**RISK Standard Operating Procedure (SOP)**

**Enrollment Database**

Last Edited: 5/29/2018 3:36 PM

Contents

[Setup 3](#_Toc513733084)

[Add to Database 3](#_Toc513733085)

[ Participant: ENROLLED 3](#_Toc513733086)

[ Participant: INFO UPDATED 4](#_Toc513733087)

[ Participant: DISPOSED 4](#_Toc513733088)

[ Visit: SCHEDULED 5](#_Toc513733089)

[ Visit: RESCHEDULED 6](#_Toc513733090)

[ Visit: CANCELLED 6](#_Toc513733091)

[ Visit: NO-SHOW 6](#_Toc513733092)

[ Visit: COMPLETED 7](#_Toc513733093)

[ Staff Call: SCHEDULED 7](#_Toc513733094)

[ Staff Call: COMPLETED 7](#_Toc513733095)

[Get Subject Info 8](#_Toc513733096)

[Get Visit Info 8](#_Toc513733097)

[Get Call Info 8](#_Toc513733098)

[Summary Functions 8](#_Toc513733099)

# Setup

* Files
  + Location: “P:\StudyData\RISK\Administration\Participants\Enrollment”
  + Name: “RISK\_EnrollmentDatabase(StaffID)”
    - StaffID is your last name and first initial, i.e. John Curtin’s staff ID is CurtinJ
* If you need to update the StudySupport package, uncomment (delete the hash mark) the very first line of code in the script and run that code
* Load StudySupport and stringr packages using the library function
* Run the code under “Setup for Database info” to set values needed to download the database
* Run the first line of code under “Download database” to download the database
  + You can uncomment (delete the hash mark) the second line of code and run that line to see the ENTIRE enrollment database

# Add to Database

* Run the code under “Add to database” to open the enrollment database qualtrics form

1. Entry Date:  
   (YYYY/MM/DD HH:MM:SS)  
   [Autofills current date and time]
2. SubID:
3. Entry Type

## Participant: ENROLLED

1. First Name:
2. Last Name:
3. Sex
   1. Female
   2. Male
   3. Not Reported
4. Race
   1. American Indian/Alaska Native
   2. Asian
   3. Native Hawaiian or Pacific Islander
   4. Black or African American
   5. White
   6. More Than One Race
   7. Not Reported
5. Ethnicity
   1. Hispanic or Latino
   2. Not Hispanic or Latino
   3. Not Reported
6. Study Arm:
7. Primary Phone  
   (###-###-####)
8. Secondary Phone Number  
   (###-###-####)
9. Email:
10. Address:
11. Notes:
12. Entry Type

## Participant: INFO UPDATED

1. Study Arm
2. Primary Phone  
   (###-###-####)
3. Secondary Phone Number  
   (###-###-####)
4. Email
5. Address
6. Notes:
7. Entry Type

## Participant: DISPOSED

1. Disposition
   1. Consent: NO-SHOW
      1. *Select this disposition if the subject was scheduled for a screening visit, but did not attend their screening visit*
   2. Consent: NO
      1. *Select this disposition if the subject was scheduled for a screening visit, attended their screening visit and refused to consent*
   3. Screen: INELIGIBLE
      1. *Select this disposition if the subject was scheduled for a screening visit, attended their screening visit and was deemed ineligible – or deemed ineligible before Intake completion.*
   4. On-Study: DISCONTINUE
      1. *Select this disposition if the participant has been enrolled in the study and chose to discontinue the study prior to completion*
      2. *Includes losing contact with a participant prior to study completion*
   5. On-Study: WITHDRAWN
      1. *Select this disposition if the participant has been enrolled in the study and the research team has chosen to withdraw the participant from the study prior to completion*
      2. *Includes subjects who are deemed ineligible at a later study date or is taken off the study for other staff initiated reasons (poor compliance, etc.)*
   6. Follow-up: LOST
      1. *Select this disposition when the study has a follow-up arm and the subject does not complete the follow-up*
      2. *Only subjects who have completed the study can be given this disposition*
      3. ***RISK DOES NOT USE THIS***
   7. COMPLETED
      1. *Select this disposition when the participant has fulfilled the minimum requirements for completing participation in a study*
   8. EXCLUDED
      1. *Select this disposition when the participant has completed the study but their data has been deemed not usable*
      2. *Only subjects who have completed the study can be given this disposition.*
2. Notes:
3. Entry Type

## Visit: SCHEDULED

1. Visit Type
2. Visit Date  
   (MM/DD/YYYY)
3. Schedule Reminder Call?
   1. No
   2. Yes
4. Notes:
5. Entry Type

## Visit: RESCHEDULED

1. Visit Type
2. Original Visit Date  
   (MM/DD/YYYY)
3. New Visit Date  
   (MM/DD/YYYY)
4. Schedule Reminder Call?
   1. No
   2. Yes
5. Notes:
6. Entry Type

## Visit: CANCELLED

1. Visit Type
2. Visit Date  
   (MM/DD/YYYY)
3. Notes:
4. Entry Type

## Visit: NO-SHOW

1. Visit Type
2. Visit Date  
   (MM/DD/YYYY)
3. Notes:
4. Entry Type

## Visit: COMPLETED

1. Visit Type
2. Visit Date  
   (MM/DD/YYYY)
3. Notes:
4. Entry Type

## Staff Call: SCHEDULED

1. Schedule Staff Call
   1. ASAP
   2. Future Date (mm/dd/yyyy):
2. Staff Call Type
   1. Reminder
   2. Other
3. Notes:
4. Entry Type

## Staff Call: COMPLETED

1. Staff Call Type
   1. Reminder
   2. Other
2. Staff Call Outcome
   1. Completed
   2. Call Again ASAP
   3. Call Again at Future Date (mm/dd/yyyy):
3. Notes:

# Get Subject Info

* Run the first line of code to get all records for a given SubID
* Run the second line of code to get all scheduled visits for a given SubID

# Get Visit Info

* Run the first line of code to get all visits for all subjects within a specified date window
* Run the second line of code to get visits of a specific type within a specified date window

# Get Call Info

* Run the first line of code to get all calls for all subjects within a specified date window
* Run the second line of code to get calls of a specific type within a specified date window

# Summary Functions

* Use the first line of code to view a table of subject statuses overall and by sex

# How NOT to Break the Database

Below are some helpful tips for using the database that will ensure the new entries you make will not obstruct the usability of the database

1. Pay attention to entry dates!
   1. The “Subject: ENROLLED” entry date should fall before ALL OTHER ENTRIES for that subject
   2. The “Visit: SCHEDULED” entry date must fall before the “Visit: COMPLETED” entry date for that visit
   3. The “Subject: DISPOSED” entry date must fall after ALL OTHER ENTRIES for that subject
2. Keep visit names consistent
   1. Be sure you are entering the same name for a visit when entering “Visit: SCHEDULED” and “Visit: COMPLETED”
      1. For example, if you submit a “Visit: SCHEDULED” entry using the Visit Type, “SV1”, then you submit a “Visit: COMPLETED” entry using the Visit Type, “Study Visit”, that “Visit: COMPLETED” entry will not mark the scheduled visit as complete in the database and will produce an error saying visits don’t align for that participant
   2. Be mindful of using the correct casing when inputting visit names
3. Keep track of rescheduled visits!
   1. R relies on Visit Dates when marking visits completed
   2. If you don’t input a visit as “Rescheduled”, the date will not get updated
   3. When you then try to enter that visit as “Completed” it won’t successfully be “Completed” due to an inaccurate date on the original “Visit: Scheduled” entry
4. Keep other staff call names consistent

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