# IRB-1 Study Protocol

**Protocol Version # and/or Date:**
Protocol Version #2
Date: 8/10/2017

**Study Protocol Title:** Testing an integrated bio-behavioral primary HIV prevention intervention among high-risk people who use drugs

**Clinical Trial/GCP Training**

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes

**Research Plan**

**Purpose/Introduction:** [State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and,

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[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.]

Power was computed for an effect size (d) of 0.37, a small-medium effect size to be conservative, based on similar intervention studies in similar facilities comparing groups in terms of high levels of medication adherence and changes in HIV risk behavior.[4] The computations assume an intraclass correlation (ICC) of 0.500, as we assume conservatively large dependence within participant overtime. Over a 44-month period, 300 participants taking PrEP and enrolled in methadone-maintenance treatment at the APT Foundation (see letter of support) will be recruited and randomly assigned to the two study cells (150 per cell). The criterion for significance (alpha) has been set at 0.05. The test is 2-tailed, which means that an effect in either direction will be interpreted. Given these assumptions (for the effect size, ICC), criteria (for alpha and tails), and plans (for the number of clusters and sample size within cluster), the study will have power of 98.5% to yield a statistically significant result. These same assumptions (for the ICC), and plans (for the number of subjects and time points within subject), the study will allow us to report the effect size (d) with a standard error of approximately 0.089. In order to maintain that power level, we must 288 retain patients at post-intervention, 276 at 3-month follow-up, 258 patients at 6-month follow-up, and 224 patients at 9-month follow-up. Even in the event that only 71% of participants complete the final 9-month follow-up assessment, which would be a conservative estimate based on the previous randomized controlled trials in the same facility among the same patient population, the proposed ample size will still provide sufficient power (94.5%) to detect the expected range of effect sizes.

**For EACH Participant Population State Describe the Study Population(s)**: [Describe the participant population(s) including gender, ethnicity, income, level of education and age range.]

Participants for trial will be included who are: 1) Are 18 years of age or older; 2) Meet DSM-V criteria for opioid-dependence and are enrolled in methadone maintenance drug treatment at the APT Foundation, Inc.; 3) Were confirmed to be HIV-negative and started on PrEP in the past week; 4) Report unsafe injection drug use practices or unprotected sex within the past 3 months; 5) Have a cell phone; 6) Are able to read and understand the questionnaires, ACASI, and informed consent form; 7) Available for the full duration of the study with no anticipated circumstances impeding participation (e.g., pending charges, jail term). Individuals unable to provide consent and who are actively suicidal, homicidal, or psychotic as assessed by trained research staff under the supervision of the PI who is a licensed clinical psychologist in Connecticut will be excluded.

We plan to recruit 60% men and 40% women (18 years or older) in order to adequately represent the proportion of men and women in the New Haven community. Recruiting 60% men and 40% women should pose no problem given that the men constitute 61% of the APT Foundation MMP (Methadone Maintenance Program), the patient population from which the subjects for the proposed studies will be recruited. However, given that women typically represent 39% of APT MMP population, we plan to increase our efforts to recruit women into the methadone treatment program by posting advertisements at the APT Foundation substance abuse treatment program.

Minorities. We plan to recruit 50% English-speaking minorities; 40% African American and 10% English-speaking Latino/Latina. These target figures are representative of African-Americans and Latino/ Latinas in the community.

**Enrollment of UConn Students and/or Employees**: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees

treatment care and being on PrEP will remain constant and the experimental CHRP-BB intervention will be compared to a time-and-attention-matched control condition. We will assess participants at baseline ($T_0$), immediately post-intervention (8 weeks; $T_8$) and follow-ups at 3- ($T_{20}$), 6- ($T_{32}$), and 9-month ($T_{44}$) post-intervention measurement points. This approach will allow us to examine whether CHRP-BB outcomes are superior to the Control condition in the short-term as well as examining the trajectory of PrEP adherence and HIV risk reduction over time. Importantly, this approach will allow a clear examination of the decay and/or emergence of intervention effects.[5] The proposed research is also designed to allow us to precisely examine the relative cost and cost-effectiveness of each intervention with regard to both individual (efficacy: e.g., PrEP adherence, HIV risk reduction behavior) and population-level health outcomes (effectiveness: e.g., new HIV infections prevented, life years gained, quality of life). Importantly, we will also examine the barriers and facilitators to optimal implementation of the CHRP-BB intervention.

All opioid-dependent patients enrolled in methadone maintenance treatment will be referred for initial screening. As another precaution, we plan to screen up to 40% more patients than will be needed to meet the proposed sample size. Therefore 420 patients will be screened (i.e., 9 patients per month). In the screening session, conducted by a member of the research staff, determination will be made as to whether the participant meets study inclusion criteria. If so, the participant will be provided with a description of the study. After meeting eligibility criteria, providing informed consent, verifying comprehension of the terms of the study – including being started on PrEP in the past week, and completing the baseline assessment, participants will be randomized to receive, in addition to standard of drug treatment care: (a) 4 weekly group sessions and the 8-week booster session that comprise the CHRP-BB intervention or (b) 4 weekly group sessions and the 8-week booster session that comprise the time-and-attention matched control condition. Participants will be randomized using a computerized "urn" randomization to ensure adequate representation of women and minorities. This technique modifies randomization probabilities based on prior composition of study conditions and reduces the possibility that imbalances between the study groups on variables such as sex and race will occur by chance. Randomization will be stratified by the presence of moderate/severe NCI levels based on the brief inventory of neuro-cognitive impairment (BINI),[6] to ensure that the proportion of participants at highest risk for poor outcome is equal between intervention arms. The clinicians supervising the MMP will be blind to which intervention the subject is receiving. The standard of care and the intervention conditions will be:

*Standard of Drug Treatment Care.* Participants in both conditions will receive routine services as part of their enrollment in APT's methadone maintenance program, which includes daily methadone and case management consisting of a minimum of one hour of monthly contact with a counselor/case manager.

*Experimental Condition.* Patients assigned to the bio-behavioral community-friendly health recovery program (CHRP-BB) will: (a) receive the standard of drug treatment care, as described above, (b) have started PrEP the prior week, and (c) participate in four weekly 50-minute HIV risk reduction and PrEP adherence groups and one booster session, all led by two facilitators trained and supervised by Dr. Copenhaver, the PI and licensed clinical psychologist. Our theory-based (IMB model of health behavior change),[3, 7] manual-guided, HIV risk reduction and PrEP adherence intervention is an integrated evidence-based intervention that uses a coping skills training approach to primary prevention and is delivered in a small group modality by two trained intervention facilitators using a motivational enhancement therapeutic style to address high risk drug- and sex-related HIV risk behaviors and PrEP adherence. Importantly, the CHRP-BB intervention includes specific behavioral and mHealth strategies designed and tested to accommodate difficulties stemming from moderate to severe NCI[8] (see manual in Appendix). Participants will receive daily text message to remind them to take PrEP. Participants will receive text message at the time as they requested in the "Text Messaging Reminder Timing Determination" form (see attached). Participants will also receive text message for appointment reminders. This directly addresses the otherwise detrimental impact of cognitive impairment on

HIV-positive individuals. These measures have been consistently used in our prior clinical trials,[19-21] confirming high test-retest reliability (.88 to .98).[22]

*PrEP adherence*. This outcome will be assessed using a biomedical and behavioral approach: (1) Biomedical - For the biomedical assessment, which will occur immediately post-intervention and at the $T_{20}$, $T_{32}$, and $T_{44}$ post-intervention follow-ups, we will quantify tenofovir-diphosphate (TFV-DP) and emtricitabine-triphosphate (FTC-TP) in RBC, measured with dried blood spots (DBS; see Dr. Anderson's letter of support) as a well validated adherence measure.[23-26] This test assesses cumulative adherence because TFV-DP in RBC exhibits a 17-day half-life and 25-fold accumulation. This enables assessment of cumulative TFV exposure (adherence) over the preceding 1-2 months for TFV-based regimens. FTC-TP has a shorter half-life (~35 hours) such that detection correlates with recent dosing, similar to detection of tenofovir in plasma. One or two drops of blood will be collected for DBS by using a standard finger-stick with a lancet (DBS-FS) by trained research staff and dried blood spots will be prepared, which will be stored at -20° C within 24 hour of collection. Specimens will be shipped on dry ice to the Colorado Antiviral Pharmacology Laboratory located in Aurora, Colorado (UC Denver-Skaggs School of Pharmacy and Pharmaceutical Sciences, 12850 E Montview Blvd, Aurora, CO 80045). TFV-DP and FTC-TP will be quantified with a validated liquid chromatography tandem mass spectrometry method.[25, 27] (2) Self-reported PrEP adherence will be included in our ACASI battery (see above description) using a visual analogue scale (VAS).[28] The VAS is empirically validated, consistently under-reports adherence, but effectively measures a "difference" in adherence that changes in response to an intervention. (3) In addition, as in our prior studies,[18, 29] we will use pharmacy refill data as an additional objective data source. As used in current studies, a release of information to obtain pharmacy data from both Medicaid and individual pharmacies will be deployed. Thus, we will allow us to triangulate PrEP adherence so that we can assess the correlation (r) between biomedical and self-report measures as well as compare with pharmacy refill data.

*IMB construct measures*. Data collected at all assessment points will include our measure of IMB model constructs,[3] including (a) Information - HIV risk- and PrEP-related knowledge; (b) Motivation - readiness to change and intentions to change PrEP adherence and change HIV risk behavior; (c) Behavioral Skills - PrEP adherence skills and HIV risk reduction skills; and (d) Behavioral Outcomes - HIV risk and HIV risk reduction behaviors and PrEP adherence. Behavioral skills will also be assessed as in prior controlled trials[4, 18, 29-31] by having patients demonstrate (a) the specific steps necessary to properly clean a needle/syringe and (b) demonstrate the specific steps to properly select and apply a male and female condom using replicas. Ratings of videotaped demonstrations of these procedures by staff blind to treatment assignment has shown excellent inter-rater reliability (inter-rater reliability = 0.98).[30] The demonstrated behavioral skills score is derived by calculating the percentage of steps performed correctly on each skill.

*Urine toxicology*. Four-panel (heroin, cocaine, oxycodone, and benzodiazepine) immunoassay (I/A) urinalyses (with confirmation of positive results) will be conducted at $T_0$, weekly during the 8-week intervention phase, at $T_8$, and at follow-ups ($T_{20}$, $T_{32}$, $T_{44}$) to detect the most common illicit substances of abuse in this patient population. As in our prior NIDA-funded studies, urine samples will be shipped to Clinical Science Laboratory Inc. (51 Francis Avenue, Mansfield, Massachusetts 02048) and will be analyzed using the Abbott Tdx method, which has been shown to be a reliable, precise, and cost-effective system.

*Weekly Assessments*. During the 8-week intervention period, weekly urine toxicology will be performed to detect illicit substance use including opiates, cocaine, and benzodiazepine. In addition, a weekly self-report of illicit drug use, other high-risk behaviors, and PrEP adherence will be obtained. All of the self-report measures given at weekly assessments will be administered using ACASI. A similar instrument has been used by our team in an RCT at the research performance site.[19, 32] Using a time-line follow-back

*Intervention Fidelity and Preventing Cross Contamination.* We use several procedures to guard against potential threats to internal validity. First, as part of our NIDA-funded work, we have already developed detailed intervention manuals that include detailed session outlines and all other supporting materials needed to conduct the CHRP-BB sessions and the Control condition session have also been manualized. Second, facilitators will complete pre-session checklists and post-session quality assurance forms. Third, we will audiotape all intervention sessions to monitor the content and time allocation of intervention sessions. Using procedures from prior and ongoing intervention trials,[19, 30, 31, 42] all sessions will be coded for protocol adherence. Fourth, intervention facilitators will meet with the project director and the PI for weekly clinical supervision. Meetings will focus on protocol adherence, resolving issues that arise in sessions, and managing potential "drift". Study participants will not have contact with each other beyond their participation in routine drug treatment services. In addition, when we become aware of relationship partners enrolling in the study, we will force-randomize them to the same condition in order to avoid cross contamination and violation of group independence. If we find that relationship partners constitute more than 5% of participants, we will include couple status as a factor in our outcome analyses.

**Data Analysis**: [For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.]

*Hypotheses related to the specific aims*: This study is designed to test the primary hypothesis for PWUD prescribed PrEP that the experimental intervention (E=CHRP-BB) is significantly more effective vs. the control condition (S: time-and-attention matched intervention), for the primary outcome of high levels of PrEP adherence (e.g., ≥700 fmol/punch or ≥4 pills/week)[25, 26] and secondary outcome of HIV risk reduction behavior. The null hypothesis is that CHRP-BB is not superior to control condition, expressed as $H_0$: $p_E = p_S$, where $p_E$ is the proportion of participants in CHRP-BB who demonstrate high levels of adherence (e.g., ≥700 fmol/punch or ≥4 pills/week)[25, 26] and are free from HIV risk behavior $T_{32}$post-intervention. Our alternative hypothesis is that the experimental intervention is superior to the control condition, and is expressed as $H_1$: $p_E > p_S$. Prior to analyzing treatment effects, the degree of pre-test equivalence between experimental and control groups on key variables (e.g., baseline demographics and clinical characteristics) will be evaluated. Baseline data will be evaluated via t-tests and ANOVAs on continuous items when normal or Kruskal-Wallis when we have a non-normal distribution of those items and chi-square tests of categorical items to evaluate pretest equivalence between and within the experimental and control groups. The presence of moderate/severe NCI will be included as a covariate to control for each of the dependent variables. We will use the Bonferroni approach[43] to correct for alpha inflation with a 0.05 family-wise alpha. Variables in which inequality at baseline is identified will be used as covariates in further analyses to address potential non-equivalence across conditions.[44] Differential attrition analyses will also be conducted on the data set to assess differential attrition by condition between baseline and subsequent measurements. A series of ANOVAs parametric or non-parametric of Condition (intervention, control) by Retention (retained, not retained) will be conducted on continuous pretest measures [45]. Any variable influencing differential attrition will be included as a covariate in subsequent analyses.

*Main outcomes analysis plan*: The framework for testing the study hypotheses will be to compare differences between the two conditions (CHRP-BB vs. Control) on the main outcome variables. Separate logistic regression models will be used to assess the log odds of having high levels of PrEP adherence and being free from injection or sexual transmission risk behaviors at $T_{44}$ post-intervention using intervention assignment as a binary coded predictor while controlling for any potential confounders. As an alternative analytical plan for assessing the impact of the two intervention arms on adherence to PrEP, we will use

questionnaires, and collection of urine sample is minimal and adds no risk beyond those normally associated with methadone maintenance treatment. Assessment measures and content of the intervention will involve sensitive and explicit topics related to sexual behavior and substance use. This is necessary given the nature of the intervention and practices that confer risk for HIV infection. However, participants may feel awkward or embarrassed when hearing about or being asked to provide information related to sexual activity. The consent procedure informs participants that sexual behaviors will be explicitly covered in measures and intervention content. Counseling staff will have been trained to observe for signs of subject emotional distress in relation to topic presentation and to employ techniques that prevent, reduce or minimize embarrassment, discomfort, or atypical distress.

Some participants may experience increased anxiety as a result of participating in the intervention. Realistic sensitization and accurate vulnerability self-appraisal are desirable and necessary to motivate behavior change efforts. The investigator is experienced in presenting risk reduction information in ways that link risk to avoidable and modifiable behaviors and risk reduction to the adoption of behavior changes. Counseling staff will observe participants for evidence of becoming overly anxious and will utilize techniques to assure that threat sensitization and vulnerability perceptions are realistic. Research staff will also be knowledgeable of social services that some participants may need, and will assist participants in accessing local resources in areas such as alcohol and other drug abuse treatment, entitlement, and supports for those in or leaving abusive relationships.

**Benefits:** [Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children). Do not include compensation or earned course credits in this section.]

The potential benefit in this study is in reduction of HIV risk behavior and improvement of adherence to PrEP via the study intervention, which may, in turn, foster improvement in subjects' global functioning. However, subjects may not experience any direct benefits from participation.

**Risk/Benefit Analysis:** [Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.]

Assessment of risks vs. benefits requires some description of the individuals to be treated. Study participants will be opioid-dependent HIV-negative individuals newly starting PrEP and enrolled in the APT Foundation's MMP. They are at high risk for contracting HIV, treatment failure, dropout, and psychosocial and medical problems associated with ongoing substance dependence. Behavioral approaches remain a standard treatment in the majority of drug treatment centers in the US. The study intervention is believed to carry lesser than greater risks and is likely to be of benefit to patients. The assessments confer minimal risks and these are minimized through confidentiality procedures and the used of skilled personnel. We believe we have included adequate safeguards for patients to address the ethical questions, including exclusion of patients at significant risk for suicide, regular contacts with program staff and close monitoring of symptoms, protection of subject confidentiality and procedures to withdraw from study treatments patients who show significant deterioration. Thus, the potential benefits for individuals and society at large are great; and the risk/benefit ratio appears very favorable toward the proposed study intervention.

addressing any unlikely negative impact. Validation and revalidation of the study Informed Consent form by the University of Connecticut's IRB is done yearly and involves Dr. Copenhaver (PI) first submitting a written report to the IRB concerning the course of the study including a full description of any adverse events or other unexpected patient-related issues. This report is reviewed by the IRB before the Informed Consent form is revalidated. In addition, members of the PI's Oversight Committee who are independent of this protocol (Declan Barry, Ph.D., and Marla Genova, M.A.; see attached letters of support from DSMP Oversight Committee members) will review all data collection protocols, data confidentiality procedures, and human participant issues via at least annual meetings convened specifically for this purpose.

**Privacy/Confidentiality Part 1:** [Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

We will make every effort to insure the privacy and confidentiality of the participants. If a participant does not meet the eligibility criteria or choose not to participate in the study, all information that the participant has given us will be destroyed immediately. If the participant chooses to participate, in all of the study records, he/she will be identified by a number and the participant's name will be known only to the researcher. The participant's name will not appear in any publication or be released to anyone without his/her written consent. Participants will be informed in the consent form that they should understand; however, there is a risk that they will be recognized by other patients or staff involved in the study and that they may be recognized as a participant in a research program. This is no greater than the usual risk of identification that occurs in clinical care at the APT Foundation, Inc.

The researchers will keep all study records (including any codes to participants' data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number (e.g. "sequential 3 digit code) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key will be destroyed after 3 years after the completion of this study. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect participants' identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and participants' will not be identified in any publications or presentations.

Data that we collect from the participants may be shared with other researchers in the future, but only after participant name and all identifying information have been removed.

We will do our best to protect the confidentiality of the information we gather from the participant but we cannot guarantee 100% confidentiality. Participants' confidentiality cannot be guaranteed if his/her record is subpoenaed in a court of law or in the event the researcher determines that the participant is a clear and imminent danger to himself/herself and/or others. In addition,

providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]

As in our prior NIH-funded studies, in order to determine whether the participant has the capacity to provide consent, we will have all the potential participants complete the 'Determination of Capacity to Consent for Participation in a Research Study' form (see attached) at the conclusion of the consent process. The form uses the corresponding 5-point scale to document the potential subject's level of understanding of the study protocol. Potential subjects scoring a 4 or 5 on all questions have demonstrated an understanding of the study and are determined to have capacity to provide informed consent. Potential subjects scoring less than 4 on any question have not demonstrated a full understanding of the study and therefore must designate a representative (research proxy) to provide permission on his/her behalf to be enrolled. The assent of the subject should be obtained.

**Parent/Guardian Permission and Assent:** [If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.]

NA

**Documentation of Consent:** [Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).]

See the attached Informed Consent form.

**Waiver or Alteration of Consent:** [The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of signed consent** (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception in research):

- Why is the study considered to be minimal risk?

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.

- Why would the research be impracticable without the waiver? For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.

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# Data Security Assessment Form

**Version # and/or Date: Version #1; 07/25/2017**

**Principal Investigator: Michael Copenhaver** **Protocol#: E17-466**

Student Investigator (if applicable):

Investigators must complete this form when research data is collected, transmitted, or stored electronically. We highly recommend the Guidance for Data Security and Internet-Based Research and Tip Sheet for Completing Assessment Form documents, available in the Researcher's Guide section of the IRB website, be reviewed before answering the questions. The IRB may request a consultation from data security experts from UITS to ensure risks to research participants are minimized and appropriate safeguards are in place. **It is important that all relevant questions are addressed to prevent a delay in review.** If you have any questions, contact the IRB at 860-486-0986.

## Part A – Identifiers to be collected (check any that apply):

**Check any identifiers that will be collected during any phase of the research:**

| | |
|---|---|
| ☒ Name | ☐ Photographic images (images are not limited to images of the face) |
| ☒ Electronic mail address | ☐ Health plan beneficiary numbers |
| ☐ Social security number | ☐ Account numbers |
| ☒ Telephone number | ☐ Certificate/license numbers |
| ☐ Fax number | ☐ Vehicle identifiers and serial numbers, including license plate numbers |
| ☐ Internet protocol (IP) address | ☐ Other (identify and explain): |
| ☐ Medical record number | |
| ☐ Device identifiers/serial numbers | |
| ☐ Web Universal Resource Locators (URLs) | |
| ☒ Biometric identifiers, including finger and voice prints (i.e., audiotapes and digital recordings) | |

Certain dates, age, zip codes or other geographic subdivision that could be personally identifiable per the standards below.

☒ Any 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(mm/dd/yyyy), admission date, and discharge date.

Education Records

☐ Information obtained from the following UConn Education Records or other Personally Identifiable Information in compliance with the Family Educational Rights and Privacy Act (FERPA) such as: Admissions, Financial Aid, Academic, Student Health Service, Student Employee, Student Residence, Disciplinary, and Veteran's Affairs.

☐ **List any other unique identifying number, characteristic, or code to be collected:**

For **ALL** the identifiable data collected above, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant? ☒ Yes ☐ No
Indicate how the coded data will be stored separately from the identifiable data: The researchers will keep all study records (including any codes to participants' data) locked in a secure location. Research records will be labeled with a code. The code will be derived from a number (e.g. "sequential 3 digit code) that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. The master key will be destroyed after 3 years after the completion of this study. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect participants' identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and participants' will not be identified in any publications or presentations.

Will you be collecting any **sensitive data**? ☐ Yes ☒ No If yes, be sure to address in the risk section of the IRB application form and describe steps to minimize any risks.
Data is considered to be sensitive when the disclosure of identifying information could have adverse consequences for individuals or damage their financial standing, academic standing, employability, insurability, or reputation.

Is this study NIH funded and will you be collecting identifiable research data? ☒ Yes ☐ No If yes, please be aware of the following specific requirements in section 2.3.12 Protecting Sensitive Data and Information in Research.

☐ Anonymous data – at no time will any of the identifiers above be collected, including IP addresses
Be sure to provide IRB with the instrument collecting demographic/medical information from participants.

## Part B – How will you collect research data?

**Mobile App** ☒ Not applicable

1. Name of the app:
2. Identify the mobile device platform(s) (IOS/Android/Windows) to be used:
3. Identify who created the app:
4. Whose device will be used: ☐ Personal phone ☐ Researcher provides phone
5. Address how the app is downloaded to the device:
6. Will data be stored on device for any period of time? ☐ Yes ☐ No
   a. If yes, please describe (e.g. queue on phone and then transmit to server, stored on device indefinitely)?
   b. Is the data encrypted on device? ☐ Yes ☐ No
7. How is the app secured on the device:
   a. Is a password or PIN for app required? ☐ Yes ☐ No
   b. Is a password or PIN for the device required? ☐ Yes ☐ No
8. Will the app be able to access other device functionality such as Location, Contacts, Notifications, etc.?
9. Where is data transmitted by device?
   a. How is it encrypted in transit?
10. Address how the data is coded:

a. Are phone numbers or mobile identification numbers stored with data: ☐ Yes ☐ No

11. When data is transmitted from the device, please list all locations where it will reside (even temporarily):
12. Provide any additional information:

**Web-based site, survey or other tool** ☒ Not applicable

UConn Data Storage Options:

☐ UConn licensed Qualtrics ☐ UConn REDCap

☐ If Other, you are required to answer all 9 questions below:

1. Name the site you are using:
2. Who created the site, survey or tool?
3. Where is it hosted:
4. What version of the software is being used, if applicable?
5. How is the data encrypted:
6. Is informed consent being obtained using the same site? ☐ Yes ☐ No
   a. If yes, how is re-identification prevented:
7. Once collection is complete, how will you access the data:
8. Does the technology utilized allow for the explicit exclusion of the collection of Internet Protocol (IP) address of the participant's connection? ☐ Yes ☐ No
   If Yes, will you utilize this option to exclude the collection of IP addresses? ☐ Yes ☐ No
9. If collecting data from minors (<18 years old), does this site comply with the Children's Online Privacy Protection Act (COPPA)? ☐ Yes ☐ No
10. Provide any additional information:

**Wearable Device** ☒ Not applicable

* Also complete the mobile app section above if a mobile app will be used with the wearable device

1. Name of wearable device:
2. Is wearable device **provided** by participant or research team: ☐ Personal device ☐ Researcher provides device
3. Is wearable device **registered** by participant or research team: ☐ Participant registers device ☐ Researcher registers device
4. How will data be transmitted by device:
   a. How is it encrypted while in transit:
5. How is the data coded:
   a. Are phone numbers or mobile identification numbers stored with data?
   b. Will GPS data be collected to identify locations?
6. When data is transmitted from the device, please list all locations where it will reside (even temporarily):
7. Provide any additional information:

**Electronic audio, photographic, or video recording or conferencing** ☒ Not applicable

1. Describe the method of capturing the photograph, video, or audio:
2. Will the photographs, video, or audio be transmitted over the internet? ☐ Yes ☐ No
3. How will the photographs, video or audio be secured to protect against unauthorized viewing or recording:

4. Provide any additional information:

**Text messaging** ☐ Not applicable

1. Are you using the current text messaging available on the device or a separate application: Current text messaging available on the device
    a. If the latter, ensure mobile app section above is completed.
2. Whose device will be used: ☒ Personal phone ☐ Researcher provides phone
3. What is the content of the messaging: Content of text message attached
4. Will messages be limited to appointment reminders? ☐ Yes ☒ No
5. Is the communication one-way or two-way: One-way
6. Is any other technology being used to collect data? ☐ Yes ☒ No
    a. If Yes, describe:
7. Provide any additional information: Text messaging is to remind participant to take their medication.

**By Hard Copy/Paper** ☒ Not applicable

1. Describe hard copy/paper procedures:

Provide any additional information:

## Part C – During research data collection, where/how will research data be stored and how will it be transmitted, if applicable?

- If sharing data outside UConn, it is important that Sponsored Programs Services Contract Office, at spscontracts@uconn.edu, be contacted as early as possible in case a Data Use Agreement or Contract is required.

**Describe how research data is stored.**

1. Server
    - ☐ UConn Managed Server Identify:
    - ☐ PI Department Managed Server Identify:
    - ☐ UConn Health Managed Server Identify:
    - ☐ Other (describe):
2. Cloud File Storage (Note: UConn Google Drive/Google Apps may not be used to store Sensitive Identifiable Human Subject Data)
    - ☐ UConn REDCap
    - ☐ UConn Office 365 (e.g. OneDrive/SharePoint)
    - ☐ UConn Enterprise File Server
    - ☐ Other (describe):
3. Any computers (laptops or desktop PCs) or devices (tablets, mobile devices, portable storage devices) used to access data stored on systems identified in questions 1 or 2 above
    - ☒ UConn owned desktop or laptop, or other device
    - ☐ UConn Health desktop or laptop, or other device
    - ☐ Personal desktop or laptop, or other device (If yes, identify and explain in item 5 below)

    Will research data be stored on the computer or device ☒ Yes ☐ No

If Yes, what product is used to encrypt data?
Is anti-virus software installed and up to date? ☒ Yes ☐ No If Yes, what product and version? Microsoft System Center Endpoint Protection (SCEP) 2012
Is the operating system kept up to date with Windows or Apple updates? Windows

4. Storage of hard copy/paper records.

   ☐ UConn Office - specify state building & office number:

   ☒ Off-site - describe where: APT Foundation. The researchers will keep all study records (including any codes to participants' data) locked in a secure location within APT Foundation.

   ☐ Home Office - describe who and where:

5. Third-party collaborator or sponsor:

6. Provide any additional information:

**Transmission of Research Data (Check All Methods that Apply)**

- ☐ Email
- ☒ Encrypted Email
- ☒ UConn FileLocker
- ☐ USB Drive
- ☒ Encrypted USB Drive
- ☐ UConn Office 365
- ☐ Secure File Transfer Protocol
- ☐ U.S. Mail
- ☒ Courier Delivery Service (e.g. FedEx)
- ☐ Other (describe):

**Part D – Once research data collection is complete (in data analysis), where/how will research data be stored and how will it be transmitted, if applicable?**

- If sharing data outside UConn, it is important that Sponsored Programs Services Contract Office, at spscontracts@uconn.edu, be contacted as early as possible in case a Data Use Agreement or Contract is required.

**Storage of Identifiable Research Data - Address Below:**

1. Server
   - ☐ UConn Managed Server Identify:
   - ☐ PI Department Managed Server Identify:
   - ☐ UConn Health Managed Server Identify:
   - ☐ Other (describe):
2. Cloud File Storage (Note: UConn Google Drive/Google Apps may not be used to store Sensitive Identifiable Human Subject Data)
   - ☐ UConn REDCap
   - ☐ UConn Office 365 (e.g. OneDrive/SharePoint)
   - ☐ UConn Enterprise File Server

☐ Other (describe):

3. Any computers (laptops or desktop PCs) or devices (tablets, mobile devices, portable storage devices) used to access data stored on systems identified in questions 1 or 2 above
   - ☒ UConn owned desktop or laptop, or other device
   - ☐ UConn Health desktop or laptop, or other device
   - ☐ Personal desktop or laptop, or other device (If yes, identify and explain in item 5 below)

   Will research data be stored on the computer or device ☐ Yes ☒ No

   If Yes, what product is used to encrypt data? BitLocker

   Is anti-virus software installed and up to date? ☒ Yes ☐ No If Yes, what product and version? Microsoft System Center Endpoint Protection (SCEP) 2012

   Is the operating system kept up to date with Windows or Apple updates? Yes
4. Storage/transmission of hard copy/paper records. records.

   ☐ UConn Office - specify state building & office number:

   ☒ Off-site - describe where: APT Foundation. The researchers will keep all study records (including any codes to participants' data) locked in a secure location within APT Foundation.

   ☐ Home Office - describe who and where:
5. Third-party collaborator or sponsor:
6. Provide any additional information:

**Transmission of Research Data (Check All Methods that Apply)**

- ☐ Email
- ☒ Encrypted Email
- ☒ UConn FileLocker
- ☐ USB Drive
- ☒ Encrypted USB Drive
- ☐ UConn Office 365
- ☐ Secure File Transfer Protocol
- ☐ U.S. Mail
- ☒ Courier Delivery Service (e.g. FedEx)
- ☐ Other (describe):

## Part E - Archival of research data over time.

# Data Security Assessment Form

1. Who will have access to the data: PI and appropriate collaborators and research staff
2. How will that access be managed: Password-protected research drive/folder with access permissions only for appropriate research personnel
3. Who is responsible for maintaining the security of the data: PI assisted by the Research Coordinator and/or Statistical Analyst
4. Describe your reporting plan should your electronic data be intercepted, hacked, or breached (real or suspected): The research staff will immediately report the occurrence of any suspected events to the PI. The PI will inform all members of the research team, and notify the IRB of such event.
5. Describe what will happen to the electronic data when the study is completed as Federal Regulations require that research records be maintained for at least 3 years after the completion/termination of the study: We will retain all electronic research data for at least 3 years after study completion as required by Federal Regulations.
    a. If children are enrolled, provide your plan for ensuring that the records will be retained until the child reaches the age of 18: N/A
6. For FDA Regulated IND research, the FDA requires that sponsors and investigators retain "records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified." ☐ Yes ☒ No
7. For FDA Regulated IND research, the FDA requires the investigator or sponsor to maintain the records "for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated of completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol." ☐ Yes ☒ No
8. Is this an application where UConn will be the data coordinating center? ☐ Yes ☒ No
9. Provide any additional information:

I certify I have reviewed and am in compliance with the **terms of service** or end user license agreement for all technologies to be used for research activities: ☐ Yes ☒ N/A as no third-party technologies are being used
Has the researcher reviewed the agreement for potential risks to participants such as: (1) giving the vendor permission to capture information from the personal device (e.g., contact list, emails) and track participants' location or (2) the possibility that data may be used for marketing or other activities or sold to another party? ☐ Yes ☐ No

| **Part F - Provide other research data security information if not addressed above.** |
| --- |
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