**RISK Weekly Meeting-1/10/17**

**Recruitment**

* Can RISK recruit with Journey now since DOX isn’t ready to begin recruitment?
* Other recruitment methods? When?   
  -Begin recruitment with Journey asap.  
  -Meet with Susan and Chris to discuss other recruitment strategies asap.

**Compensation**

* Should we compensate participants for call and text logs? -Consider later if participants are deleting a lot of logs from phone.

**Data Storage**

* Sarah’s pilot data (except for beddit) was transferred to the raw data file on the shared drive.-John reviewed. No concerns noted.
* Outstanding Issues
* Beddit Data-John and Susan still need to meet.
* Running Compliance-Didn’t discuss, discuss at next weekly meeting.
* Empatica-Data Files Question (RISK\_001, RISK\_002, RISK\_003, etc)
* EMA
* MOVES
* Global/Carrying iPhone
* Determining Drinking Days since Last Visit

**Finalize EMA Survey**

* Discussion of additional follow-up question when participant reports drinking.

***Is your goal to remain abstinent from alcohol from now on? -***This isn’t necessary anymore. We can get this information based on participant’s reports of alcohol use.

**Crisis Intervention Planning w/ Chris**

* Candace to update John and Susan
* Chris to attend RISK weekly meeting on 1/24/17

**Discussion about privacy surrounding study participation at Intake**

* Consider eliminating or moving to screen -Eliminate for now

**Submission of consent and information sheet update**

* Should we submit this now? -Yes

**Candace’s Schedule beginning June 2017-**Let’s plan to have additional staff trained to be able to run sessions by this time.

**RISK Weekly Meeting-1/17/17**

* **Study Information Sheet for Journey-Approved by John. Final version was printed and given to Chris G. to distribute at Journey.**
* **Review and Discuss Interview Forms and Script-Candace to make changes based upon conversations in meeting and email new versions to John.**
* **Discuss Organization of RISK Study Folder-Began discussion and completed some re-organization. Will continue discussion. Meeting TBD**
* **Discuss New ID Screen Battery-Will complete today, Jill will complete tomorrow-Did not discuss at meeting. Candace and Jill did complete test of battery. Candace assigned John asana task to review battery.**
* **Early Termination Fees-Did not discuss at meeting.**
* **Reminder: Recruitment Meeting with Chris and Susan Tomorrow at 2:00 p.m.**

**RISK Weekly Meeting-1/23/17**

* **IRB ($99 deduction Issue)-Resolved, Remains the same. Participant can get one replacement phone. Participant is able to keep replacement phone if they complete the study.**
* **Discuss “confiscation” of cell phones alternative-IRB change of protocol will be submitted to reflect that we would like to temporarily keep phones of participants when they are unable to transfer their current cell service to our account, or if they have more than one cell phone. Began discussion of possible concerns that may arise from temporarily keeping cell phones and what can be done to minimize risks/address concerns. TBD what specific risk management strategies we will utilize until change of protocol is approved.**
* **Consider follow-up on new locations based on duration of time spent, instead of number of times visited.-John will consider this.**
* **Datagain App Demo-Not likely to use given the bugs that still need to be addressed so that iPhone users can efficiently use the app to upload audio text files for transcription.**
* **Clinical Crises SOP meeting-Will schedule sometime next week. With John, Chris, and Susan.**
* **Termination Fees (Sarah’s Experience)-Lessons Learned: Direct participants to transfer service in person at a corporate store once they complete the study.**
* **Flyers for UHS (Print More w/o back) once they approve flyer.-Didn’t discuss.**

**RISK Weekly Meeting-1/31/17**

* **Clarifications/Lessons/ & Suggestions from Practice Interview**
* **When completing the reminder call, remind them to bring the location and contact forms when they come to their intake appointment. Good plan.**
* **Give them time to complete (30-40 Minutes) at Intake if they forget to bring the forms. Consider giving participants who do complete the forms a few minutes to review them and add additional locations/people as needed**
* **Do we need this question-Do you generally have alcohol in your home? They are likely to say yes since they are newly recovering from alcoholism. Are you trying to see if other people are bringing alcohol into the home? Reword: In the future, do you generally expect to have alcohol in your home? Never/Sometimes/Always**
* **RISK Categories-Add Medium Risk? Add medium risk to location form.**
* **Health Care Category (Why not distinguish between health care and mental health care?) Trying to determine if participant is generally proactive with health needs thus not important if mental of physical health care, will unlikely be able to tell based on address if participant is receiving mental health care vs. general health care as many places do both, PCPs often provide mental health care too-lines get blurred**
* **In Recovery-Is this just for alcohol? Currently not drinking vs. ever in recovery? Obtain information on “in recovery” from alcohol/other substances. We are only concerned about people who are currently in recovery from alcohol or other substances.**
* **Consider removing non-recurrent events-will capture this on EMA-Decided to remove this section from interview form.**
* **AA and NA Meeting Sites for Study Recruitment**
* **Jill obtained list of AA/NA meeting sites in Madison. What’s next? Reported where list is saved (P:\Study Data\RISK\Human Subjects\Recruitment). Will utilize later when we decide that it is time to recruit from the community. John will also use when analyzing data.**
* **Update on “1st participant” Scheduled to complete screen on 2/1/17 at 11:30 a.m.**

**RISK Weekly Meeting-2/14/17**

* **Recruitment at Journey-Questions**1) We do sometimes run into these folks that may meet criteria for alcohol use disorder within the context of receiving care for opioid use disorder, especially medication assisted therapy. In this case, the opioid use disorder would likely be primary for most of our consumers. How do you see these types of people participating in your study? Is this a population that can be of use to you? We are not actively screening out participants who fit this profile, however this is not our target population. Let Andrew from Journey know that we want clients who have alcohol use disorder has their primary concern.

2) I was also wondering if the level/type of treatment that people are getting would possibly be a confounding variable. Does it matter if we refer people that are receiving different types of services, such as individual and group therapy sessions vs psychiatry only?-This is not a confounding variable. It is perfectly acceptable to refer clients receiving different treatment and services.

* **Defining Mobile Health  
    
  NIH:** “the use of mobile and wireless devices to improve health outcomes, healthcare services, and health research.”-Add this one, minus health research to phone screen.

**WHO:** “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.

* **UHS Handout-**Modify to fill page and add pull tabs with study line contact information. Ask Austin to help with this task.
* **Update on RISK Participants**

**3-Total**1-Second half of session to be completed on 2/15/17  
\* Keep emergency phone/both phones if unable to transfer service?  
Do not attempt to transfer Obama phone. Transfer emergency phone if possible. IF unable to transfer either phone, offer to keep both phones for the duration of the study and give participants a new number.

1-Scheduled for Screen 2/17/17 @ 2:00 p.m.

1-Scheduled for Screen 2/22/17 & 1:30 p.m.

* E4 Wristbands (3)-Order new one when all three are in use. We will temporarily stop screening once all three wristbands are in use.
* Data Notes-Review SMS and Call Logs-Reviewed with John and Susan. This task was marked complete in Asana.
* Clinical Crises Mtg. 1:30 p.m. on 2/20/17

RISK Weekly Meeting-2/16/17, **Meeting was cancelled because John had another appointment during the weekly scheduled meeting.**

* **Participant Updates**-2 waiting for intake sessions (Scheduled Dates: 2/23 @ 11 am & 3/15 @ 2:00 pm)  
  -1 scheduled for 2/22-Need to reschedule as she drank since completing phone screen
* **Review UHS advertisement-**Emailed advertisement and put subtasks in asana for John and Susan to review and approve before sending to printing.
* **Has anyone heard of Smart Recovery (Similar to AA, but “Science Based”)?**-Wil-Mar Neighborhood Center  
  -New Self Renewal Center
* **Transferring contacts**  
  -Basic vs. Smartphone
* **Call forwarding**  
  -Obama Phone  
  -Does not allow us to forward text messages
* **Can participants use androids?**
* Beddit
* MOVES
* Audio Surveys (tested on 2/21/17. In TestData folder)
* Daily Surveys via Qualtrics

Need to Discuss:  
-Make sure participant has internet access or a hot spot  
-Reimbursement for monthly cell phone cost  
-Compensation: iPhone or cost of iPhone  
-Getting SMS and Voice

* **Discuss and review draft of phone release agreement-Jill**

**RISK Weekly Meeting-2/27/17**

**Participant Updates**-2 waiting to complete intake sessions (001-3/1 @ 11 am & 002- 3/15 @ 2:00 pm)  
-1 scheduled for screen on 3/7@ 10:30 am (rescheduled from 2/28)  
-1 scheduled for screen on 3/7 @ 9am  
-1 was scheduled for 2/22-Participant cancelled because she drank since completing phone screen  
It was decided that RA will not try to engage participants who have only completed a phone screen. If they miss/cancel an appointment and do not try and reschedule, RA will not call them back. Participant is free to call on their own and reschedule whenever they please.

* **Tomorrow’s intake  
  -**Complete Multidimensional Scale of Perceived Social Support Yes, have participant complete since it was missed at 1st intake appointment.   
  -Sobriety Check-In? Yes, complete. If participant drank, intake must be rescheduled.   
  -Any other issues? None
* **Asana Task-Review of data collected at screen and intake  
  -Ongoing review plan?** John will review screen and intake ID batteries completed to date and check data quality.
* **A few comments on 001 interview:**-Have you drank alcohol with this contact?   
   Clarify: in their presence or with them?

**-**Did not identify any emotionally important days-Identifying time periods was a little challenging

* **Transferring contacts**  
  -Basic vs. Smartphone  
  \*Participants who have not backed-up their contacts via email may need to go to Verizon store for help. RA may need to accompany participant to store as they may be unable to go solo since the account is not in their name.
* **Can participants use androids?**
* Beddit
* MOVES
* Audio Surveys (tested on 2/21/17. In TestData folder)
* Daily Surveys via Qualtrics

Need to Discuss:  
-Make sure participant has internet access or a hot spot  
-Reimbursement for monthly cell phone cost & Compensation: iPhone or cost of iPhone  
Participants who utilize their own smart phone will be compensated as follows:  
**For participants who are not interested in iPhone as Study Compensation:**  
\*$66 (cost of cell phone service) will be added to their monthly follow-up compensation + $ 99 (cost of cell phone) will be given to participant upon study completion.   
  
**For participants who are interested in iPhone as Study Compensation:**\* Participants are given iPhone upon completion of study.  
  
-Getting SMS and Voice from androids-Susan still needs to look into this

* **Discuss and review draft of phone release agreement-Jill**John approved draft with minor changes to be made. 1) Remove liability section 2) We will not send phones via USPS. Participants will have to come collect their phone.
* **Has anyone heard of Smart Recovery (Similar to AA, but Science Based**)?-Yes, John has heard of this.  
  -Wil-Mar Neighborhood Center  
  -New Self Renewal Center

RISK Weekly Meeting-03/07/2017  
  
**Participant Update**

|  |  |
| --- | --- |
| **Completed** |  |
| Phone Screens | 5/5 |
| In-Person Screens | 3/5 |
| Intakes | 1/3 |
| Withdrawn | 1 |

|  |  |
| --- | --- |
| **Scheduled Sessions** |  |
| In-Person Screen | **1**-3/9/17 @ 9 a.m. |
| Intake | **2**-3/14 @ 10:30 am & 3/15 @ 2 pm |
| Follow-up #1 | **1**-3/31 @ 11 am |

* **Update on 001**
* EMAs (missing evening ones)-Have Susan update the rolodex so that participant receives EMA one hour earlier
* Audio Surveys
* Beddit
* Empatica-Issues (not sending)
* MOVES is enabled
* **Staffing Needs**\*Sarah Kittlelson to join project when she begins grad school this coming summer. She will dedicate a minimum of 20 hours a week towards RISK.   
  \*John also shared that the lab plans to hire a full-time tech to begin sometime this summer. The tech is likely to help with RISK. Candace shared that the current undergrad RA Jill is graduating this May and is seeking work in a lab to help with her application to a graduate clinical psychology program. Candace to tell Jill about tech position.   
  \*John will reach out o Esra to see is she is interested in helping conduct the recovery environment interviews.

**RISK Weekly Meeting-3/21/17**Participant Update

|  |  |
| --- | --- |
| **Completed** |  |
| Calls to Study Line | 7 (Journey-2, ACCESS-2, Word of Mouth-3) |
| Phone Screens | 6 |
| In-Person Screens | 4 |
| Intakes | 1 |
| Withdrawn-Change to Discontinued | 1 |
| Referred to Dox | 1 |

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| --- | --- |
| **Scheduled Sessions** |  |
| In-Person Screen | **1**-3/28/17 @ 9:30 a.m. |
| Intake | **2**-3/21 @ 1 pm & 3/23 @ 2:30 pm |
| Follow-up #1 | **1**-3/31 @ 11 am |

Discussion Items

* Empatica order arrived (2 E4s)
* 001-Empatica Issues Persist
* Review Study Protocol Doc.-Interview Section

-Should we develop a data entry check procedure? Yes. Have establish second reviewer procedure.

- Do we need to add interview type to the spreadsheets? No, as we have UTC.

-Woodman’s Question

* Training Standards Development
* After Hours Crises? Chris/Linnea availability? Not necessary as we can always call 911 or access ER as needed. Ideal, but not necessary. Change voice mail for study line to direct callers to contact 911 or ER when in immediate danger. Use language used by PRTC.
* Data Collection and Study Administration Weekly Time Estimates
* Order more iPhones 6’s

**RISK Weekly Meeting-3/28/17**Participant Update

|  |  |
| --- | --- |
| **Completed** |  |
| Calls to Study Line | 7 (Journey-2, ACCESS-2, Word of Mouth-3) |
| Phone Screens | 6 |
| In-Person Screens | 4 |
| Intakes | 3 |
| Discontinued (Use a different term) | 2 |
| Referred to Dox | 2 |

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| --- | --- |
| **Scheduled Sessions** |  |
| In-Person Screen | **1**-2/29/2017 @ 9:30 am |
| Intake | None Scheduled |
| Follow-up #1 | **3** |

Discussion Items:

* Participant Updates

\*100% Compliance from 002 and 003  
\*One reported lapse (002)

\*Long voice notes (002)  
\*Beddit Sleep Times (001 & 002)  
\* Not wearing wristband frequently (001)

* Reconsider colleting household composition data-Add this to the Dem. Measure on the screen battery
* Not capturing non-alcohol/drug tx & prescribed medication for mental health concerns-Add questions to capture this on the MAM measure on the intake battery.
* Do we need to continue to record sessions? -No
* Update on phone transfer to T-Mobile
* Data Collection and Study Administration Weekly Time Estimates
* Review time estimates document and sample calendar
* Sample calendar does not account for:

\*Completion of other tasks

\*Training and supervision of RAs

\*Phone Screening beyond 4 Hours Weekly  
\* 1x Weekly SCID for DOX

Sample calendar shows that RISK is in need of at least 2.5 staff members. Additionally, RISK can also benefit from an undergraduate RA who can commit at least 10 hours a week on RISK.

* Imazing Update-Jill & Susan-Susan to contact Imazing to inquire about UTC.
* Obama Phone Carriers-Should we enroll them? -Depends

-Are they willing to get a new number and have us temp. hold phone, if so, they can enroll in the study.

-Jill states that Obama phones cannot be transferred to other accounts.

**RISK Weekly Meeting-4/4/2017**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| Calls to Study Line | 7 (Journey-2, ACCESS-2, Word of Mouth-3) |
| Phone Screens | 6 |
| In-Person Screens | 4 |
| Intakes | 3 |
| Follow-up #1 | 1 |
| Follow-up #2 | 0 |
| Follow-up #3 | 0 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 3 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 0 |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

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| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 0 |
| Intake | 0 |
| Follow-up #1 | 2 |
| Follow-up #2 | 1 |

|  |  |
| --- | --- |
| **REFERRALS TO DOX** |  |
| Referred to DOX w/o Completing Phone Screen | 1 |
| Referred to DOX after Completing In-Person Screening Visit | 1 |

**RISK Weekly Meeting-4/4/2017**  
Discussion Items

* **Participant Updates:**

- Continued 100% Compliance from 002 and 003  
- Three reported lapses (003)  
- Two reported lapse (002)

Per our discussion at today's meeting, Susan will add the following questions to the EMA Batteries:   EMAM\_1E: Is your goal still to remain abstinent in the future? No Uncertain Yes

This question will only appear if participant answers yes to EMAM\_1: Have you drank alcohol that you have not yet reported?

Candace to contact 002 and 003 to alert them to change in daily EMA surveys. Also, Candace will remind them of opportunity to participant in BMI session at FU #1.

- Continued non-compliance with wristband usage (001)-Request that 001 return wristband at FU#2 if he continues to be non-compliant. No need to continue checking-in with participant about wearing/not wearing wristband.

* **Follow-up #1 Review-**Candace reported that FU#1 went smoothly. Session time: 1.5 Hours
* **Phone Purchases**

- Purchased 3 new iPhone 6s’  
- iPhone 6 is no longer available for purchase through Do IT. The iPhone 6s is the next model

iPhone available for $99.

-Current promotion of free iPhone 6s 32 GB with activation of new line of service

- Bill incentive credit (BIC) ended on 3/31/2107

* **Social Environment Interview**

- Need to add risk level (High, Medium, Low, No risk) to interview form for Home. Missing for 002 and 003

- When Family Other is selected do you want to insert “other,” or have us specify the relationship? Insert “Other.” Add grandparent as kin category on interview form.

- When Parent is selected do you want us to specify mother or father? Others to consider: grandmother vs grandfather, aunt vs uncle, brother vs sister-Not necessary, just specify kin term on interview form. No need to distinguish gender.

* **Revision of Qualtrics Batteries  
  -** Monthly Addiction Monitor

**New Questions:**

1) Who do you live with? Check all that apply.  
-Spouse/Significant Other  
-Child/Grandchild

**-**Parent  
-Other Relative  
-Non-Relative

**Participant will be asked to insert a number for each category selected, except for Spouse/Significant Other**

2) Have you been enrolled in other counseling in the past 30 days (don’t include drug and alcohol abuse counseling0?

-No  
-Yes

**If yes is selected, participant will be asked:**How many days have you attended other counseling in the past 30 days?

3) Have you taken any prescribed other psychiatric medication in the past 30 days (for mental illness other than alcohol and drug addiction)?  
-No  
-Yes

**If yes is selected, participant will be asked:**How many days did you take other psychiatric medication directly as prescribed in the past 30 days?

- Demographics-Create Demographics II Survey with the following questions:  
**1) Do you have living parents (include biological, adopted, or step-parents)?  
-No  
-Yes**

**If yes is selected, participant will be asked:  
How many living parents do you have?  
How many deceased parents do you have?**

**2) Do you have children (include biological, adopted, or step-children)?   
-No  
-Yes**

**If yes is selected, participant will be asked:  
How many living children do you have?  
How many deceased children do you have?**

* **Discuss column change to Audio.xlsx-Changed FileName to MessageName for cell A1. Candace to contact Datagain to update them on change.**
* **RISK Training Back-up Plan-Schedule separate meeting to discuss this item.**
* **SU reports on EMA-Jill-Taken from EMA as it was too burdensome for participant. Will capture at FU sessions.**

RISK Weekly Meeting-4/11/17

* **Participant Updates Since Last Weekly Meeting**
* Two additional lapses reported by 003 (5 total reported lapses). Participant still has a goal of abstinence.
* 7 reported lapses to date
* 002 is beginning to miss surveys delivered during her work day due to poor reception in her building. Participant plans to step out when she can, but may continue to miss a handful of mid-day surveys. Candace to research how text messages are sent and received (via WiFi or Data).
* **RISK Training Back-Up Plan**-Train Susan by first week in May on screen and all follow-up sessions.

-Train Sarah by August-John to reach out to Sara re: her availability to come in for training sessions

-Train new Tech-TBD start date

* **Battery Revisions**
* DEM II added to screen battery & MAM revised in intake and follow-up 1&2 battery
* John & Susan need to preview changes and check for errors in-John completed this task. No errors found. Will review batteries again after used for the first time by a participant.
* DEM II screen battery
* MAM in the intake and follow-up 1&2 battery
* **Empatica File Naming Convention for Zipped Archives**
* Answer from Empatica:  
   **T**he convention is as follows: [Device SerialNumber] [yymmdd-HHmmss]. The date is local time zone-John viewed files from 001 and verified that the time is UTC not local time. Candace to add file naming convention to the study protocol document. Example: A00b1b\_161104-112253.zip  A00b1b (Device ID)\_161104 (Date)-112253 (Time)
* Let’s Review Our Files:

- Extra Meeting-001: 3/15/17 test sessions would have taken place around the 10 to 11 am hour [Device ID: A00B1B]

-Intake Date-002: 3/23/17 the test sessions would have taken place around the 4 or 5 pm hour [Device ID: A00852]

-Intake Date-003: 3/21/17 the test sessions would have taken place around the 3 or 4 pm hour [Device ID: A009BB]

* Reminder-Empatica has API Access-John may consider getting API access in the future.

RISK Weekly Meeting-4/25/17

* **Participant Updates**
* 003 is out of the hospital and scheduled for her first follow-up on 4/26/17
* 002 completed her first follow-up on 4/21/17

-Added 4 New Locations

-“Witching Hour” 3 am-4 am

* 001 has not been completing EMAs since 4/20/17. He needs to install update on his phone to begin receiving text messages again.
* Updated Raw Data Folder Prior to Follow-up #1 for 002

-MOVES (Overwrite?)

-EMA Morning and EMA Later

-Empatica

* Compliance
* Are the scripts ready? -No
* Training
* Jill N. has completed training on clinical SOPs, phone screening, and data compliance checking. In progress: Screening Session
* Susan S. scheduled to meet 2x this week to begin follow-up training
* Staff and Participant Dynamics-Are supportive and encouraging comments OK, or should we remain as neutral as possible?-It is OK to respond to participants in a supportive and encouraging manner when the situation calls for it.
* Candace out all day 4/27/17 for a CEU training from 8 am-4 pm

**RISK Weekly Meeting-4/25/2017**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| Calls to Study Line | 8 (Journey-2, ACCESS-3, Word of Mouth-3) |
| Phone Screens | 7 |
| In-Person Screens | 4 |
| Intakes | 3 |
| Follow-up #1 | 2 |
| Follow-up #2 | 0 |
| Follow-up #3 | 0 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 3 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 0 |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

|  |  |
| --- | --- |
| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 0 |
| Intake | 0 |
| Follow-up #1 | 1 |
| Follow-up #2 | 2 |

|  |  |
| --- | --- |
| **REFERRALS TO DOX** |  |
| Referred to DOX w/o Completing Phone Screen | 1 |
| Referred to DOX after Completing In-Person Screening Visit | 1 |

**RISK Weekly Meeting-5/10/17**

* **Participant Updates**
* Three people on study
* All three study participants have completed their 30 day follow-up interviews
* One study participant (001) has completed his 60 day follow-up interview
* 001 continues to have a lot of missing data (Beddit, EMAs, Emaptica)
* 001 returned Empatica
* 001 Disabled MOVES app for the first time
* 002 reported two new lapses since we last met
* **Recruitment ideas to try this month**
* Facebook Ad
* Community Filer at 1-2 AA/NA Meeting Sites
* **Beddit Log-In**
* The beddit log-in page is currently not working
* Inquiry email sent to beddit customer support
* **EMAs**
* Does it matter if participants are completing the wrong survey, but at the appropriate time. Ex: A participant completes a morning EMA survey at 8:00 am on 5/4, however it was the morning survey from 5/3.

-When participants adjust their awake/bedtimes the send time, still shows the original sent time. Ex: A participant used to complete his bedtime EMA at 7 pm (1900), however the bedtime EMA was adjusted to be sent at 6 pm (1800) but the time still shows a 7 pm (1900) sent time. When the participant completes this survey the completed time displays earlier than the sent time.

* **Stray Data Files for 001 and 003**
* Review and delete/organize files
* **Study Protocol to Collect SMS and Voice**
* Susan to update study protocol document with revised/new procedure for collecting and storing SMS files
* Where are the SMS and phone logs for 002 (Android User)?
* Carbonite time zone for time stamps-any updates?
* Can we see if a participant has blocked a phone number?
* **Data Log and Qualtrics Recoding Values Project**

-Do we need to adjust values recorded in the data log?

* **Adding questions to the Monthly Addiction Monitor**
* Have you lost someone close to you in the past 30 days? Who?
* Have you had a near death experience in the past 30 days?
* **Update Demographics Info at Intake, FU #1 and Fu#2**
* Has your employment status changed in the last 30 days? How?
* Has your martial status changed in the last 30 days? How?
* **Review Qualtrics Database for Phone Recruiting**
* **Candace out next week for vacation 5/15-5/19**

**RISK Weekly Meeting-5/10/17**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| Calls to Study Line | 8 (Journey-2, ACCESS-3, Word of Mouth-3) |
| Phone Screens | 7 |
| In-Person Screens | 4 |
| Intakes | 3 |
| Follow-up #1 | 3 |
| Follow-up #2 | 1 |
| Follow-up #3 | 0 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 3 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 0 |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

|  |  |
| --- | --- |
| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 0 |
| Intake | 0 |
| Follow-up #1 | 0 |
| Follow-up #2 | 2 |
| Follow-up #3 | 1 |

|  |  |
| --- | --- |
| **REFERRALS TO DOX** |  |
| Referred to DOX w/o Completing Phone Screen | 1 |
| Referred to DOX after Completing In-Person Screening Visit | 1 |

**RISK Weekly Meeting-5/23/17**

* **Participant Updates**
* Three people on study
* All three study participants have completed their 30-day follow-up interviews
* Two study participants (001 & 002) have completed their 60-day follow-up interviews
* 002 reported one new lapse since we last met
* 003 reported three new lapses since we last met
* **Training Update**
* **Recruitment**
* Facebook Ad activated on 5/19/2017
* Should we reach out to Journey and Access?
* **Beddit**
* The beddit log-in page (cloud account) continues to be inactive
* Susan is still able to access sleep data via API and plans to download data for current participants today
* Jill is currently investigating how to access beddit data going forward. Specifically, she is trying to confirm whether our current API access with remain unchanged.

**Beddit Issues Reported by Participant 002:**  
Participant 002 reports that she sometimes has difficulty getting the beddit device to connect. She eventually gets it to connect by unplugging it from the powercube/directly from the outlet and then reconnecting it. It has also not recorded her heart rate for the last week and a half. It did not record her time slept one day in the last month.

* **EMAs**
* Participant 002 reports that she has received multiple "bedtime" surveys at varying times.
* 003 has reported receiving late “bedtime” surveys.
* Susan is looking into these issues
* **Issues with Audio EMA Delivery**
* 4 undelivered messages from 002
* **Empatica and Firmware Updates**
* Should we disable the firmware update on Empatica Manager?
* Participant 002 reports that she has been asked to complete a firmware update for her wristband. She reports that she completed it, however the Empatica Manager software continues to ask her to complete an update when she goes to upload her data.
* **Study Protocol Changes**
* Separate amount for Audio EMA Surveys
* Should we offer a study completion bonus?
* **Data**
* MOVES Data-Has then been reviewed yet?
* Data Transfer and Updates
* Checking Compliance Updates
* **Adding questions to the Monthly Addiction Monitor**

**RISK Weekly Meeting-5/23/17**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| Calls to Study Line | 8 (Journey-2, ACCESS-3, Word of Mouth-3) |
| Phone Screens | 7 |
| In-Person Screens | 4 |
| Intakes | 3 |
| Follow-up #1 | 3 |
| Follow-up #2 | 2 |
| Follow-up #3 | 0 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 3 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 0 |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

|  |  |
| --- | --- |
| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 0 |
| Intake | 0 |
| Follow-up #1 | 0 |
| Follow-up #2 | 1 |
| Follow-up #3 | 2 |

|  |  |
| --- | --- |
| **REFERRALS TO DOX** |  |
| Referred to DOX w/o Completing Phone Screen | 1 |
| Referred to DOX after Completing In-Person Screening Visit | 1 |

**RISK Weekly Meeting-6/6/17**

* **Participant Updates** 
  + 001 completed final visit on 6/5/17
  + 002 Returned Empatica wristband because it wasn’t “keeping a charge.”
  + 005 Intake scheduled for 6/19/17
* **Training Update**
* Susan is fully trained on Follow-up #1 and #2
* Jill is on her way to being fully trained on the screen
* Jill is shadowing all sessions being run
* **Recruitment**
* The facebook advertisement was successful.
* 1 screen completed and intake scheduled (005)- inquiry from facebook
* 1 new ACCESS referral today (phone screen not completed)
* 6 screening sessions scheduled
* 4 people waiting to be screened
* 8 weeks without alcohol?
* Phone meeting with Beth from ACCESS is scheduled for Monday, 6/19 at 2 p.m.

Talking points?

* **Beddit**
  + Consent to updated terms of service and Apple’s privacy policy has been accepted for:

[uwarcrisk+001@gmail.com](mailto:uwarcrisk+001@gmail.com)

[uwarcrisk+002@gmail.com](mailto:uwarcrisk+002@gmail.com)

uwarcrisk+003@ gamil.com

* + API Access= “no plans to change the API access immediately”
  + Should we explore “back-up” sleep sensors?
* **Compliance Discussion**
* **Audio File Transcription**
  + Transcription service does not include ums, ahs, etc. is this an issue?
  + Inaccurate transcription
* **Empatica Firmware Updates**
* “Fixed” Device # A00852-Firmware Issue
* Must leave firmware enabled on Empatica Manager
* Getting Sessions from Empatica Connect
* **Reallocation of study bonuses**
* $40 for carrying the cell phone-change to:

-$20 for carrying the cell phone

-$20 for completing the daily audio EMAs

* **Motivational Enhancement Therapy**
* Should we pay participants for the 30 minute session?
* Documentation of session
* **Evening Study Visits**

Issues:  
\* M.E.T Issue  
\* Manpower  
\* Initial Visit

**RISK Weekly Meeting-6/6/17**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| In-Person Screens | 5 |
| Intakes | 3 |
| Follow-up #1 | 3 |
| Follow-up #2 | 3 |
| Follow-up #3 | 1 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 2 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 1 (After Completing Screening Session) |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

|  |  |
| --- | --- |
| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 6 |
| Intake | 1 |
| Follow-up #1 | 0 |
| Follow-up #2 | 0 |
| Follow-up #3 | 2 |

**RISK Weekly Meeting-6/13/17**

* **Participant Updates**
* Three scheduled intakes (6/14, 6/15, 6/19)
* 2 Tablets Needed (Expected to Arrive tomorrow)
* **Compliance Discussion**
* **Audio File Transcription**
  + Datagain agreed to include filler words. Ex: ums, ahs, etc.
  + Inaccurate transcriptionExamples-Jill
  + Inconsistent identification of inaudible sections-Jill
* **Reallocation of study bonuses for recently consented participants**

**-**Should we tell them about change at intake?

* **Sub ID Assignment System**
* **Management of Raw Data**
* **UTC timestamp issue and how it will impact time stamps already entered for the interview data**
* **Recruitment & Race**

**RISK Weekly Meeting-6/13/17**Participant Update

|  |  |
| --- | --- |
| **COMPLETED** |  |
| In-Person Screens | 7 |
| Intakes | 3 |
| Follow-up #1 | 3 |
| Follow-up #2 | 3 |
| Follow-up #3 | 1 |
| Subject-Withdrawn (by Subject) Prior to Enrollment | 2 |
| Subject-Withdrawn (by PI or Study Team) Prior to Enrollment | 0 |
| Subject-Withdrawn (by Subject) After Enrollment | 1 (After Completing Screening Session) |
| Subject-Withdrawn (by PI or Study Team) After Enrollment | 0 |

|  |  |
| --- | --- |
| **SCHEDULED SESSIONS** |  |
| In-Person Screen | 3 |
| Intake | 3 |
| Follow-up #1 | 0 |
| Follow-up #2 | 0 |
| Follow-up #3 | 2 |

**RISK Weekly Meeting   
July 19, 2017**

* **Participant Updates**
* ON STUDY: 7
* Next Intake: 7/25/17=@ current capacity
* 012-“Ineligible”
* 003-Quick Update
* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 005-008-Terminate 008 at next follow-up appointment  
  \* Jill’s Caseload: 009-011 & 013
* **Travel and Compliance-Utilize devices as much as possible. Ultimately, it is participant’s choice.**
* **Work and Compliance**
* **Beddit API-Expiring -Jill to contact Apple and beddit to try and get a date when the API will expire.**

Dear Beddit API Users,

Thank you for signing up to use Beddit’s API and for your feedback thus far! We have recently shifted our focus and as a result, will be retiring our Beddit web API.  
  
This means that Beddit users can no longer grant your application access to their data (using OAuth2).

Best,  
The Beddit Team

* **Datagain-Audio File Transcription**
* **No transcripts have been sent since 6/8/17-Send email requesting that they modify transcription to include consistent documenting of inaudible portions, and non-verbal sounds. Also, request that they add a column for transcriber.**
* **Missing Empatica Sessions-Jill to reach out to Empatica support again to try and obtain missing sessions.**
* **Phone and Porting Numbers-Should we discontinue offering to port numbers**? -Not now. Will reassess after the last three phones have been used by participants.
* **Recovery Environment Interview Revisions**
* Are they supportive/unsupportive/mixed/neutral of your recovery goals? \* Many of the participant have not told friends and family about their recovery goals so they are answering in general if this person supportive, etc, and if they think they would be if they knew about their recovery goals.
* Should we ask: Does x know about your goal of sobriety?-Yes
* Update Contact Log-Review New Form-Yes, begin to use
* **Update on Training**
* Jill is fully trained on screen
* Partially trained on intake (just needs to be trained on recovery environment interview)
* Will begin training of follow-ups this month
* Ideally, Jill will be fully trained by end of July
* Chris G. to continue training on suicide risk assessment
* MET Training-Hold off on this for now due to lack of clinical experience. MET is not as structured as the SCID.
* SCID Training & Jill-John gave OK for Jill to be trained. Candace to reach out to Jesse and Chris for OK.
* **Ordering More Equipment**
* Tablets-Order 4 More
* E4s-Order 4 more E4’s
* Computer Sleeves
* **Study Handouts**
* Sending Audio Text Messages-Yes, begin to use
* Troubleshooting Handout-For study staff use only
* Take-Home Checklist-Yes, begin to use
* **Change of Protocol**
* Consider Payment for Text & Phone Logs-Can’t do this as we won’t be able to determine % of undeleted phone and text messages.
* We need to change payment schedule or submit PIR for final visit-We will mail final payment to participants for amounts over $225. [Decided after the meeting to pay up to $240 since it is written in the consent form.]
* **Additional Visit Tracking-Should we do this?-Not necessary**
* **Consider adding family history of alcoholism or substance abuse to screening batteries-Assign John an asana task to add question Re: family history of alcoholism and substance use**
* **Compliance Scripts-Update?-Candace to schedule separate meeting to discuss this issue.**

**RISK Weekly Meeting  
July 24, 2017**

* **Participants**
* On Study: 7
* Next Intake: 7/25/17
* Next Screen: 8/1/17
* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 005-008  
  -Still no word from 008
* -008 and MOVES  
  \* Jill’s Caseload: 009-011 & 013  
  -009 and Streaming -No, due to high likelihood that the band will disconnect from the app. Troubleshoot first.
* Recruitment Goals 200 people in 3 years=66 people each year=16-17 people on study every 3 months
* **001 and Phone Transfer**
* **Changes to EMA Delivery Times**

\*Enter in new time in the sleep time log (make sure new time stamp is also entered)-Susan will do this when she makes changes to the EMA surveys.

* **Phone Screen Modification**
* Adding an additional eligibility question to account for phone numbers that cannot be ported (Obama Phones, Trac Phone, and Prepaid Phones)-May be more of a discussion rather than a direct question. We will likely need to add a few questions to get the answers we need to determine their eligibility. Possible questions: Do you have a smart phone? Is it portable? Are you willing to port your number?
* **Beddit**
* API Expiring
* Alternatives-Jill to explore alternatives and share with study team. Jill to make a spreadsheet of alternatives and include cost, battery life, and what it measures. Jill too look into getting sleep data from phone.
* **Empatica**
* Missing Sessions-Still not resolved. Jill to continue to reach out to Empatica.
* **Qualtrics**
* Qualtrics SOPs-Jill to be with screen only. Jill to incorporate the SOP with the session form. We will move on to the other sessions after the kinks have been worked out.
* **Recovery Environment Interview**
* Adding a question: What time/times did you typically drink?-No need to add this question. We can ask on our own if needed and then add it as a risky time point.

\*011 Anomaly

* **Compliance Scripts-**Did not discuss
* **Data Log Usage-John**Going forward, we will notify John when we add items to the data log. We will also make it part of our project meetings to review items added to the data log.

**Risk Weekly Meeting   
August 2, 2017**

* **Compliance Scripts-Jill to bring compliance information for participants 1-3-**Jill to check compliance information for 001 against R compliance scripts for 001. Update John via Asana.
* **Participant Updates**
  + On Study: 6 (7 with 008)
  + Briefly Discuss Enrolled Participants/Participant Compliance:  
    \* Candace’s Caseload: 005-008 & 014  
    \* 014 has a Google voice #, can we enroll her?-No   
    \* Jill’s Caseload: 009-011
  + Enrollment Goal: 17 on study every 90 days
* **Should we continue to offer porting?** -No, as we need to maintain participants on our line for 1 year (participants who fail to transfer service upon completion of study)  
  Discuss recent email from DoIT-Cellular Services
* **Should we move to only using iPhones in the future? -**Too early to make decision on this itemIssues with Android and third-party apps – especially when moving away from external sensors
* **Sleep Quality Data**
* Beddit and API Access-Available through December 2017
* Beddit and Cloud Access-Not available
* Sleep Cycle-Fine for Apple, need to test out more with Android devices
* **MOVES-Update on connecting participants to Craig’s downloader app**
* 010 is still not connected to the downloader app?
* Downloads-Complete weekly
* **Empatica**
  + Will we continue to use the band?-Not sure yet
  + Missing sessions-Jill will continue to try and get missing sessions from Empatica
  + Issues with band-Returning two bands-Jill returned two bands to Empatica to repair
  + Cancellation of recent order-No update yet
* **Change to Demographics Response Option for the Following Question:**  
  DEM\_6 What is your current employment status?  
  \* Temporarily laid off, sick leave, or family leave (instead of maternity leave)-No need to change maternity leave to family leave
* **Recovery Environment Interview Questions-See list of Questions**

\*No need to enter in interview data for 008

* **Documenting vacations-**Begin documenting participant reported vacations in separate Excel document. Distinguish in-town vs out of town vacations
  + Helpful in knowing when participants may not be able to complete study activities
  + Helpful in knowing when participants may be at risk, even if they do not identify it as a Risky time-period (vacations are stressful)
  + Applicable to the study and use in the “real world”
* **Change of Protocol-**Not yet
* Sleep Cycle App
* Compensation Change
* Phone records from Verizon for participants who ported their numbers
* Other ?
* **Can we purchase beverages to offer to participants?-**Yes
* **Clinical Training**
* MET Sessions for RISK-Candace-Training date with Chris is set for 8/10/17 at 9:30 am
* SCIDs for Dox-Candace-Candace will not commit to doing SCID for DOX on a regular basis. Candace will be available to complete SCIDs through mid-September, and then as needed after that.
* SCIDs for Dox-Training in Progress-Jill
* **Data Log Check-In**Has anyone added anything to the data log since our last meeting?-No one has added new items to the data log.

To Do:

* Test out Signal Survey (Jill & Candace)
* Susan to test how to obtain sleep cycle data from her Android device
* Alpha Test Sleep Cycle for Androids (Candace and Susan)
* Check compliance information for 001 against R compliance scripts for 001. Update John via Asana. (Jill)
* Send back recent order of tablets to Amazon (Jill)

**Risk Weekly Meeting   
August 21, 2017**

* **Participant Updates**
  + On Study: 7
  + Briefly Discuss Enrolled Participants/Participant Compliance:  
    \* Candace’s Caseload: 005-007 & 015 \*008 Update  
    \* Jill’s Caseload: 009-011
* **Compliance Scripts**
* Inaccurate physiology for all participants
* Accurate for EMA for off-study participants
* Inaccurate EMA for on-study participants
* **Sleep Quality Data**
* Sleep Cycle Update

\* Unable to get data from androids

\* Does not measure sleep as well as beddit (according to Susan)

* **Signal Survey Update**
* iPhone not receiving audio messages from android-Candace to investigate further
* **MOVES**
* **Update on connecting participants to Craig’s downloader app**

\* All participants are connected to the downloader app

\* Can we add a log-out option-Discuss at next meeting

* **Should we have participants remove app from phone at FU#3-**Discuss at next meeting
* **Empatica**
  + Will we continue to use the band?-No, we will discontinue use of the wristband. The next enrolled participants will not use the wristband, and current participants will use until their next scheduled follow-up appointment.
  + Still missing sessions-Email sent to Empatica
  + Received refund for 2 bands ($3, 964.81)
  + Waiting for information on 2 bands that we returned for repair-Email sent to Daniel Bender
* **EMAs**
* Is the time a participant completes the audio voice message significant? -To discuss at next meeting
* If participants no longer have a goal of sobriety, should we ask a follow-up question?-To discuss at next meeting
* **Family History for Alcoholism-Do you still want to add a question to the screening battery?-**We will not be adding this measurement
* **Raw Data Folder**
* Can we create a folder within the raw data folder to store off-study participant data? -No
* **Clinical Training**
* MET Sessions for RISK-Candace-Training began. Two more sessions need to be completed.
* MET and consent to audio record sessions-Hold…Chris does not plan to train Heather or Jill on MET for a while. If he decided to do so, we will discuss COP.
* SCIDs for Dox-Candace added time slots to research availability calendar.
* SCIDs for Dox-Training in Progress-Jill
* **Phone Screening**
* Plan: Hire a phone screener prior to next Facebook advertisement being posted.-Yes
* Phone recruiting database and completed screens prior to its development-Yes
* **Data Log Check-In**Has anyone added anything to the data log since our last meeting on 8/2?

To Do:

* Jill to send EMA percentages for participants 001, 002, and 003 to John
* Candace to schedule meeting this week to discuss COP
* Candace to look into iPhone receiving texts from non-iPhones
* Jill to email beddit to inquire about the ability to access data directly from iPhone-Draft to be sent to John first
* Have Jill enter in phone screens completed prior to development of phone recruiting database-First participant contact and Lab Contact (Passed Screen)
* Change weekly meeting to Thursday on RISK calendar beginning 9/7 meeting will be held on Thursdays at 11 am

**August 24, 2017  
RISK Meeting**

**Sleep Quality-We will continue using beddit. Susan to purchase additional devices asap.**

* **Beddit vs Sleep Cycle**

**Survey Signal-Susan is still waiting to hear from tech support. Survey links not working on Jill’s iPhone.**

* **What’s up?**

**EMAs**

* Is the time a participant completes the audio voice message significant?-No, they can complete anytime during the day.
* If participants no longer have a goal of sobriety, should we ask a follow-up question?-Did not discuss

**MOVES  
Downloader and Expert GPS Program**

* Missing dates that were present in prior downloads-John to contact Craig to address problem.
* Can we add a log-out option?
* Should we have participants remove app from phone at FU#3-Not necessary. Show them how to disconnect from app if they ask.

**Change of Protocol Items-**Wait to discuss COP at separate meeting.

* No longer offering to port numbers
* Offering non-smart phones users the use of study iPhone if they are willing to get a SIM card with their current number to use in the study iPhone
* Eliminate Use of Wristband

**Compensation Changes**

* **Compensation for using own cell phone: $297**
* Reimbursement for use of cell phone service-$66 a month (3 Months) =$198
* Bonus for Study Completion-$99 ($99 or iPhone if they inserted their own SIM into one of our phones)
* **Compensation for EMAs**
* Audio: $25/monthly=$75
* Qualtrics: $25/monthly=$75
* **Eliminate Use of Wristband**
* $45 deducted from total study compensation

**Old Compensation Package**  
Total Amount: $842

* less $45 for wristband:

**New Compensation Package**  
Total Amount: $800

* Use of Cell Phone: $300 ($67/month + $99 bonus)
* Office Visit Time: $230 (11.5 hours Max Estimate)

\*Screen 3 hrs. \* Intake 4 hrs. 3 Follow-ups: 4.5 =11.5 Hours

* Carrying Cell Phone: $45 ($15/monthly)
* Voice Text Messages: $75 ($25/monthly)
* Daily Surveys (Qualtrics): $75 ($25/monthly)
* Sleep Monitoring: $45 ($15/monthly)
* GPS: $30 ($10/monthly)

Add in the homework: $40  
Bus Pass Value ($8)

“Total compensation is not changing”**RISK Weekly Meeting  
August 28, 2017**

**Participant Updates**

* On Study: 7
* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 005-007 & 015   
  \* Jill’s Caseload: 009-011
* 3 people waiting to complete phone screening

**COP Submission Update-Susan**

**Survey Signal Update-Susan -**Still waiting to hear back from tech support

**RISK Advertisement**

* Facebook-Launch of ad as soon as COP is approved
* RISK Flyer-Print more as soon as COP is approved

**Phone Screening for RISK**

* One phone screener hired for RISK/DOX
* Can we train Megan S. to complete phone screening? Yes

**New Weekly Meeting Time**

* Thursdays @ 11 am beginning 9/14

**Evening RISK Visits**

* One evening RISK day per week Jill committed to working one evening day each week as needed to complete follow-up interviews
* When will Sarah start working on RISK? Can she commit to working one evening each week?
* Follow-up appointments only Fine for now, this may need to change in the future.

**Data Log Check-In**Has anyone added anything to the data log since our last meeting on 8/24? -No

**RISK Weekly Meeting   
September 14, 2017  
  
Participant Updates**

* On Study: 7

Completed Interviews:  
-Intake: 7/7

-Follow-up #1: 6/7

-Follow-up #2: 4/7

* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 005-007 & 015   
  \* 001 and lost cell phone-Call back and give guidance on how to access find my iPhone via icloud  
  \* Jill’s Caseload: 009-011
* 2 people waiting to complete phone screening. Should we complete phone screening, or wait until after IRB COP approval? Complete screening now. Will reconsent any participants we enroll prior to COP approval.

**COP Update**

* IRB Meeting on 9/26/17
* Recording of MET sessions and consent form-We won’t add it to the consent form, but we can add it to the study overview script.

**Sarah’s Role on RISK**

* Lab Work Hours: Will vary
* Tasks:  
  \* Running Sessions/Caseload 2-4 participants  
  \* ? Sarah will have no additional task on RISK at this time.

**Recruitment**ACCESS & Journey

* Should we contact them to let them know that we are no longer giving away cell phones? Not necessary.
* Upcoming Follow-up with Elizabeth @ ACCESS re: recruitment-Not now, wait a bit longer.

**MOVES Data**

* Should we continue weekly downloads of GPS data?-Yes, as there will be no automatic downloads for some time. Make sure that all the expected dates are there before you delete the old file.

**EMAs**

* If participants no longer have a goal of sobriety, should we ask a follow-up question? No
* Signal Survey Update-Make high priority!

**Interview Data**

* **Data Entry Questions**

1. Do you want to distinguish between family other and other for contact type? Yes, note family other in spreadsheet to distinguish from other.
2. Should we leave the fields that don’t pertain to business contacts empty or should we enter in not applicable, etc. Leave blank
3. Is the “end date” relevant? No

**If a participant makes a change to their risky time periods, or adds a risky time period, the RA must add the new risky time period to the participant's subid\_Times Excel spreadsheet with the new time stamp, and re-enter in the previously reported time-periods that are still relevant.**

**If a participant changes the risk level of a location the RA needs to enter in the location again with the changed risk level.**

**Updating Follow-up #1,2 & 3 ID Batteries**

* The burden measure needs to be updated. The wristband questions need to be removed.   
  When should we do this? We will continue to use the measure to capture the participants that are still using the wristband. The participants that are not using the wristband will have to complete the wristband questions. A note will be added to the data log to indicate that the responses for participants that are not using the wristband need to be deleted. We will delete the wristband questions from the battery once there are no more study participants using the wristband.

**Training**

* Jill-SCID Training in Progress-Will complete by the end of September 2017
* Candace completed MET Training on 9/13/17-Sarah K. will eventually be trained.
* Jill began training with new phone screener (Alyssa)
* Megan trained to transfer audio files, review audio transcripts, and enter in interview data

**Data Log Check-In**Has anyone added anything to the data log since our last meeting on 8/28?

Yes, Jill add information about 009’s text message logs. John reviewed this entry.

To Do:

* Post Facebook ad prior to COP approval
* Begin training Sarah how to run study sessions
* Add recorded MET sessions to the study overview script
* Update participant interview files as needed to reflect changes to data entry changes for risky time periods and locations
* Update participant interview files as needed to distinguish between family other and other

**RISK Weekly Meeting  
September 21, 2017**

**OneReach and 009**

* Next steps?-We need to report event to IRB. Susan to begin drafting reportable event today.
* Survey Signal Update-Susan & Jill-Issues still need to be worked out! This task is priority.
* Rule-Out Criteria -Needs further discussion.
* Should we begin to ask participants if they have ever been diagnosed with a mental health disorder?

Nothing Beyond the First Bullet Point was Discussed   
  
 **Participant Updates**

* On Study: 5

Completed Interviews:  
-Intake: 5/5

-Follow-up #1: 4/5

-Follow-up #2: 3/5

-Completed Study: 5

* Screens Scheduled: 1
* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 005 & 015   
  \* Jill’s Caseload: 009-011

**Recruitment**

* Estimated date Facebook ad can be posted? -Susan

**GPS Data**

* Is Craig’s app designed to only collect 90 days of data?

**Interview Data**

* Family Other category has been updated as needed in participants’ raw data files
* Clarify timestamp used for updates to risky time periods and location risk levels
* Currently: date and time of follow-up 1 or follow-up 2 interview
* Discuss: 006 timestamp issue and 009

**Compliance**

* R scripts are not working properly

**Training Updates**

* Jill is still on track to complete SCID training by end of September
* Sarah began training to complete the initial screening session
* Jill continues to train new phone screener (Alyssa)
* R training database is not working properly

**Data Log Check-In**Has anyone added anything to the data log since our last meeting on 9/14?

**Next Week’s Meeting-9/28/17**Can we meet at 3 pm instead?

**RISK Weekly Meeting-September 28, 2017  
  
Participant Updates**

* On Study: 4

Completed Interviews:  
-Intake: 4/4

-Follow-up #1: 3/4

-Follow-up #2: 2/4

* Completed Study: 6
* Upcoming Screens: 2
* Briefly Discuss Enrolled Participants/Participant Compliance:  
  \* Candace’s Caseload: 015   
  -015 and beddit  
  \* Jill’s Caseload: 009-011

**Recruitment**

* Facebook ad was activated on 9/22/17. To date we have gotten 13 inquiries.

-We pay 32 cents a click for our Facebook ad

**GPS Data**

* Downloader app does not consistently collect range of dates specified for download.

**Updating Follow-up #1,2 & 3 ID Batteries**

* The burden measure needs to be updated. The wristband questions need to be removed.

-John will remove these questions

**Interview Data**

* Family Other category has been updated as needed in participants’ raw data files
* Clarify timestamp used for updates to risky time periods and location risk levels
* Currently: date and time of follow-up 1 or follow-up 2 interview-If RA has more precision than the date and time of the follow-up interview, enter in that date and time
* Discuss: 006 timestamp issue and 009

006 (change new address to move date)

**Audio Messages-Participant Feedback**

* To open ended
* Participants have reported not knowing what to say
* More structure on talking points
* Morning was not always a convenient time
* Mornings are “fine,” it would be better if I responded later in the day
* One participant asked: What are we looking to get out of the messages

-We will begin giving examples of messages

**Compliance-Jill**

* R scripts are not working properly

**Survey Signal Update-Jill & Susan**

**Training Updates**

* Jill is expected to complete SCID training by end of October
* Sarah-screen training in progress
* Sarah-will work directly with Chris to schedule suicidal and homicidal SOP training
* Jill continues to train new phone screener (Alyssa)

**Data Log Check-In**Has anyone added anything to the data log since our last meeting on 9/14?

-Always send John a quick note to review new items added to the data log. Send the note through asana.

**RISK Weekly Meeting-October 5, 2017  
  
Participant Updates**

**Completed Study**: 7  
**On Study:** 5

**Completed Interviews:**  
-Intake: 3/5  
-Follow-up #1: 3/5  
-Follow-up #2: 2/5  
  
**Upcoming Screens:** 4

**Briefly Discuss Enrolled Participants/Participant Compliance:**  
\* Candace’s Caseload: 015, 016, 017   
\* Jill’s Caseload: 010, 011

**Recruitment**

* Facebook ad was activated on 9/22/17.
* To date we have gotten 31 inquiries
* 26/31 have had at least one lab contact
* Consider adding referral source to web inquiry form and phone recruiting database
* Jill and Sarah will pick one evening day each week to work (w/ availability until 6 pm or 7 pm)

-Tuesdays and Wednesdays will be our evening dates through the end of this semester.

-Candace to update phone screen survey with AA meeting option with text entry box so we can select the location of the recruiting site.

-Candace to make excel spreadsheet to document enrollment statistics from start of study until present.

**Compliance-Jill**

* R scripts   
  \* Accuracy

\* MOVES  
\* Beddit

**Survey Signal Update-Jill & Susan**

**Training Updates**

* Jill is expected to complete SCID training by end of October
* Sarah-screen training in progress
* RISK phone screener, Alyssa, is fully trained. Her first shift post training is tomorrow.
* Megan S. will be trained to complete RISK Phone Screens next week

**Question of the Day:** Can we/Should we do more to assess for SPMI?-No time to address this question

**RISK Weekly Meeting-October 12, 2017  
Attendees: Candace, Jill, John, Sarah, and Susan   
Participant Updates**

**Completed Study**: 7  
**On Study:** 7 (+2 from last week)

**Completed Interviews:**  
-Intake: 4/7  
-Follow-up #1: 3/7  
-Follow-up #2: 2/7  
  
**Briefly Discuss Enrolled Participants/Participant Compliance:**  
\* Candace’s Caseload: 4 (+1 from last week)  
\* Jill’s Caseload: 3 (+1 from last week)  
\* Sarah’s Caseload: 0

**Scheduled Screens:** 11 (+7 from last week)

**Recruitment**

* Facebook ad was activated on 9/22/17.
* 9/22-10/11we have gotten 48 inquiries (+ 17 from last week)
* 41/48 have had at least one lab contact

**Clinical Components of RISK Discussion**Questions Under Consideration:  
 **1) Are there any clinical aspects of RISK that are non-essential and worth removing from our current protocol?-Yes**

**During the meeting it was decided that both items on the SCL-90(Thoughts of ending your life and thoughts of death and dying) should be removed from this measure to eliminate the need to complete this assessment with all participants who endorse either of these items. The discussion of participant’s endorsement of these items is not ideal as the current staff is not highly trained to assess for suicidality and it can lead to confusion about the RA true role, which is research staff and not a counselor.**

**It was also decided that the offer of MET session will be eliminated from the protocol. This was decided for the following reasons:**

1. Unnecessary for study goals
2. May of our participants are already enrolled in some type of individual or group treatment and therefore it is not necessary by many of the participants. For the participants who are not enrolled in treatment, we do not want to risk participants using the MET sessions as replacement for pursuing treatment in the community by thinking of the MET sessions as a replacement for treatment. Study staff will encourage these participants to seek treatment in the community by giving them our mental health resource guide.

* We will continue to implement the protocol as reported to the IRB. After we have discussed question number 2 we will submit a COP.

**2) Should we be doing more to evaluate for severe and persistent mental illness (SPMI)? If so, why? The second question will be discussed at the next RISK meeting.**

**Survey Signal Update-Jill**\* Issue with 019

Participants morning survey will come at his earliest reported wake time, and his bedtime survey will come one hour before his earliest reported bedtime.

**Room Availability**

* The clinic is not available for both RISK and DOX visits on Monday
* Can we remodel the sink room to make it more welcoming for study participants? -Yes

**Training Updates**

* Jill completed SCID Training and can now help with running initial DOX sessions as needed
* Sarah-screen training in progress
* Jill to begin training Megan S. and Kleah Fernandez on RISK phone screening today

**RISK Meeting  
November 2, 2017  
Attendees: Candace, Chris, John, Sarah, and Susan  
  
Participant Updates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Completed Study** | **On Study** | **Scheduled Intakes** | **Scheduled Screens** |
| 9 | 16 | 9 | 7 |

**Caseloads**

|  |  |  |
| --- | --- | --- |
| **Candace** | **Jill** | **Sarah** |
| 8 | 6 | 2 |

**Recruitment**

* Facebook ad was activated from 9/22/17-10/17/17
* 67 “First Participant Contacts” made from 9/22/17-10/17/17
* 32 “Screen Pass/Scheduled” from 9/22/17-11/1/17
* 15 Screens completed from 9/22/17-11/1/17
* When should we reactivate the Facebook ad?
* Should we consider other sources of recruitment after the New Year?

**Clinical Components of RISK Discussion  
MET Sessions-**We decided to eliminate this aspect of our protocol at our last RISK meeting.   
Does anyone have any additional thoughts? -We did not discuss this during the meeting.

**Questions Still Under Consideration:** We will remove these items after COP approval **1) Should we remove SCL-90 Items:**

1. **Thoughts of ending your life**
2. **Thoughts of death and dying**

**2) Should we be doing more to evaluate for severe and persistent mental illness (SPMI)? No, as having an SPMI is not automatic rule-out criteria**

**Training Updates**

* Jill completed SCID Training and can now help with running initial DOX sessions as needed on Fridays.
* Sarah-Intake and follow-up training in progress. Sarah is also learning how to transfer phone and text logs.
* Jill and Sarah are scheduled to complete risk assessment training with Chris on November 7.
* Megan S. completed Survey Signal training with Jill
* Jill plans to train Sarah and Candace on entering surveys into Survey Signal

**Next Week’s Meeting Topic:** The Recovery Environment Interview

**RISK Meeting  
November 9, 2017  
  
Participant Updates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Completed Study** | **On Study** | **Scheduled Intakes** | **Scheduled Screens** |
| 9 | 16 | 7 | 7 |

**Caseloads**

|  |  |  |
| --- | --- | --- |
| **Candace** | **Jill** | **Sarah** |
| 7 (-1 from last week as participant 022 withdrew due to health concerns) | 7 (+1 from last week) | 2 (no change from last week) |

* **Recruitment**
* Participation Limits
* With expected support from Megan F. and undergrads, we can handle more than 20 participants at a time.
* Can we order more beddits?-Yes, 5 more
* **Change of Protocol Items  
  1) We decided to remove the following SCL-90 items:  
  -Thoughts of ending your life  
  -Thoughts of death and dying**

**-John, will take care of removing these items and submitting it to the IRB  
  
2) MET Sessions-Are we keeping these sessions as part of the protocol?**

-Yes, for now

* **Sober Living Homes and Documentation (029)**

-No need to document

* **Sleep Data/Beddit**
* Is it important to document when a participant has sleep apnea and is using a cpap machine?
* No need to document
* **EMA Sleep and wake Times in Qulatrics**
* Now that we are using Survey Signal, do we still need to enter in the start and end date for a participant to receive surveys? -Yes
* **Undergrad RAs**
* Is the plan to have 1-2 NRT1 RAs transfer to RISK when NRT1 data collection is complete?-Yes
* Possible RA Tasks:

\* Data entry of information from beddit app (after December)   
\* Data entry of information from health kit at follow-up visits (after Dec.)  
\* Clinic coverage  
\* Data entry of interview information

\* Help with Follow-up Interviews (They can download data from phone and run R scripts for contacts and locations)

* **Recovery Environment Interview**
* Should we begin checking for updates at FU#3?-Yes
* We should schedule a separate meeting to discuss changes to the interview-Yes
* **Training Updates**
* Jill and Sarah completed risk assessment training with Chris on November 7.
* Candace and Sarah completed Survey Signal training with Jill on November 6.

**RISK Meeting  
December 7, 2017**

**Participants and Enrollment**

**Study Visits**

* October 2017-Novemver 2017
* Screens: 20
* Intakes: 16
* Follow-up Visits: 12
* Total Study Visits: 48!

**Participant Updates**

* Completed Study: 10
* On Study: 18
* Scheduled Screens: 0
* Scheduled Intakes: 0

**Caseloads**

* Candace: 8
* Jill: 10 (2 participants were transferred from Sarah’s old caseload)

**MOVES**

* Updates?
* Re-Connect Participants?
* Re-download info?  
  MOVES is working again, Begin downloading GPS data for all on-study participants.

**Survey Signal**

* A few participants have reported not receiving surveys-Fix: Set reminder prompt to be sent
  + Reminders are only sent if they have not completed the survey (as per preliminary testing has shown) User Preference-set as needed
* Do you want participants to continue to complete all study activities until follow-up visits 3? -No, stop at 90 days.
* Sleep Schedule and Qualtrics (Enter @ Screen or Intake) @ Intake
* Audio Survey – set for a more convenient time for participant OR reach out to Survey Signal about getting reminders that extend further than 60 mins-Not possible
* 034 and wake variability – asked to get morning surveys at 8:30 am is this ok? - Do you want us to check with you every time we have a question like this?-No

**Review and discuss new contact log for recovery environment interview**

* See attached

**Weekly Participant Compliance Checks**

* Goal: Train Megan S. on how to complete checks

**VisitDates**

* Are these used only for compliance? Can we use discrete 30 day increments? How it affects bonuses if more or less than 30 days for follow ups? -Compliance is calculated from visit to visit, this may be under or over 30 days.

Add column in visit dates excel spreadsheet: Study End (this may differ from the 90 day end date for participants who drop out early from the study).

**Cell Phone Storage and Data Collection (Jill)-Didn’t discuss to at this meeting**

**Beddit and Transition away from the API-Didn’t discuss at this meeting**

* What sleep data needs to be documented? Is the list below still accurate? Where do you want the data documented?   
  Primary measures I want are:  
  Time get into bed at night  
  Time awake in morning  
  Total time in bed (calculated from the previous two)  
  Total sleep time  
  Sleep efficiency (calculated from total time in bed and total sleep time)  
  Latency to fall asleep

Secondary measures that indicate restless sleep would be nice but I tend to think that sleep efficiency and time to fall asleep will generally capture the "worry/rumination" in bed construct I'd like to capture as well as anything else

* Beddit APK – is it working ok?
* Should we limit study participation to iPhone users? What are the pros and cons of doing this?

**Research Staff-Didn’t Discuss at this meeting**

* Additional Support Needed

-RAs

-New Hire (Associate Research Specialist)

\*John wants us to begin getting permission from participants to leave voice messages on their telephone.

**RISK Meeting  
December 15, 2017**

**Participants and Enrollment**

* Completed Study: 10
* On Study: 18
* Scheduled Screens: 2
* Scheduled Intakes: 0

**Caseloads**

* Candace: 8
* Jill: 10

**Participant Issues**

* 017-Termination and Final Payment
* 024-Missed FU #1
* 032-Beddit
* Android Users and apks-Do we want to continue using these? Yes, for now.
* Should we limit study participation to iPhone users/participants willing to use a study iPhone? What are the pros and cons of doing this? No, we will continue to take android users. Participants will have to have a 16 GB phone to participate -iPhone or android.

**Updates on Additional Study Visits for Off-Study Participants**

* 005-2 call attempts
* 006-Called today
* 007 was scheduled for 12/15/17-He cancelled today. He plans to reschedule.

**Beddit and Transition away from the API**

* What sleep data needs to be documented? Is the list below still accurate? Where do you want the data documented?   
  Primary measures I want are:  
  Time get into bed at night  
  Time awake in morning  
  Total time in bed (calculated from the previous two)  
  Total sleep time  
  Sleep efficiency (calculated from total time in bed and total sleep time)  
  Latency to fall asleep

Secondary measures that indicate restless sleep would be nice but I tend to think that sleep efficiency and time to fall asleep will generally capture the "worry/rumination" in bed construct I'd like to capture as well as anything else

* Beddit APK – is it working ok?

**Recovery Environment Interview**

* New Template (Phone 1, Phone 2, Phone 3 instead of Home, Cell, Other Phone).   
  Can we make this change now, or do you need to adjust your code first?-Don’t change. We still need to distinguish cell and landlines
* Reported numbers and locations appearing on unreported contacts and locations-Give John Examples
* Multiple Survey Line Numbers-Issue is resolved for now. John has coded in survey line numbers.
* Procedure for collecting unreported contacts and locations-Participants will be left alone to review unreported contacts and to complete contact logs when applicable.

**Audio File Transfer-New Procedure**

* Review Jill’s Document

**Cell Phone Storage and Data Collection (Jill)**

**12/15/17-Meeting Highlights Below (Typed by Jill)**

-switching to iMazing as soon as we confirm that files contain relevant naming information  
-investigating universal Android "health kit" options to supplement Beddit data from local app  
-If participants miss Follow Ups and cannot get into the office to complete one of the follow ups we will offer to send them an ID battery via email and pay them $10 to complete it  
-Add notes column to Final Visit Dates  
-017 off study  
-Beddit - see separate task  
-16 GB minimum storage capacity for participants on study OR they have to use a study iPhone to participate  
-watch MOVES data on Androids for any issues  
-Candace and Jill to continue to try to contact Off study participants about coming in to review their unreported contacts and locations  
-Moving forward we will instruct participants not to use a battery saving feature as it disrupts MOVES data

**RISK Meeting-January 11, 2018**

**Participants and Enrollment**

* Completed Study: 11
* On Study: 15
* Scheduled Screens: 2
* Scheduled Intakes: 0

**Caseloads**

* Candace: 6
* Jill: 9

**Recruitment**

* RISK Facebook ad will be activated on 1/12/18
* Discontinue use of Journey and ACCESS as a recruitment strategy
* Do we want to post at 1-2 AA meeting sites? -Yes
* Let’s begin thinking about strategies to get a more diverse ethnic and racial pool of participants…..-On Hold until we reach 30 completed study participants. In Facebook we can target future ads to a more diverse racially diverse demographic.
* Recording outcomes for participants who do not complete 90 days-Make spreadsheet to document outcomes for all completed participants. Send to John for review.

**Beddit**

* Should we continue to download data via API until it is officially discontinued, or begin recording data in Excel? Continue to utilize API download.
* Downloading Health Kit Data from iTunes-Susan and Jill plan to look into this possibility.

**Audio Message**

* Should we begin having participants state date and time in voice message to have a more precise timestamp?-No  
  Encourage participants to send audio message immediately after recording so that the message is time stamped appropriately.
* Deleting backups from iMazing-Yes
* John to work on program to automatically rename files-not for a couple of months

**RISK Staff**

* Update on open RA position-The open ad will close this week. Susan will send at least one to two applicants to review.
* Undergrad RAs-In progress. RISK should have 1-2 RAs soon.
* Evening Coverage Needed (Wednesday coverage until 7/7:30 pm)-Susan will ask RA or Phone Screener to Provide Coverage

**Interview Items**

* Landlines-There is no way to distinguish who the participant speaks with on any reported landline.-John understand this. No need to change the current protocol for collecting landline contact numbers.
* Do we want to add participant phone numbers to their contact data? Some participants text themselves and therefore their phone number comes up as an unreported contact.-Yes, add their phone number and enter Self for the category type.
* Irrelevant /Spam-Appt. lines, Rx, etc… & monthly visiting Not necessary to say yes to visiting Walgreens, counselor, etc in the contact log. The “yes” to monthly visiting in the contact log is only for friends and family.
* Notes Field -Create individual data log for participants and store in their raw data folder

**RISK Meeting-January 25, 2018**

**Participants and Enrollment**

* Completed Study: 14 (+3 since RISK Meeting held on 1/11/18)
* On Study: 14 (-1 since RISK meeting held on 1/11/18)
* Scheduled Screens: 6 (+2 since RISK meeting held on 1/11/18)
* Scheduled Intakes: 1 (+1 since RISK meeting held on 1/11/18)

**Caseloads**

* Candace: 6 (no change since RISK meeting held on 1/11/18)
* Jill: 8 (-1 since RISK meeting held on 1/11/18)

**Recruitment**

* RISK Facebook ad was activated on 1/12/18
* All of the phone screening since the ad was activated has been completed by Jill
* Megan S. will help with phone screening when possible
* Jill to complete training with a new RISK phone screener in the next couple of weeks

**Beddit**

* The API remains open
* 032-Issue with sleep data
* iPhone export options-Jill
* 032-Issue with sleep data

Get sleep data from 32 and record in excel spreadsheet for first two weeks on study. Jill will begin downloading 32 beddit data via API.

**Audio Message**

* Participants #30 and #32 “Time stamped based on when they arrived on the phone and not when they were sent” (3 days 1/16, 1/17, and 1/23) Try to speak with participants to get correct dates. Leave phone on at all times.
* Should we begin having participants state date and time in voice message to have a more precise timestamp?-NO

**GPS, SMS & Voice Data**

* What is meaningful?/Is the cut off too low?-John will reconsider raising the 2 contact/visit minimum for collecting unreported contacts and locations.
* How should we document locations/contacts that aren’t meaningful/that the participant doesn’t know about? Continue to document all know locations and contacts for now. If the participant doesn’t know an address or number, staff will simply not record this information. No need to document that participant did know the information, it will be assumed because it is missing.
* Duplicate Locations (unreported locations script) ?
* Missing GPS days-Continue to take note in participant data logs.
* MOVES and Calculating Usage (app enabled, but participant didn’t go anywhere)-John will look into this more once he submits the RISK 2 grant.

**Study Compensation**

* The 90% compliance rate is too high, let’s consider lowering it. John plans to run compliance rates to get an average score. Staff will continue to offer the “90%” bonus to participants who they feel have done well with completing study activities.

**Reporting Lapses**

* Is a sip a lapse? (case example 021)-No, for 021. This will have to be determined case by case.

**ID Battery**

* John, do you still plan to submit a COP to remove the SCL-90 items about death and dying? -Yes, after the RISK 2 grant is submitted.

**RISK Meeting – March 22, 2018**

**Participants and Enrollment**

* Completed Study: 24 (+10 since RISK Meeting held on 1/25/18)
* On Study: 15
* Scheduled Screens: 2
* Scheduled Intakes: 6

**Caseloads** Ideally we will have more (~30) on study.

* Candace: 5
* Jill: 7
* Kerry: 3

**John’s Follow-up to Contacts Log**

* Within a list of contacts, the phone numbers need to be unique to one person only. If a number is shared by multiple people, we must ask who the participant is most likely to talk to when in contact with that number. EX: If a landline number is shared by ‘grandma’ and ‘grandpa’, then ask the participant who they are more likely to speak to when calling the number. If it is ‘grandma’, then assign that number to ‘grandma’, and leave ‘grandpa’ off the log.
* If a relationship changes with someone on the contact log, then go with that the participant reported at their initial report of the contact as that will be the most accurate. The same applies for location logs.
* If an individual has more than one active phone number, then put them in the same line. If an individual changes numbers and does NOT maintain the previous number, enter a new line in the log.
* More information to come for ‘NA’ and ‘N/A’.

**Recruitment**

* Primary recruitment method continues to be Facebook
* Kerry has taken the lead on exploring other recruitment opportunities
* **Other Recruitment Ideas:**
* Advertise in the community at AA meetings (In process)-Kerry to share details on where she posted flyers and contact she made with a new recruitment source
  + Advertisement through church email newsletter given the O.K.
* Craigslist
  + Kerry to meet with Susan to post Craigslist ad (take 1-8 weeks information out)
* Diverse Publications to get a more diverse sample (Example: Capitol City Hues)
  + Kerry to search more affordable publications. Candace to take care of Capitol City Hues – will post in early April.
* Bus Ads
* Madison College-Susan to explore once COP is approved.
* Email blast at UW?-Susan to get approval for this once COP is approved.

**SCL-90**

* Will we remove “Thoughts of death and dying,” and “Thoughts of ending your life” from the SCL-90? Did not have time to discuss.

**Additional Study Handout (Jill)**

* Intake Reminders handout review (Do we need to have this material approved by the IRB?) No IRB approval needed. The form was approved by John. We can begin using the form.

**GPS, SMS & Voice Data**

* Discontinue use of Samsung Galaxy Phones models 7 and under
  + Participants are ineligible if Galaxy 7 or under, unless they want to transfer SIM card. Possibly ineligible at phone screening. (\*Since meeting it was decided that any participant who reports having a Samsung Galaxy 7 and under during the phone screen is ineligible for study participation. We will not offer them the option of getting a SIM card to use in our study phone.)
* All participants who have used a Samsung Galaxy 7 and under have had significant gaps of missing data: 002, 019, 021, 030, 039 (On-Study), 042 (On-Study), 45 (Intake Pending)
  + 042 – look at data closely, if we are not getting data, but they are willing to work with getting a SIM card and using a study phone, we will continue them
  + 045 – Discontinue
* 034-Samsung Galaxy 8 (no issues with missing data)

**Beddit**

* The API remains open
* Has this data been reviewed to date?

**EMA Data (Jill)**

* Survey Signal – can we delete old/completed surveys? Getting really clogged up and difficult to manage
  + As long as we have downloaded the surveys, there is no reason to keep them. Susan to show Jill how to download this information from Survey Signal.
* Discuss recent example of schedule that varies significantly throughout the week (Jill)

**Future Project Meetings**

* Phone screening meeting needed
* Workload Meeting
  + What are the daily tasks that take away from our 40 hours? Keep track of daily activities that take up time.
  + How many hours a week does it take to run a person?
  + Have RAs take some of the workload
* Meet two weeks from now

**RISK Meeting-April 5, 2018**

**Participants and Enrollment**

* Completed Study: 25 (+1 since RISK Meeting held on 3/22/18)
* On Study: 16 (Post Intake: 14)
* Scheduled Screens: 1
* Scheduled Intakes: 2

**Caseloads**

* Candace: 4
* Jill: 6
* Kerry: 6

**Recruitment**Since our last project meeting the following recruitment activities have occurred:

* Jill posted RISK advertisement at LGBT Outreach Center-3/22/18
* Craigslist ad was posted-3/23/18
* Facebook Settings Changed-4/2/18
* Advertisement was posted in Capitol City Hues-4/2/18
* Advertisement to be posted in the Isthmus on 4/5/18 and 4/12/18
* Susan plans to post advertisement with Television network for RISK and DOX mid-April 2018

**Participants who have been w/o alcohol for less than 7 days at intake**

* Reschedule? Yes, let’s continue to reschedule participants.

**On-Study Participants w/ Samsung Galaxy (39, 42, 51)**

* Jill -present data and rationale for wanting to keep them on study It’s fine to allow them to stay on study. We will not continue to enroll new participants with a Samsung Galaxy.

**Work Load Discussion**

* Maximum Number of Weekly Visits: 24
* 2 visits daily per RA=10 visits weekly (Jill and Kerry can complete a maximum of 20 visits weekly) \*Will not allow for SCIDs
* Coordinator: 1 visit daily 4x per week-To allow for supervision of RAs and undergrads, METs, data oversight, and task assignment, etc..)
* We can have a maximum number of 30 visits per week if Candace is not responsible for supervision, etc…-This is not an option. Our current max is:24
* **Need:** Help with data management and administrative tasks. There will be no time for RAs to consistently have data management and administrative duties if they run 2 visits daily as the study visits and participant administrative tasks will take up the majority of their time.
* **Where will help come from?  
  Proposal:** Utilize Megan/Heather to assist with study related tasks to help us meet our current goal of **30+ people** on study & Undergraduate RAs. John stated that he will have Megan or Heather join our study and commit 50% of their time to RISK.
* **SEE TASK Handout**
* **SCL-90 Items: We will remove when possible (after COP submitted for Sarah’s first-year project is returned, we will submit a COP is remove these items)**
* Thoughts of ending your life
* Thoughts of death and dying

**HANDOUT**

**RISK Task Distribution Ideas**

**Priority Task Ideas for Megan/ Heather:**

* Recruitment Team: Megan/Heather to work one-one with Susan to plan and implement recruitment strategies for both RISK and DOX. Recruitment planning and implementation will occur each week until studies reach maximum capacity for on-study participants and have a large call volume (waitlist for initial screens). Details about recruitment efforts will be included in emailed project updates. \* Yes, this task will be assigned to Susan, and Megan/Heather.
* Phone Screening: **PROJECT NEED: Additional phone screening staff, with at least 1-2 who will be able to make calls between 4 pm-6pm.** Megan/Heather to assist with phone screening until we have sufficient phone screening staff (set hours that do no overlap with current phone screener). Currently RISK has one phone screener, who works 4-6 hours weekly Kleah’s work hours fall between 10 am and 5 pm. Kerry and Jill also assist with phone screening as needed. \*It was decided that the lab needs to have a pool of trained phone screeners. The training of these phone screeners will be done by Susan/Megan/Heather. The phone screeners will report for supervision to Susan. While we are waiting for phone screeners to be hired and trained, Megan and Heather can complete this task.

**Other Tasks Ideas for Megan/Heather:\* John does not want the transfer of data to be a regular part of Megan or Heather’s job duties. The plan is to have Heather/Megan oversee RAs and train them on this task.**

* Daily Audio Message Transfer \* 2 Minutes per message  
  *Weekly Time Estimates:  
  15 on Study-Weekly: 3 Hours and 30 Minutes  
  30 on Study-Weekly: 7 Hours  
  60 on Study-Weekly: 14 Hours*
* Survey Signal Set-up
* Check Facebook comments Daily-Move to RA duty
* Tech Set-Up during Intake Visits (Requires Dedicated Time)
* Phone Transfer and R scripts during follow-up visits (Requires Dedicated Time)
* Motivational Enhancement Therapy (Requires Dedicated Time) We did not discuss the feasibility of completing this task.

**Undergrad RA Tasks-Yes, these are fine tasks for an RA to complete.**

* Printing Study Packets
* Wash Beddits
* Compliance Reports
* Survey Signal Set-up
* Survey Signal Downloads (Off-Study Participants)
* Interview Data Entry and Checking Interview Data Entry
* Downloading GPS Data
* Downloading MOVES Zip Files Data
* Tech Set-Up during Intake Visits
* Phone Transfer and R scripts during follow-up visits

**Susan Tasks-Yes, Susan will take on all of the tasks below.**

* Recruitment Team Lead
* Daily Download of beddit data
* Incorporating beddit data into R scripts
* IRB lead w/ Candace assistance
* Misc. Data Tasks

Ex: Recent Spreadsheet that Jill Created

**HANDOUT**

**Current RISK Task**

* Data Collection (Average visit takes 2-3 hours to complete)
* Participant Admin (Check-Ins, Troubleshooting Issues, Scheduling, Sending Appointment Notifications and Final Payments)
* Audio Message Transfers
* Motivational Enhancement Therapy-Requires Clinical Note (Infrequent)
* Suicide Assessment-Requires Clinical Note and consultation (Frequent)
* Interview Data Entry and Checking Interview Data Entry
* Compliance Checking
* Downloading GPS Data
* Downloading MOVES Zip Files Data
* Phone Transfer and R scripts during follow-up visits
* Wash beddits
* Daily Download of beddit data (Jill Only)
* Processing Phone Calls
* Phone Screening
* Survey Signal Set-up
* Misc. Data Tasks

Ex: Recent Spreadsheet that Jill Created

* Supervision and Task Assignment (Candace)
* Training
* Recruitment Activities
* Review Transcription Files
* SCID (Infrequent)
* Through May 2018 (SCID and MET Training for Kerry: 3 Hours Weekly)
* Through May 2018 (MET Training Weekly for Jill: 1.5 Hours Weekly

**RISK Meeting-April 25, 2018**

**Participants and Enrollment**

* Completed Study: 25 (No change since last staff meeting held on 4/5/18)
* On Study: 16 (Post Intake: 15)
* Scheduled Screens: 8 (April: 4, May: 4)
* Scheduled Intakes: 0

**Caseloads**

* Candace: 4
* Jill: 7 (+1 since 4/5/18)
* Kerry: 5 (-2 since 4/5/18, 2 participants withdrew from the study (#50 and #55)

**Megan S. and Undergrad Research Assistant Update**

* RA Count (Current: 2, Summer: 2, Fall: 2, maybe 3)
* Training Update
* Goal: Megan will be fully trained on all RA Tasks by the end of May and fully transitioned to lead Supervisor for RAs

**Interview Data and Cleaning**

* Update on insertion of NA for missing or irrelevant/spam data-No update yet.
* Ideas on a more reliable way to check interview data entry… Double data entry? –Yes, let’s do this. Megan will take the lead on this.

**Audio Survey Data**

* Can participants leave multiple daily audio messages per day?-No

**Survey Signal Downloads**

* Update from Jill
* File name? File format? –John already approved the current file format and file name, no change needed.

**QS Access and tabulation from all sleep monitoring sources**

* Update from Kerry-need to work more on this to determine how we can isolate beddit data from other sleep data.

**Budget for Snacks**

* We have spent $267 for snacks in the last 5 months. We have run 101 visits in the last 5 months. We will likely need to purchase additional snacks in late May/early June. Can we continue to purchase snacks for participants? –Yes, we can continue to purchase snacks.

**Old Study Tech –**Try to sell

* Laptops (7)
* Empaticas (8)
* Phone Cases, Anker (2) Apple (2)

**RISK Meeting-May 24, 2018**

**Participants and Enrollment**

* Completed Study: 30 (+5 since last staff meeting on 4/25/18)
* On Study: 20 (Post Intake: 17)
* Scheduled Screens: 3 (May:3)
* Scheduled Intakes: 3 (067 scheduled for part II on 5/25/18)

**Caseloads**

* Candace: 5
* Jill: 7
* Kerry: 8   
  -Discuss #53-Continue on-study with original end date   
  -Discuss #055/061 and ID Screen Battery-Delete 61 ID Screen battery and put note in data log to indicate the 55 is 61

**Recruitment Ideas-Revisited**

* Email blast at UW –Employees/ Grad Students-Susan will submit COP.
* Email Blast -Madison College-Susan will inquire about this recruitment possibility and update team via asana.

**Megan S. and Undergrad Research Assistant Update**

* RA Count (Summer: 4 Fall: 3)
* RA Training Update
* Megan is trained on all RA Tasks except for tech set-up
* Double Data Entry of Interview Data-Update from Megan S.

**QS Access and Isolating Beddit Data**

* Update from Jill –Going forward, we will get the QS Access data from our lab phone only at the final study visit, for iPhone and Android users, to ensure that we isolate the beddit data. So there is no need to have iPhone participants download the QS access app and email us the data from their personal accounts any longer.

**New Enrollment Database**

* Training with Heather today
* Jill to draft SOP for RISK use of Database
* Issue with new study support package and running compliance

**GPS Compliance**

* How is this calculated?

**SCL-90 Items-Let’s Keep Them, Really ☺**

* Kerry, Jill, and Candace have sought out additional SI training opportunities and feel more confident in their ability to handle these circumstance if they arise.

**Next Meeting-June 21, 2018 @ 11 am Room #311**

**RISK Meeting-June 21 2018**

**Participants and Enrollment**

* Completed Study: 35 (+5 since last staff meeting on 5/24/18)
* On Study: 19 (Post Intake:13)
* Scheduled Intakes: 6
* Scheduled Screens: 4 More in June

**Caseloads**

* Candace: 6 (May need to discontinue 074)
* Jill: 4 (079, Traumatic Brain Injury)
* Kerry: 8 (Discontinue 061 Tomorrow)

**Recruitment**

* Email blast to UW –Employees/ Grad Students (5,000) is expected to go out by the end of this week.
* DOX and RISK study advertisement is expected to be included in MATC employee e-newsletter asap
* New Recruitment Idea: Presentations to potential participants and providers
* TV may not be worth the money   
  June Referral Sources for RISK: 6 screens completed, New Start: 3, Chris Farley House: 1,  
  Other (online): 1, and TV: 1

**Undergrad Research Assistant Update**

* Introduce new research assistants
* RA Training Update

**Interview Data**

* All Caps Issue
* Locations and risk-level changes
* No longer relevant time-periods (How should we indicate this in the excel spreadsheet?)

**Next Meeting-August 2, 2018 @ 11 am in Room 311**

**RISK Meeting-August 2, 2018**

**Participants and Enrollment**

* Completed Study: 42 (+7 since last staff meeting on 6/21/18)  
  Completed Through….FU#3: 38, FU#2:1, FU#1:3
* On Study: 29 (Post Intake:22)
* Scheduled Intakes: 7
* Scheduled Screens: 7

**FollowMee Update**

* We still need to add one more participant to FollowMee (80) – Kerry continues to reach out to the participant; additional note that FollowMee does not backdate info so we need participants to come in to put FollowMee on their phone
* No location update in last 24 hours notifications-Protocol? – Kerry to contact FolllowMee regarding the 24 hour notice (what triggers the notification? Are there any indicators in the API? Reasons for low track points), Kerry will check in with FollowMee re their data log; RAs advised to keep an eye out for notices and follow up with participants when deemed necessary
* Data downloads and compliance – Kerry to work with FollowMee regarding the timestamp issue, is it a location service buffer; staff will investigate with new Intakes

**Recruitment-Kerry**

* Presentation at New Start (Tentative Date: 8/8/18)
* Flyers at Starbucks/Coffee Shops near AA meeting sites
* UW Clinic App space approved (Susan)

**Withdrawn Participants and Enrollment Database**

* Should we discontinue participants who enter rehab? – Completed at least 1 month and they will be discontinued – all other decisions on a case-by-case basis
* How should we enter withdrawn participants who have also completed at least one follow-up visit? Ex: #47 and #53 – Mark as completed in the Enrollment Database with a note; withdrawn/discontinued only prior to completing a follow up

**RA Update and Time Harvest** – Megan updated us on RAs 5 total – may give one full time to FACE

**Misc. Items:**

* Beddit and heart rate – Heart rate not collected for RISK; should still return defective sensors if possible
* Church (Other on location logs) – add church as a location
* 081-no caller ID issue – John will look into this issue
* 90-Extreme Work Schedule Variation – ordering of surveys doesn’t matter as much as long as participants are doing the EMAM (Morning) survey once a day – do our best with entering sleep schedules
* 084 and 84 –FollowMee (Can we save and delete old file and remove from account?) – John took care of this 8/3/18
* Updating completed participants on outcome of study – Jill to make spreadsheet of participants who express interest in study outcome at Follow up 3
* SOP for calls with intoxicated participants/participants in crisis via telephone – Jill and Megan to work with Susan and Chris Gioia on creating these documents
* Mak\_Database downloads FollowMee GPS data – to be checked weekly
* John updated us on Model building and working on the Qualtrics issues that prevents us from running Compliance scripts with the updated Qualtrics package – he will build a package for us

**Next Meeting-September 6th, 2018 @ 11 am in Room 311-Canceled**

**RISK Meeting-October 25, 2018**

* Recruitment Resources-Candace shared the three resources below and discussed what she learned at the recruitment methods class presented by ICTR.
* Free consultation with UW Institute for Clinical and Translational Research (ICTR)
* Wisconsin Network for Research Support (WINRS)
* Community Advisors on Research Design and Strategies (CARDS)
* Sobriety Commitment Discussion-Jill presented lapses rates for the past 60 days. It was determined after Jill’s presentation that the majority of the reported lapse were concentrated to roughly 4 participants. These participants have relapsed. It was determined that there will be no change to the study protocol at this time, other than the change we made to phone screening (not screening anyone until they are at least 7 days sober).
* Outstanding COP
* IRB Meeting: 11/6/18
* Should we re-consent participants?-YES! When COP is approved all active participants will be re-consented.
* Participant #92-Missed FU#2, but plans to attend Final Visit-This participant does not need to complete the follow-up 1&2 ID battery at their final visit.

To Do:

* Candace to submit a free consultation request to ICTR for help with the lab’s recruitment methods. Include Gaylen on any meeting with ICTR.
* Kerry to connect with New Start contact to arrange regular presentations to participants each time a new IOP session begins.
* Begin advertising in newspapers again-Kerry and Candace will explore this with Susan

**RISK Meeting-December 3, 2018**

* **Recruitment**
* Between now and 12/2019 we need 114 participants to complete the study. We are not on track to reach this goal with our current enrollment rates. New Goal: **N=150 not 200**
* When will we end participant enrollment-9/30/19 or 11/30/19? **We will end on 9/30/19**
* Phone Screening: Rotating between RISK and DOX for eligible participants **Not now. John wants to continue giving DOX preference.**
* **Audio Data-Should we continue to listen to it?**
* Review list **Yes**
* **Staff Workload**
* Are there any stretch projects or long-term tasks that we can work on when enrollment is low? **None. John wants us to use an extra time to work on recruitment activities.**

Jill

1. Provides us context - we only see participants once a month, a LOT can happen in a month, especially with people who are newly pursuing abstinence/sobriety, it gives us a heads up as to what to expect when they come for a follow up visit, which prepares us for situations that are more difficult to deal with, e.g., if they lost a job we can expect that that may be something they are struggling with and we can be more empathetic when reviewing Interview data - it gives us insight on what is going on in their lives.

2. Quality control and data management - if someone isn't completing the messages as instructed we know to intervene - e.g., despite us reminding participants SEVERAL TIMES not to leave messages regarding study technology or questions regarding appointments or study activities, several participants are still confused about the purpose of the audio message - when we hear these messages we can talk to the participants about it and remind them that we don't check these messages every day and that if they need to get in touch with us to call our study line - there isn't evidence that passive monitoring alters the way in which they respond to the prompt - e.g., participants I have spoken to regarding tech issues or in the case of 128 have not altered the way they respond to the prompt other than (hopefully) calling us with tech issues rather than leaving them on the audio message.   
  
3. The problematic responses have been few and far between, and when they have occurred they have given us useful insight regarding the participant's ability to do study activities.

4. Possible personal safety - we work with a vulnerable and often unstable population - it is in our best interest to use all of the available information at our disposal to keep our lab safe from any possible issues that may result from working with this population, especially given the level of personal information we need to obtain from participants in order to ensure the success of the model - this also gives us an opportunity to re-enforce boundaries, to further clarify the goals of the project and our roles as research specialists - and it gives us an opportunity to refer them to services that can help them.   
  
5. It is unethical to have this information, and use it to support the goals of the study while dismissing the human element - we may not be doing anything to exacerbate their situation, but knowing that they are struggling - whether or not it is explicit - and not doing the bare minimum of acknowledging that we know about the issues and providing them resources to services is unethical. It may not be our "job" to refer people to services, it's not data that is necessarily useful towards the goals of the project, but these are real people, with serious issues, and we ask them to tell us about their entire life and subjective experiences as it pertains to drinking, we make it clear that this is not a treatment study and that we are not counselors, but we are doing this work because we want to help people help themselves, so why shouldn't we provide people with resources to help themselves. In the real implementation of this wouldn't there be an implementation that if a person expresses that they are struggling with sobriety they would be connected to resources?

Kerry

I understand that there may be some concerns regarding liability when it comes to listening to the audio messages. We do what we can by instructing participants to not leave concerning messages on the audio line, and as the amount of concerning messages are so few and far between, I am confident that most participants respect our request. We also let participants know that the messages are listened to, although not every day. We reiterate that if they report anything within the five limits of confidentiality, that we will need to do a risk assessment to determine what the current level of risk is to either the participant or other person(s) involved.  
  
When it comes to the actual liability concern, I believe we are liable if a participant leaves an audio message indicating intent to harm themselves or someone else and follows through with it, whether we listened to that message or not. Even if it not legally, I believe we are morally liable to address these situations and concerning messages. If we do not listen to a concerning message, send it to Datagain for transcription, and later review it to find something that could have been addressed, I know I would feel VERY guilty for having had that information and not doing anything with it. Regardless if we listen to the messages or not, we have that information.  
  
As Jill stated, we are working with a vulnerable population, and we talk to participants every single day and are reminded of the humanity in this work. We are not clinical psychologists or therapists, but we provide them with human contact and a level of support they may not receive in their environment, even with reminding them that we are here for data collection and not treatment. I believe we do carry some responsibility for their safety when the five limits of confidentiality come up in the context of our study.  
  
There is also a context factor when it comes to assessing an individual’s fit for the study and potential problematic interactions. In the case of 053, we were aware they had previous problematic interactions, as we had been able to listen to their audio messages. When the time came and they made the phone call during which we needed to intervene, we had context behind the call and had more evidence to provide a write-up that supported our decision. Having the audio messages as context for possible future write-ups and indications of fit for the study are very important, as without listening to the messages, we would not have that as an extra layer of rationale for decision-making when it comes to our participants.