research includes the use of student educational records include the following language in this section (otherwise delete):** The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

**Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator’s assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see “HRP-312- Worksheet- Exemption Determination”) is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.**

## Obtaining Informed Consent

### Timing and Location of Consent

Describe where and when the consent process will take place.

Respondents will be presented with the consent documentation on the first page of the survey link. This will include basic information about the survey content, study aims, study team contact information, associated risks, and a statement that their participation is voluntary and they may end the survey at any time if they choose. At the end of the consent information, respondents will be asked to provide their consent to continue on to the eligibility and main survey questions, in the form of a “yes” or “no” question. Those who respond “yes” will move on to the eligibility questions. Those who respond “no” will not move on to the survey.

### Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

Respondents will be reminded prior to the survey that their participation and responses are strictly voluntary and they end at any time throughout without consequence.

## Waiver of Written Documentation of Consent

Review “HRP – 411 – Checklist – Waiver of Written Documentation of Consent.”

### Indicate which of the following conditions applies to this research:

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

OR

The only record linking the subject and the research would be 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. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

n/a

### Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

A research summary consent form will be provided to potential survey respondents prior to starting the survey questionnaire. The content of this is detailed in the attached consent form. This will note what type of information will be asked of them and what measures will be taken to preserve their confidentiality, including their response data collected and stored anonymously (without collecting any personal identifiers).

## Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

### Indicate the elements of informed consent to be omitted or altered

n/a

### Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

n/a

### Describe why the research involves no more than minimal risk to subjects.

n/a

### Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

n/a

### If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

n/a

### Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

n/a

## Informed consent will not be obtained – request to completely waive the informed consent requirement

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

### Indicate why the research could not practicably be carried out without the waiver of consent

n/a

### Describe why the research involves no more than minimal risk to subjects.

n/a

### Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

n/a

### If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

n/a

### Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate “not applicable.”

n/a

## Consent – Other Considerations

### Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review “HRP-091 –SOP- Written Documentation of Consent” and “HRP-103 -Investigator Manual” to ensure that you have provided sufficient information.

As the survey will be developed in English, only English speaking respondents will be eligible for the study.

### Cognitively Impaired Adults

Refer “HRP-417 -CHECKLIST- Cognitively Impaired Adults” for information about research involving cognitively impaired adults as subjects.

#### Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

n/a

#### Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state of Pennsylvania, review “HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “legally authorized representative.”

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013 -SOP- Legally Authorized Representatives, Children, and Guardians.”

Only adults capable of providing their own informed consent will be eligible for this survey study.

##### Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

n/a

### Subjects who are not yet adults (infants, children, teenagers)

#### 

#### Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state of Pennsylvania, review “HRP-013-SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “children.”

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians.”

Only respondents aged 18 or older will be eligible for this study.

#### Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

n/a

# HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See “HRP-103 -Investigator Manual” for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

## Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

**Check all that apply:**

**Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

**Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

**Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

**Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

**Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

## Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

### Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

#### Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

*n/a*

#### Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

n/a

### Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

n/a

### Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

n/a

## Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

*n/a*

# Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (<http://irb.psu.edu>). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

[Do not type here]

## Study Design

Describe and explain the study design.

This study will consist of the one-time survey deployment. The survey will include close-ended and open-ended questions related to: bipolar disorder symptoms, symptomatic spending behaviors, insight on personal finances, debt anxiety, use of financial technologies (e.g., banking, online shopping, gambling, etc.) and demographic information.

## Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

* HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
* WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

This study will be a survey completed online via Qualtrics. Participants will be asked about their spending behaviors related to their mood, however no questions will be mandatory to continue through and submit their responses.

## Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

The one-time survey should take approximately 30 minutes to complete.

# Number of Subjects and Statistical Plan

## Number of Subjects

## Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

For a wide scale analysis, we would like to recruit approximately 500 respondents. This would include those recruited through existing organizations in the US, UK, and Ireland, as well as on their social media platforms.

## Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Previous survey research with BD and related populations with serious mental illness, a similar number of high respondents have been surveyed through similar methods, indicating this as a feasible sample size [1,2]. This wide-scale survey distribution would allow us to gather more generalizable insights about BD behaviors and financial decisions more broadly, as well as investigate possible individual, cultural and country-bound differences in behaviors across different sub populations.

## Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Survey data will be analyzed both quantitatively and qualitatively. Open-ended responses will be analyzed using a bottom-up thematic analysis. Close-ended questions will be analyzed regarding distribution and frequency of reported attitudes and behaviors held across different demographics and financial backgrounds. This survey study is exploratory in nature and as such, specific hypotheses will not be tested as part of this analysis.

# Data and Safety Monitoring Plan

**This section is required when research involves more than Minimal Risk to subjects as defined in “HRP-001 SOP- Definitions.”**

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.**

[Do not type here]

## Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

n/a

* 1. **Data that are reviewed**

## Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

n/a

## Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

n/a

## Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

n/a

## Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

n/a

## Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

n/a

## Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

n/a

## Suspension of research

Describe any conditions that trigger an immediate suspension of research.

n/a

# Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

* If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
* If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
* If applicable, describe risks to others who are not subjects.

The potential risks for respondents include:

* Discomfort with some of the questions asked – questions will ask about their experiences with bipolar disorder and financial difficulties
* Loss of confidentiality – While no personal identifiers will be collected during the survey that will tie responses to individual respondents, it is possible for confidentiality to be compromised. However, the study team will take all reasonable measures to insure confidentiality to the best of their abilities.

# Potential Benefits to Subjects and Others

## Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

There will be no direct benefits to the respondents.

## Potential Benefits to Others

Include benefits to society or others.

The findings of this work stands to benefit the larger public (with and without serious mental illnesses), by highlighting existing technology-based drivers of problematic spending and informing future interventions aimed to reduce problematic spending behaviors and provide resources to support better financial wellbeing.

# Sharing Results with Subjects

## Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how information will be shared.

# 

Data resulting from this survey will not be directly shared with anonymous respondents.

# Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Respondents will be entered into a random drawing to win a number of $50 gift cards. Because of the financial aspects of the survey, we did not want to provide compensation too high as to coerce those with potential financial difficulties, who may not wish to participate, to do so anyway based solely on compensation. At the end of the main survey, participants will be asked if they wish to provide their email address to deliver this gift card electronically, should they be selected. If the participant indicates yes, they will be moved to a second survey the asks for their email address. This email recorded through the second survey will not be connected to their responses from the main survey and will be stored separately to maintain anonymity of all responses.

# Economic Burden to Subjects

## Costs

Describe any costs that subjects may be responsible for because of participation in the research.

## 

Respondents will accrue no costs as a result of participating in this online survey study.

## Compensation for research-related injury

**If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.**

**If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

**For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written -** **DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

n/a

# Resources Available

## 

## Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator’s experience conducting research at these locations and familiarity with local culture.

## 

These study procedures and recruitment will be completed online. Participants will respond to the survey question on their own time, in their chosen location.

## Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Previous survey studies of populations with bipolar disorder and other serious mental illnesses have shown recruitment numbers within our anticipated 500 respondent range [1,2]. Our study team also has previous research-related relationships with a number of mental health related organizations to extend the recruitment reach of this study.

## PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI (Blair) has conducted survey studies in the past, as well as conducted in-depth interviews with patients with bipolar disorder. This survey will be a component of her dissertation research, and therefore she will have a significant amount of her time devoted to this project.

## Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

Because this survey will ask about respondents’ bipolar disorder and potential financial difficulties, this may possibly be distressing. Therefore, in the consent documentation, we will provide national-level resources, as well as advise contacting any existing clinicians they may have as a means of discussing potential concerning thoughts or feelings prompted by survey questions. No resources will be directly provided by the research collaborators or their respective research institutions.

## Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

The research team has been and will continue to hold bi-weekly full group meetings to discuss on-going steps and progress with this project. Additionally, the PI, her advisor and an additional grad student will hold weekly lab meetings for this same purpose. All study team members keep in steady contact via email, Zoom, and remotely collaborate on all study procedural documentation and eventual data analysis.

# Other Approvals

## Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

n/a

## Internal PSU Committee Approvals

**Check all that apply:**

Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of “HRP-902 - Human Tissue For Research Form” in CATS IRB.

Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

Clinical Laboratories – **Penn State** **Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use.

Clinical Research Center (CRC) Advisory Committee – **University Park** – Research involves the use of CRC services in any way.

Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

Radiation Safety – **Penn State** **Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of “HRP-903 - Radiation Review Form” in CATS IRB.

IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

St. Joseph Administrative Review – **Penn State Health only** – Penn State Health Research that will be conducted at St. Joseph Medical Center or St. Joseph Community Medical Groups.

# Multi-Site Study

## If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

## Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

## 

n/a

## Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site’s IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

n/a

## Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

n/a

## Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

n/a

## Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

n/a

## Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

n/a

# Adverse Event Reporting

## Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

*In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.*

# Study Monitoring, Auditing and Inspecting

## Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

*The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).*

# Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined** **research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

[Do not type here]

## Data and/or specimens being stored

## Identify what data and/or specimens will be stored and the data associated with each specimen.

n/a

## Location of storage

Identify the location where the data and/or specimens will be stored.

n/a

## Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

n/a

## Access to data and/or specimens

Identify who will have access to the data and/or specimens.

## 

## n/a

## Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

n/a

## Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

n/a

# References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

[1] Morton, E., Ho, K., Barnes, S. J., & Michalak, E. E. (2021). Digital Health Literacy in Bipolar Disorder: International Web-Based Survey. JMIR mental health, 8(10), e29764.

[2] Prochaska, J. J., Reyes, R. S., Schroeder, S. A., Daniels, A. S., Doederlein, A., & Bergeson, B. (2011). An online survey of tobacco use, intentions to quit, and cessation strategies among people living with bipolar disorder. Bipolar disorders, 13(5‐6), 466-473.

[3] Richardson, T., Jansen M. & Fitch, C. (2018). Financial Difficulties in Bipolar Disorder Part 1: Longitudinal Relationships with Mental Health. *Journal of Mental Health*, 27(6):595-601.

[4] Richardson, T., Jansen, M., Turton, W. & Bell, L. (2017). The Relationship Between Bipolar Disorder and Financial Difficulties: A Qualitative Examination of Patient’s Views**.** *Clinical Psychology Forum,* 295, 2-6.

[5] Richardson, T., Elliott, P.A. & Roberts, R. (2013). The Relationship between Debt and Mental and Physical Health: A Systematic Review and Meta-Analysis. *Clinical Psychology Review*, 33, 1148-1162.

[6] Merlyn Holkar and Polly Mackenzie 2016. Understanding the link between money and mental health. Money and Mental Health Policy Institute.

# Confidentiality, Privacy and Data Management

**IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete “HRP-598 Research Data Plan Review Form.” In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all other sub-sections of section 22.**

**For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using “HRP-598 – Research Data Plan Review Form.”**

**Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data,” which is available on the IRB’s website. In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all sub-sections of section 22.**

**For all other research**: complete the following section. Please refer to [PSU Policy AD95](https://policy.psu.edu/policies/ad95#C) for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State’s Policy AD95 or standards or need a consultation regarding data security, please contact [security@psu.edu](mailto:security@psu.edu).

## Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

|  |  |  |
| --- | --- | --- |
|  | Hard Copy Data | Electronic  Stored  Data |
| Names and/or initials (including on signed consent documents) |  |  |
| All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, |  |  |
| All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older |  |  |
| Telephone numbers |  |  |
| Fax numbers |  |  |
| Electronic mail addresses |  |  |
| Social security numbers |  |  |
| Medical record numbers |  |  |
| Health plan beneficiary numbers |  |  |
| Account numbers |  |  |
| Certificate/license numbers |  |  |
| Vehicle identifiers and serial numbers, including license plate numbers |  |  |
| Device identifiers and serial numbers |  |  |
| Web Universal Resource Locators (URLs) |  |  |
| Internet Protocol (IP) address numbers |  |  |
| Biometric identifiers, including finger and voice prints |  |  |
| Full face photographic images and any comparable images |  |  |
| Any other unique identifying number, characteristic, or code (such as the pathology number) |  |  |
| Study code number with linking list |  |  |
| Genomic sequence data |  |  |
| State ID numbers |  |  |
| Passport numbers |  |  |
| Driver’s license numbers |  |  |

## If storing paper records of research data, answer the following questions:

### Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

No paper copies of survey data will be used in the study.

### How will the paper records be secured?

**n/a**

### How will access to the paper records be restricted to authorized project personnel?

n/a

## If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

Penn State REDCap

Other – Specify - provided and approved database application:

**Penn State OneDrive**

Penn State, College, or Department IT file server

Box.psu.edu (To be retired Sept. 2021; see <https://storage.psu.edu/>)

Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:

Other – Specify the database application or server:

Provide details about the data security features or attach security documentation provided by sponsor or group:

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

## Is there a list/key that links code numbers to identifiers?

Yes - explain how the list that links the code to identifiers is stored separately from coded data:

Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

## Is there a list of people who have access to the list/key?

Yes – explain how access to that list is restricted and why certain persons require access.

No – explain why not:

## Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

Password-protected files

Role-based security

Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

The use of mobile devices or wireless activity trackers to collect identifiable research data must be approved by the Office of Information Security. Before completing this section, please contact [security@psu.edu](mailto:security@psu.edu) to confirm approval.

## Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

No

Yes - answer the following questions:

### Specify the provider of the mobile devices(s)

Supplied by the sponsor

Penn State owned device

A personal device

Other – Please specify source:

* + - 1. Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

**Respondents will use a personal computer, tablet, or smartphone of their choosing to access the online survey and provide responses.**

### Specify the type of data collected on the mobile devices(s).

**Only the responses to survey questions will be collected using their mobile device. No personal identifiers will be asked throughout this survey. No information, identifiable or otherwise, will be collected from their mobile devices outside of the survey**

### Specify the application or website used to collect the data from the mobile device, if applicable.

**Survey data will be collected through PSU Qualtrics and then stored in a secured PSU OneDrive folder, accessible only to the study team.**

* + - 1. Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

**Respondents will be advised to access the survey only from the link provided, complete the survey on their own trusted device, and do so in a private location, as to help protect their own confidentiality beyond the efforts of the study team, as noted in**

* 1. Specify the

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu.

## Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

No

Yes - answer the following questions:

### Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

**No identifiers will be collected from respondents.**

### Specify the type of data collected over the internet or via email.

**Only the self-reported survey responses will be sent from respondents to the study team. No other data will be collected outside of the survey data.**

### Describe the measures taken to protect the confidentiality of the data collected?

**The survey is written as to not collect any personally identifiable information from respondents. Resulting data will then be stored in secure files, accessible only to the immediate study team, as to further protect confidentiality of de-identified, ano**

### Describe how the research team will access the data once data collection is complete.

**Once survey data is collected through PSU Qualtrics, it will be moved and stored in a secure PSU OneDrive file, where it will be accessible to the study team for data analysis.**

### If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

Penn State REDCap

Penn State Qualtrics (de-identified data only)

Other - Please specify:

Application:

URL (If applicable):      

### If the answer above is “Other” contact [security@psu.edu](mailto:security@psu.edu) for approval of an alternative data capture method

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact the Office of Information Security at [security@psu.edu](mailto:security@psu.edu) to confirm whether these requirements are required.

* 1. Specify the

## Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

No - skip to section 22.10

Yes - answer the following questions:

### What will be used to capture the audio/video/images? Give a brief description of content.

Audio – Describe the intended content of the audio recording:

Video – Describe the intended content of the video recording:

Photographs of the subjects – Describe the intended content of the photographs:

3-D Images – Describe the intended content of the of 3-D images:

Other - Specify:

### How will the recordings/photographs/images be stored (electronically or physically)?

### Where will the recordings/photographs/images be stored?

### Who will have access to the recordings/photographs/images?

### Will any of the recordings be transcribed?

Not applicable

No

Yes – indicate who will be doing the transcribing?

### Will the recordings/photographs be used for purposes other than this research study?

No

Yes - specify purpose(s) (e.g., publication, presentations, educational training, future

undetermined research):

* 1. What type of r

## Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

Yes - check one of the following:

The research involves human subjects as defined by the DHHS regulations (See Worksheet

HRP-310).

The research involves collecting or using biospecimens that are identifiable to an individual.

If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

The research involves the generation of individual level, human genomic data.

**Note: If any of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.**

No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?

No

Yes

**Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.**

## What steps will be taken to protect subjects’ privacy interests? (Check all that apply.)

Identification and recruitment of potential subjects follows procedures consistent with privacy standards

Consent discussion and research interventions will take place in a private setting

Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes

Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process

Other – Specify:

## What is the process for ensuring correctness of data entry?

Double data entry to reduce risk of errors

Electronic edit checks to ensure data being entered are not obviously incorrect

Random internal quality and assurance checking of research data

Direct entry by subjects

Other - Specify:

## Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (<http://gds.nih.gov>)?

No

Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

## The European Union (EU) General Data Protection Regulation (GDPR)

### To determine if the research is subject to the GDPR answer the following questions:

#### Will the Penn State principal investigator, or another entity under the Penn State principal investigator’s direction, be collecting, recording, storing, using, any personal data\* of any subjects physically located in the European Economic Area (EEA)\*\* at the time of data collection (even if the subject is NOT an EEA resident) or any EEA citizens? (This includes recruitment through social media sites, use of third party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)

No

Yes (This research may be subject to the GDPR)

#### Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

No

Yes (This research may be subject to the GDPR)

### If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

#### Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

No

Yes

#### Will any of the data be related to criminal convictions or offenses?

No

Yes

**Comments on any of the above responses:**

\* “Personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

\*\* European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

## Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

No - skip the remainder of section 22.15.

Yes - answer the following questions.

Check all that apply:

**Data** are being transferred or disclosed **to** Penn State

What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

Is the third party requiring us to sign a contract regarding the data?

Yes - If Yes, this contract must go through the Office of Sponsored Programs [**https://www.research.psu.edu/osp/overview-pages/data-use-agreements**](https://www.research.psu.edu/osp/overview-pages/data-use-agreements)

No

**Data** are being transferred or disclosed **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data? Dr. Thomas Richardson from the University of Southampton, UK.

**Note: Data transfers or disclosures may require a Data Use Agreement (DUA).**

**Specimens** are being transferred **to** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

**Specimens** are being transferred **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

**Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA).  Please contact the Office of Technology Management for more information.**

### Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies). A de-identified .csv file will be added to a separate secure PSU Google Drive folder. Our research team will then give Dr. Richardson read and download access to this file.

### How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

#### Data being transferred or disclosed to Penn State:

Data are being received in aggregate/metrics (just counts, no individual data)

De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list

Data with identifiers along with the linking list are being received

Other – Specify:

#### Data being transferred or disclosed from Penn State:

Data are being sent in aggregate/metrics (just counts, no individual data)

De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list

Data with identifiers along with the linking list are being sent

Other – Specify:

#### Specimens being transferred or disclosed to Penn State:

De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

Coded specimens with identifiers along with the linking list are being received

Other – Specify:

#### Specimens being transferred or disclosed from Penn State:

De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

Coded specimens with identifiers along with the linking list are being sent

Other – Specify:

### If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

\*None of the following identifiers will be included in the data transferred.

|  |  |
| --- | --- |
| Names | Medical record numbers |
| Initials | Health plan beneficiary numbers |
| Street address | Account numbers |
| City | Certificate/license numbers |
| Driver’s License numbers | Passport numbers |
| State | State ID numbers |
| Zip Codes | Vehicle identifiers and serial numbers, including license plate numbers |
| County | Device identifiers and serial numbers |
| Geocodes | Web Universal Resource Locators (URLs) |
| Precincts | Internet Protocol (IP) address numbers |
| All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death | Biometric identifiers, including finger and voice prints |
| Ages > 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older | Full face photographic images and any comparable images |
| Telephone numbers | Any other unique identifying number, characteristic, or code (such as the pathology number)  Specify: |
| Fax numbers | Study code numbers |
| Electronic mail addresses | Master list linking study code numbers to subject(s) |
| Social security numbers | Genomic sequence data |
|  | Other – specify: |