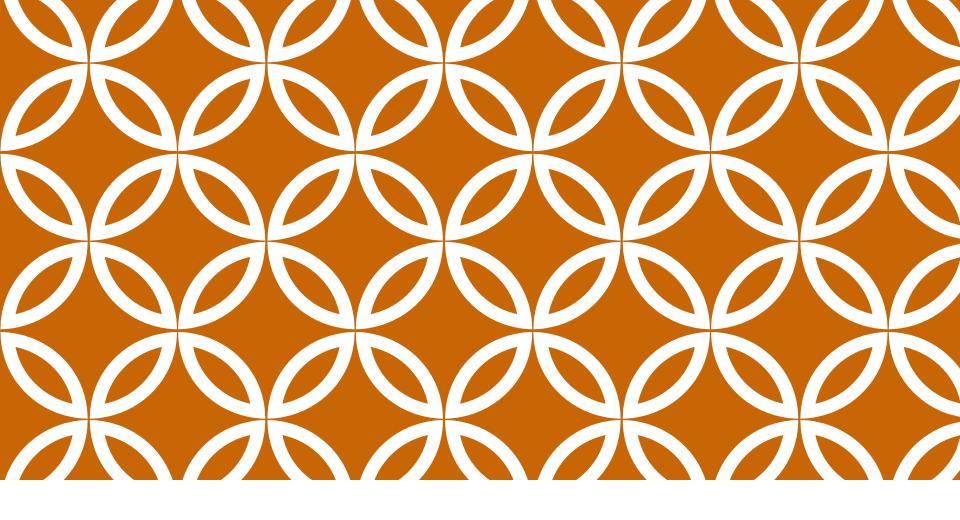


MTN-026 SITE TRAINING GUIDE

Administering Behavioral Assessments



IN-DEPTH PHONE INTERVIEW (IDPI)

Administering Behavioral Assessments



SETTING UP THE IDI

- Make sure that the office where the IDPIs will be held affords privacy.
- •The following equipment will be needed to conduct the teleconferences:
 - A telephone that has international calling availability



IDPI PROCEDURES

- Pre-IDPI Communication:
 - Inform participants to allot about 45-60 minutes extra for Visit
 3 & Visit 14
 - Email the interviewers of expected time of interview:
 - Titcha Ho: <u>kedsri@gmail.com</u> (cc Ryan: <u>rtingler@upenn.edu</u>)
 - Make sure to note time difference U.S. Eastern Standard Time 12 hours ahead of BKK
 - Receive confirmation from interviewer (add to Google Calendar)



IDPI PROCEDURES

•Day of the IDPI:

- Before connecting with the interviewer, make sure to let the participant know that the interviewer will be:
 - Looking at the CASI questionnaire data prior to the interviews to ask the appropriate questions for the IDIs
 - Recording the call
- Call interviewer via telephone to inform them that a participant is ready for the IDIs
 - Titcha: 347-280-6205



IDPI PROCEDURES

•Day of the IDPI:

- Once participants are connected with the interviewer they should be informed where they may find study staff if assistance is needed or in case equipment fails.
- Study staff should leave the room to give participants privacy.



TROUBLESHOOTING

- If the participant is unable to complete the teleconference during her study visit, make arrangements for her to return within the next visit window.
- If the call is not going through, make sure to have dial the appropriate international calling numbers.



TROUBLESHOOTING IDPI

- •In the event of a technical problem (i.e. server or power outage) that would preclude a participant's ability to complete an IDPI, please document the in the chart notes & brief description recorded on the applicable CRF.
- •If a participant need to interrupt their computer sessions (i.e. attend to a call, go to the bathroom), at the discretion of the interviewer, they can do so & resume the IDPI where they left it as long as the interviewer has time.
- •If a participant cannot complete an IDPI they day of the scheduled final visit or early termination visit, please notify the interviewer to schedule another time (only to be used in case of emergency).
- •For cancellations/changes to interview: Please notify interviewer (Titcha) (cc: Ryan) via email/phone 24 hours prior to designated interview time.



- Study coordinators will email Titcha Ho to inform them of all scheduled appointments, so that they can prepare for teleconferences.
- Titcha will confirm the appointment via email.
- To minimize scheduling conflicts between sites, Study Coordinators will enter the confirmed appointments into the Gmail calendar.
- Study coordinators can view the calendar prior to scheduling appointments to make sure Titcha will be available to do the interviewer.



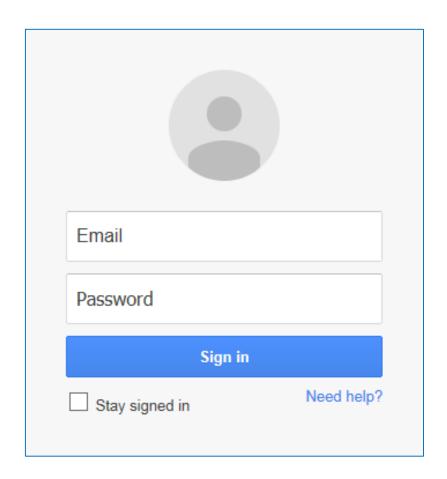
1. To access the Google calendar site, go to:

https://www.google.com/calendar

 Sign in with the account login below, and click on the "Calendar" tab at the top left

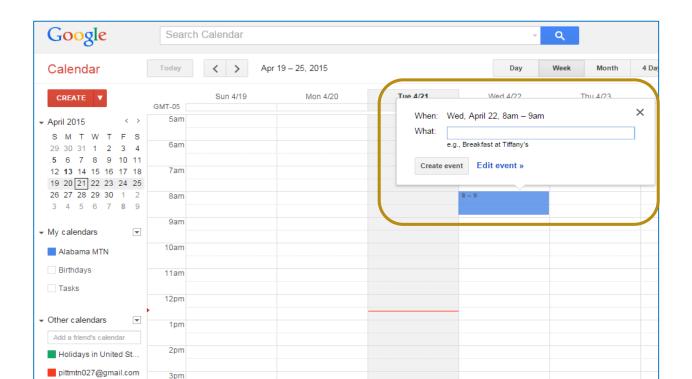
Silom Site Login

- Account email login:
 silomcommunitymtn026@gmail.com
- Password (case sensitive):
 microbicides026



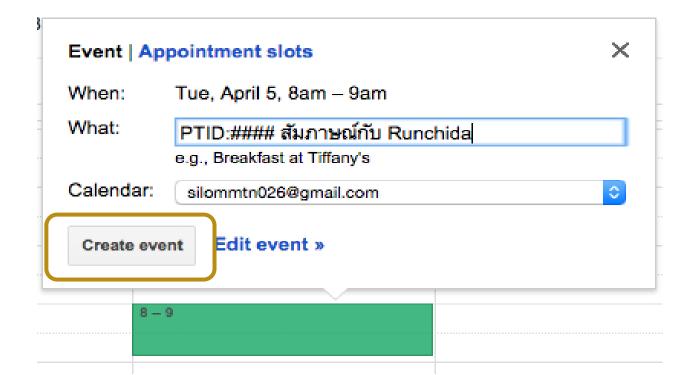


- To add an event:
- 1. Click on a time in the calendar (a box will pop-up)





- •To add an event:
- Name the event and then click "Create Event".
 Please Note: Time Zone





•To add an event:

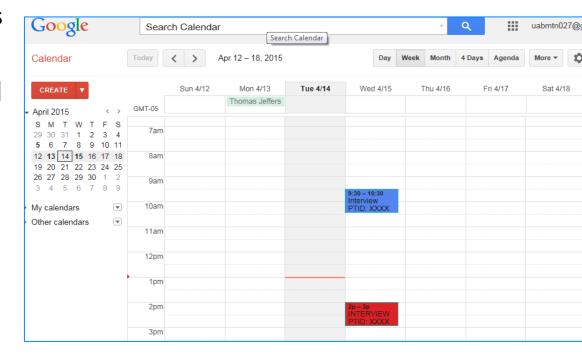
3. The appointments are color-coded by study site, and can be viewed by every site.

Silom: GREEN

Pittsburgh: RED

University of

Alabama: **BLUE**





IDPI SAFETY REPORTING

- •As required by DAIDS safety reporting policies, any potential Adverse Event (AE) or Social Harm (SH) reported by a study participant during the IDI will be brought to the attention of the clinical staff (section 11.4.2.4 of SSP)
- •In the rare event a suspected AE or SH is reported during the IDPIs, the qualitative interviewer will make note of the participants' comment(s) in the interview notes that will be maintained in the participant files at the University of Michigan
- •The qualitative interviewer will then alert the participant that she will need to report the AE or SH to the clinic staff



IDPI SAFETY REPORTING

- •The qualitative interviewer will then alert the clinic staff (by phone) that the participant reported an AE or SH.
- •The qualitative interviewer and the clinic staff will document in chart notes the notification made to clinic staff (by the qualitative interviewer) and the receipt of the notice (by clinic staff).
- •Clinic staff will follow-up with the participant to assess the AE or SH as needed and report/document the AE on the AE log CRF or SH on the Social Impact Log CRF



NEXT STEPS

- •Site staff will go through practice teleconference call with interviewer
- Can be scheduled at a specific time before study activation
 - Schedule with Titcha Ho
 - Kedsri@gmail.com
 - Only hardware run through for IDI will be completed (i.e. Google calendar scheduling and telephone call)



QUESTIONS?

Thank you!