Header				
Is this a real participant or pilo	t/test/training session?			
O Real data				
Fake data				
What session is this?				
Followup #1				
O Followup #2				
Who were the research assista semicolon.	ints today? Enter RA last nam	e and separate RAs with a		
JohnsonHurwitz				
☐ Keiser				
Nagler				
Schneck				
Other				
SubID				
SOP Start				
RISK Follow Up 1 & 2 Session SOP Location: P:\StudyData\RISK\Methods\SOPs\Session SOPs\RISK Screening Session SOP				
STUDY TEAM				
Principal Investigator	John Curtin	608-217-6221		

Study Coordinator	Candace Johnson-Hurwitz	314-899-3276
Research Specialist/RA	Jill Nagler	608-220-2631
Research Specialist/RA	Kerry Keiser	608-333-6741
Lab Manager	Susan Schneck	608-293-2412
Assistant Director of PRTC	Chris Gioia	608-235-3659

Prior to participant arrival (please arrive 30 min early):

Go to the RISK file cabinet. You will need the following items:

Participant's Study Folder (Identified by Subject ID#)

Participant's mHealth payment form (in RISK filing cabinet)

2 iPads

Clip Board

Snacks and Beverages

Checkbook *If you are not an authorized check signer, be sure to have one of the following individuals sign the participant's check: Candace Johnson-Hurwitz, Kerry Keiser, or Jill Nagler

Located in Study Rooms:

Interview - Updates Form (check for updates since Intake/Follow-up #1)

Monthly Contact Questions

New Location Log (Check for Updates)

New Contact Log (Check for Updates)

New EMA Form (Check for Updates)

Counseling Resources (if they report a lapse)

Participant Payment Form

Clinical Crises

If you are leading a session you have already been trained on each of the lab's clinical crises SOPs. Consult them as needed. Please **NEVER** hesitate to contact a member of the study team, especially clinical support (Chris Gioia), for guidance on how to address a crises situation.

Dates to Know

You will need to reference the dates below during the visit.

Date of Participant's Last Drink

Review participant's EMA Morning and EMA Later surveys in Qualtrics. Under the Data & Analysis tab, filter responses using the participant's Sub ID and the question EMA_1 to see if they have reported any alcohol since their last visit to the lab. If the participant's last alcoholic drink was prior to the in-person screening date, no date will be recorded in any of the EMA forms. If a participant has not reported drinking on the EMA surveys, the date of the participant's last reported drink can be found on a sheet of paper stapled to the inside of the participant's study folder.

Check for "False"/Incomplete EMA Morning and EMA Later Surveys

Review the participant's surveys in Qualtrics to identify the "false"/incomplete EMA surveys. Participants who have incomplete/false surveys, and have responded "yes" to drinking, need to

have their "yes" response verified. Was the response truly yes, or was it accidentally marked? Document the outcome of this verification process in the Data Log.

At Scheduled Session Time:

Meet participants in the Psychology Research and Training Clinic, Rm#351 OR the Psychology Research Waiting Room, Rm #151. Greet participant, introduce yourself and take them to the assigned clinic room.

If the participant has not yet arrived, wait for 5 min. After 5 min, check for a voicemail from the participant.

- Go to https://voicemail.doit.wisc.edu/main.php [(Mailbox:8904796)] (Pass: 12769#)]
- After checking the voicemail, return to the waiting room to see if the participant has arrived.

If the participant has still not arrived, wait an additional 5 minutes.

• If after 15 minutes there's no call from the missing participant, check voicemail again. Additionally, check email if you have ever corresponded with the participant via email: Go to wiscmail.wisc.edu (Study Email: arl4_psych@wisc.edu)

NetID: arl4_psych Pass: Curtin@rl

- If you still haven't heard from the participant call them to verify that they cannot make it and/or reschedule. Reschedule the appointment if possible.
- Remember to update the appointment status in the Enrollment Database. If the appointment was rescheduled, enter the new appointment time in the Enrollment Database.

Did the participant arrive? (if yes, note what time they arrived (e.g. 4:00 pm)

0	No	
0	Yes	

Script

Let's start by giving you a quick rundown of what we are going to do today.

Today's visit will last about 2 hours.

We will start the session by doing a quick check-in about the last time you had any alcohol, as we've done during your other visits.

After the check-in, we will collect your call logs and text messages from your phone. Before the transfer occurs, you will have the opportunity to review your phone and text logs and delete any information you do not feel comfortable sharing. [If applicable] Someone from our staff will come to our room at the time we are ready to complete the transfer and transfer the data from your phone right here in the room onto our lab's computer.

Next, you will complete a series of questionnaires. These questionnaires will ask about your recovery efforts, your personal support network, your current life situation, and your emotions.

Finally, we are going to review the information you shared about the people, places, and events that have an impact on your recovery goals. I want to check-in with you to see if there are any updates to this information. We'll also review and add any new locations from the GPS data we've collected, and any new contacts from the collection of your text and phone logs.

Please remember that all the information you share with us is completely confidential. I want to be very clear that we will NOT contact any of the numbers we obtain from your phone today. We only need access to your call and text logs so that we can tell when you are spending time with people who you have identified as supportive of your recovery, and when you are spending time with people who you have identified as not supportive of your recovery.

IF FU#1: You will be paid today for the time you spent with us during your last visit, and the time you will spend with us today.

IF FU#2: You will be paid for the time you spend in our lab today and for any collection bonuses you earned last month.

Do you have any questions before we get started?

Sobriety Date Check-In and MET

Sobriety Date Check-In

No Alcohol According to EMA: According to the daily surveys that you have completed you have had no alcohol since your last visit here in our office. Is this correct?

Has had Alcohol According to EMA: According to the daily surveys that you have completed the last time you had alcohol was on______. Is this information correct? Is this the last time that you drank alcohol? To the best of your memory, have you reported all of your lapses in your daily surveys?

*If participant reports having a drink that they have not yet reported. Ask them the date and time of their first and last drink and make note of this information. If participant has more than one drinking episode that they have not yet reported, make note of the dates and times

of each drinking episode. If the participant does not know what time their lapse was, ask them the location of where the lapse occurred. Upon completion of the interview, this information will need to be added to the "Qualtrics EMA Later Battery" section of the Data Log. The data log is located here:

P://StudyData/RISK/RawData/Data Log.docx

Has the participant had any alcohol to drink since their last vis

	NIC
\cup	INC

OY

If No Alcohol Use Reported-Read:

Thanks for sharing with me the last date you drank alcohol.

Each time you come to a session, I will verify the date you last drank alcohol. Please know there are no consequences to your participation in our study if you do drink alcohol. Knowing when participants begin drinking again, even if it is only one drink, helps us accomplish our study goals. As you know one of the main goals of our study is to create a resource that people trying to recover from alcoholism can use. Knowing when people in our study have had a lapse will contribute to this resource because we will be able to see what circumstances may lead an individual in recovery to begin drinking again.

Do you have any questions?

If Alcohol Use Reported-Read:

Thanks for sharing with me the last date you drank alcohol.

Each time you come to a session, I will verify the date you last drank alcohol. Please know there are no consequences to your participation in our study if you do drink alcohol. Knowing when participants begin drinking again, even if it is only one drink, helps us accomplish our study goals. As you know one of the main goals of our study is to create a resource that people trying to recover from alcoholism can use. Knowing when people in our study have had a lapse will contribute to this resource because we will be able to see what circumstances may lead an individual in recovery to begin drinking again.

Do you have any questions?

If the participant is not enrolled in AODA treatment, ask them if they would like another list of mental health and substance use resources.

Call and Text Logs

<u>Upload Phone Log and Text Log Content to Shared Drive</u>
*Trained Staff will complete this task

*Give participant a few minutes alone to review their call and text logs to be sure that they feel comfortable with the content that will be uploaded.

Now, we are going to upload your phone call logs and text message content from your phone to our lab's computer. Someone from our lab will be here shortly to complete the upload. This will take about 5 -10 minutes, depending on how much content you have stored on your phone. Please take a few minutes to review the content on your phone to be sure that you feel comfortable with the information you will be sharing with us. Please delete any call or text content that you do not wish to share.

Did lab staff retrieve phone log and sms content from participant's phone?
No Yes
) les
f no, please explain below.
Please record name of staff member below.

Mobile Technology Questions and Concerns

Mobile and Wireless Device Questions and Concerns

Now, we are going to discuss the different apps you have been using in this study. I want to check-in with you about each app to make sure that you are completely comfortable with using them, and to give you the opportunity to ask any questions you may have.

Go over each app below with the participant and ask the following questions. If there are any issues that are specific to a participant, please discuss them now.

FollowMee App

1. Do you have any issues with the FollowMee app that you would like to discuss today?
Did RA ask participant if they had any questions or concerns about FollowMee?
O No
○ Yes
Responding to EMA
 Are you receiving four notifications to complete a survey each day? Do you have any issues with responding to the daily surveys that you would like to discuss today?
Did RA ask participant if they had any questions or concerns about responding to daily EMA?
O No
○ Yes
Audio Survey Response to Daily Check-In Question
 Are you receiving notification each day to complete your daily recovery check-in question? Do you have any issues with receiving or responding to the daily surveys that you would like to discuss today?
Did RA ask participant if they had any questions or concerns about responding to daily audio survey?
O No
O Yes

Are there any other issues or concerns that you would like to address today?

Please note any questions or concerns expressed by participant about the use of mobile and wireless devices. If participant did not have any questions, or express any concerns, please indicate that below.
ID Followup 1 & 2 battery-Risk
Qualtrics Procedure: Individual Differences Questionnaires
Next, I am going to have you complete some questions about your recovery efforts, current life situation, your personality and emotions, and your experiences with the technology used in the study. Each set of questions will have instructions. Please let me know if you have any questions as you complete the questionnaires.
Set-up participant with an iPad and open the individual difference questionnaires in Qualtrics survey labeled: ID Follow up 1 & 2 Battery-RISK
Ask the participant to tell you when he/she is finished with the surveys.
Did participant complete ID Followup 1 & 2 battery?
O No
O Yes
If no, please explain below.

9/2019	Qualtrics Survey Software
Interv	view
made most r found	urpose of this part of the session is to ask participants about any changes that need to be to their interview form since you last saw them. You will need to reference the participant's ecent interview form when completing this part of the session. All prior interview forms can be in the participant's study folder. Have a blank copy of the interview form and location and ct logs available to document potential updates.
places inform	The last time you were here we completed an interview with you and discussed the people, and events that have an impact on your recovery efforts. Today we are going to review the ation you shared with us last time and update any information that has changed, or that is since the last time we saw you.
Ask th	e participant the following questions:
1) The us?	e last time we saw you, you resided at Have you moved since your last visit with
。 <u>I</u>	f No , move to question #2. f Yes , update Participant Information section of interview form. Ask the participant the questions under the Participant Information section of the interview form.
avoid (list all there a	e last time we saw you, you shared the names and addresses of places that you are trying to as you seek to maintain sobriety. You shared that you are trying to avoid going to the places participant shared under the Risky Locations section of the interview form). Are any new places that you are trying to avoid ("risky" locations) while in recovery because they u at high risk to begin drinking again?
	f No, move to question #3. f Yes, add each new location to the Risky Locations section of the interview form. Fill in

requested information (name of the place, type of place, has participant ever drank alcohol at

the location, is alcohol available at the location, and what emotional experience does

participant typically have at the location).

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- 3) The last time we saw you, you shared some specific dates that put you at an increased risk to begin drinking again. You shared that ______ (list all the emotionally important dates the participant shared during their last visit) are days that put you at an increased risk to begin drinking again. Are there any other dates that put you at an increased risk to begin drinking again that you didn't share with us last time?
 - o If No, move on to question 4.
 - If Yes, add each new day to the Emotionally Important Days-Recurrent section of the interview form. Fill in requested information (date category, and actual date-mm/dd.
- 4) The last time we saw you, you shared with us time periods during the day that are protective, meaning you are confident that you will not drink, and time-periods that are risky, meaning that you are at high-risk to begin drinking again during these times. Have you identified any additional protective or risky time-periods since we last saw you?
 - If No, move on to question 5.
 - If Yes, add each new time-period to the Weekly Time-Periods section of the interview form. Fill
 in requested information (time-period category, the day of the week, time, and if it is a
 protective or risky time-period).
- 5) The last time we saw you, you shared some upcoming vacation dates with us. You shared that ______ (list the participant's upcoming vacation dates) are days that you plan to take a vacation while enrolled in the study. Are there any new vacations that you have planned, that you will take while enrolled in this study?
 - o If No, move on to guestion 6.
 - <u>If Yes</u>, add each new day to the vacation section of the interview form. Fill in requested information (city, state/country, dates, and in town or our of town).
- 6) Have you begun visiting any new places that you anticipate visiting on at least a monthly basis while enrolled in the study?
 - If No, move on to reviewing Unreported Locations.
 - If Yes, use the Take-Home Location Log to document each new location. Fill in the requested information (location address, type of location, if the participant has ever drank alcohol in this location, is alcohol available in this location, what emotional experience does participant typically have at the location, and the risk level of this location).
- 7) Review with the participant any Unreported Locations. Use the Take-Home Location Log to document each new location. Fill in the requested information (location address, type of location, if participant has ever drank alcohol in this location, is alcohol available in this location, what emotional experience does participant typically have at the location, and the risk level of this location).
- 8) Have you begun speaking with anyone new on your cell phone or via text that you anticipate communicating with on at least a monthly basis while you are enrolled in the study?
 - If No, move on to reviewing Unreported Contacts.

0	If Yes, add each new contact to the Take-Home Contact Log. Ask the participant the monthly
	contact questions.

Review with the participant any Unreported Contacts. Use the Take-Home Contact	Log to
document each new contact and ask relevant follow up questions.	

Did the participant report any updates to their previously reported interview data?
O No
O Yes
If Yes, please briefly explain what sections of the interview need updating.

EMA Form

Participant's EMA Form

Blank copies of the EMA form are in the RISK filing cabinet or on the shared drive: P:\StudyData\RISK\Methods\Study Forms\Forms\EMA Form 2018 0712

Review EMA form completed at intake/follow-up #1. This form is stored in participant's study folder.

READ: The last time we saw you, you reported an awake time of _____, and a bedtime of _____, Are these times still accurate?

• <u>If No</u>, record new awake/bedtimes on EMA form. Make sure to update this in Survey Signal as well as filling out a new Sleep Schedule survey in Qualtrics.

Did the participant update their wake and bedtimes?

29/2019	Qualtrics Survey Software
O No	
O Yes	
If yes, please explain the updates needed	below.
	//
Session Wrap-up	
Schedule Follow-up #2/Follow-up #3	
Now, let's schedule your next interview/Verify 3] still works.	that the date we scheduled for [follow-up#2/follow-up
	schedule the interview 60 (FU#2)/ 90 (FU#3) days from ew days). Participant's intake date can be found on a
the remaining scheduled follow-up sess	ail/email them an appointment reminder letter outlining sions. Also, let the participant know that you will call ppointment to confirm their ability to attend.

O No

O Yes

Scheduled Session

Was participant's follow up appointment scheduled?

O Follow-up #2
O Follow-up #3
Enter session date (mm/dd/yyyy) for follow-up #2 appointment.
Enter session time for follow-up #2 appointment.
Enter session date (mm/dd/yyyy) for follow-up #3 appointment.
Enter session time for follow-up #3 appointment.
Feedback Form We are very interested in getting your feedback about your experience participating in this study. The last questionnaire that you will complete today is a feedback form. This questionnaire will help us learn more about the things that are working well in our study, as well as the things that we can improve.
Set-up participant with an iPad and open the individual difference questionnaires in Qualtrics survey labeled: Feedback Battery-RISK
Did participant complete feedback form? O No O Yes
Please explain below why feedback from was not completed.

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Payment for Today's Session

If Follow-up1: Today you will be paid for the time you spent in our lab during your last visit, the take-home assignment you completed, using you cell phone service, and the time you have spent in our lab today.

As discussed in previous sessions, you will be compensated at the rate of \$20 per hour for all the time you spend in our lab. If you earned any data collection bonuses for month 1, you will receive that payment at your next visit.

- 1. Complete mHealth payment form for today's visit. *Always round up to the next closest half hour.
- 2. Review participant's mHealth payment form for their intake session.
- 3. Pay participant for the time they spent in the lab during their intake and follow-up#1 appointment (\$20/hr.), \$66 towards their cell phone service, and if applicable \$40 for completing the take-home assignment, with a check from the green checkbook. Write down the check # date paid, and total earned and paid on the participant's payment form.
- 4. Present check to the participant. Have the participant complete and sign the participant payment form.

If Follow-up 2: Today you will be paid for the time you spent in our lab today, cell phone usage, and for any collection bonuses from last month.

As discussed in previous sessions, you will be compensated at the rate of \$20 per hour for all the time you spend in our lab. If you earned any data collection bonuses for month 2, you will receive that payment at your next visit.

- 1. Complete mHealth payment form for today's visit *Always round up to the next closest half hour.
- 2. Review participant's mHealth payment form for their follow-up #1 session-Bonuses section.
- 3. Pay participant for their data collection bonuses for month 1, in addition to the amount they earned today. Write down the check # date paid, and total earned and paid on the participant's payment form.
- 4. Present check to the participant. Have the participant complete and sign the participant payment form.

Check below when participant has been paid.		
O Participant Paid		
What time did the participant depart from the lab? (e.g. 4:00 p.m.)		
Did participant complete this session? No		
O Yes		

If no, please explain below why session is incomplete.

https://uwmadison.co1.qualtrics.com/Q/EditSection/Blocks/Ajax/GetSurveyPrintPreview

Documentation
Check below when mHealth payment form has been completed.
O Payment Form Completed
Was participant's follow-up appointment scheduled?
O No
Check when you have updated the enrollment database with the outcome of this visit and the participant's next appointment.
O Completed
O Unable to complete
Check when you have updated the RISK Google Calendar with participant's next appointment.
O Completed
O Unable to Complete

Qualtrics Survey Software

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Have you have emailed the individuals on the RISK list serve of the follow-up #1 appointment?	ie scheduled
O No - Please Remember to send this email ASAP	
O Yes	
O Not Applicable	
Please explain below why participant's follow-up appointment wa	s not scheduled.

Once the Participant is Finished (Important)

- 1. Be sure to log off all computers logged into.
- 2. Clean up any trash that may have been left by the participant.
- 3. Enter any scheduled visit dates into the RISK Google calendar, and Titanium if the visit will be held in the Clinic.
- 4. Enter in current study visit as **completed**, and the new scheduled study visit as **scheduled** in the enrollment database.
- 6. *If applicable*, update the participant's VisitDates spreadsheet in their raw data folder with any new visits scheduled.
- 7. *If applicable*, update participant's EMA times in Survey Signal AND the Qulatrics Sleep Schedule battery.
- 8. Add Interview to the Interview Data Entry Tracking spreadsheet located here: P:\StudyData\RISK\Administration\Participants\Compliance\Interview Data Entry Tracking. The hard copy of the interview form will be stored in the RISK filing cabinet in the participant's study file. SEE STUDY PROTOCOL FOR ENTERING INTERVIEW DATA HERE: P:\StudyData\RISK\Methods\SOPs\RA SOPs\RISK_SOP_Interview Data Entry_2018_0524
- 9. Enter information from participant payment form into the RISK payment spreadsheet, found here: P:\StudvData\RISK\Participants\Participant Payment\RISK Participant Payment Tracker

- 10. File the completed participant payment form in the folder labeled 'Completed RISK participant payment forms' located in the main lab filing cabinet in Room #195A (second drawer).
- 11. Update participant's mHealth payment form and file it alphabetically in the mHealth payment folder in the main filing cabinet in Room #195A (second drawer).
- 12. File the participant's folder in numeric order in the RISK filing cabinet in Room #195A
- 13. If applicable, document any "yes" responses to EMA_1 for false surveys in the RISK Data Log. The log can be found here: P:\StudyData\RISK\Raw Data\Data Log
- 14. Return checkbook to RISK file cabinet in room 187
- 15. Return iPads to the charging station and laptop to the cabinet in room 187.

Confirmation Letter

Email/Mail the participant a confirmation email. A sample letter can be found at: P:\StudyData\RISK\Administration\Participants\SchedulingDocuments\Mail and Email Correspondence\Appointment Reminder Letters\Letters (or Emails)-Select appropriate letter

Confirmation Letter:

- 1. Go to wiscmail.wisc.edu (Study Email: arl4@psych.wisc.edu) Use the NetID: arl4_psych Pass: Curtin@rl
- 2. Email text from the selected file with details specific to the participant.
- 3. Attach this file: Parking and Bus Map-Word P:\StudyData\RISK\Administration\Participants\SchedulingDocuments\Mail and Email Correspondence\Parking and Bus map2017_0120
- 4. For participants that don't prefer email, mail the appointment reminder letter and parking map to their home address.

Parking Pass

If the participant needs a parking spot:

- 1. Go to http://psych.wisc.edu/RoomsAndEquipment/ and log in: Username: arc@psych.wisc.edu Password: Curtin Lab
- 2. Click Bookings in left hand menu
- 3. Change "View Schedule" to "Parking Schedule"
- Click at the start time of an available slot. Change the end time to reserve for the correct amount of time
- 5. Under Summary type "RISK"
- 6. Go to the main office in room 238. Take a green parking pass and stamp the session date twice.
- 7. Mail the participant his or her parking pass along with a reminder letter for the date and time of their screening visit and a map showing how to find the Psychology building and the spaces that are available to them. *You can also give them a pass at the end of their appointment for their next scheduled visit.

Have you booked parking/sent confirmation letter/email?
No - Please Remember to Book parking/Send participant Confirmation letter/emai
→ Yes
Not Applicable
Check below when session notes are complete.
Completed

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