

Risk Factors for Invasive Methicillin-resistant Staphylococcus aureus (MRSA) Infections among Recently Discharged Patients

PHONE INTERVIEW ATTEMPTS LOG

PATIENT NAME: _____ **STUDY ID:** _____

NAME OF THE HOSP WHERE HOSPITALIZATION OF INTEREST OCCURRED: _____

DATE OF INITIAL HACO MRSA CULTURE: __/__/____

PHONE NUMBER: _____

STATUS OF PHONE NUMBER: _____

PHONE TYPE: Home Office Cell

STATUS CODES: 1=correct, 0=not correct, 9=couldn't determine

ATTEMPT NUMBER	DATE	TIME-OF-DAY CODE	OUTCOME CODE	COMMENTS
1				
2				
3				
4				
5				
6				
7				
8				

TIME-OF-DAY CODES

- 1 = Weekday, 10AM – 11:59AM
- 2 = Weekday, Noon – 4:59PM
- 3 = Weekday, 5PM - 8PM
- 4 = Saturday only, 10AM-11:59AM
- 5 = Weekend, Noon – 4:59PM
- 6 = Weekend, 5PM – 8PM

OUTCOME CODES

- 1 = Enrolled
- 2 = Not home, left message
- 3 = Not home, no message left
- 4 = Refused to participate
- 5 = Unable to answer questions
- 6 = Unable to enroll (after 8 attempts)
- 7 = Need to call back
- 8 = Other, specify in **NOTES**

[GUIDELINES: A MINIMUM OF 8 ATTEMPTS ON AT LEAST 6 DIFFERENT DATES USING A VALID PHONE NUMBER SHOULD BE MADE BEFORE GIVING UP ON A POTENTIAL CASE OR CONTROL. AT LEAST ONE ATTEMPT SHOULD BE MADE BETWEEN 5-8PM; AND ONE WEEKEND DAY]

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).

TELEPHONE SCRIPT/SCREENING - FOR CASES

START TIME: _____

Screening Questions for case-patients

[Note: if the respondent indicates at any point in the interview that s/he is driving, end the interview and schedule a call back.]

[To the person who answers the phone, IF ADULT, otherwise ask to speak to an adult]: **“Hello, my name is _____.**
I am calling from the [State health dept]. May I please speak to _____ [Potential enrollee]?”

___ Yes: person who answered is potential enrollee; [go to Section A: Q2.]

___ Yes: coming to the phone; [go to Section A: Q2]

___ No: person is deceased:

- **“I am sorry. I was not aware of your loss. When did s/he pass away?”** ___ / ___ / ___
[Record date of death and proceed.]

“I would like to offer my condolences to you and your family. Would this be a good time to talk to you about a public health study about a severe infection caused by “MRSA” or “mersa”; or should I call back another time?”

- Call back
 - [Record person’s name to ask for, and day/time to call on phone log and say thank-you.]
- Now is a good time
 - [If now is a better time, go to Section C: Q4.]

___ No: person is incapacitated; [Go to Section C: Q4]

___ Does not speak English; [record language in comment section of phone log.]

- **“We will try to call back with someone who speaks Spanish, thank you.”** [If case speaks a language other than English or Spanish, he/she is not eligible. Record on case tracking as “No English or Spanish. =stop=”]

SECTION A: INTRODUCTION FOR CASES

Q2. “I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [STATE HEALTH DEPT] because you may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. We are calling you because you were hospitalized and then developed an infection with a germ called MRSA. Participation is voluntary and involves completing a 15-20 minute interview over the phone. It will include questions about your visits to hospitals, illnesses, and recent medications. Please know that your answers will be kept secure and you may choose not to answer any question. If you agree to participate we will send you a \$10 Target gift card for the time you give us. May I tell you more about the study?”

___ YES; [GO TO SECTION B].

___ NO; [GO TO Q3].

Q3. “Your participation in this study is very important. We are trying to better understand why people develop severe MRSA infection. May I schedule a time to talk that would be better for you?”

___ YES; [RECORD DAY/TIME ON PHONE LOG].

- **“Thank you very much for your time, I will call you back later.”**[=STOP=and call the person back at the requested day/time.]

___ No;

- **“Sorry to have disturbed you. Good-bye.”** [=STOP=and record in the interview tracking log as “Refused to participate.”]

SECTION B: ELIGIBILITY OF LIVING CASE

“Before I proceed, I would like to ask you a few questions about the time after your hospitalization at _____ [Name of hospital] to make sure you are eligible to participate in this study. Do you have a calendar? Many of our questions are going to refer to the time period after your discharge on ____/____/____ [Date of discharge from hospitalization of interest] and it might be helpful for you to look at a calendar. I can hold if you want to get a calendar.

CASE ELIGIBILITY:

1. “Between the time when you left _____ [Hospital name] on ____/____/____ [Date of discharge from hospitalization of interest] and the date of your MRSA infection on ____/____/____, [Date of initial HACO MRSA culture] did you make any other visits to a hospital where you had to stay overnight?”

- ___ Yes.....1 [Go to Q.1A]
- ___ No.....2 [Go to Q.1D]

1A. “During this overnight stay at the hospital, did you sleep there for 3 or more nights?”

- ___ Yes.....1 [Go to Q.1B]
- ___ No..... 2 [Go to Q.1D]
- ___ Don't know/Not sure..... 7

- “Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3. Even though we were not able to enroll you in this study, we appreciate your time and willingness to participate. Do you have any questions for me?” [STOP! EXCLUDE THIS CASE FROM STUDY]

1B. “What is the name of this hospital where you stayed in for 3 or more nights between the time you left _____ [first hospital name] and the date of your MRSA infection on ____/____/____ [date of initial HACO MRSA culture]?”

Name of Hospital: _____

___ Not Sure/Don't Know then say:

- “Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll you in this study, we appreciate your time and willingness to participate. Do you have any questions for me?” [EXCLUDE THIS CASE FROM STUDY = STOP=]

___ If facility is not participating in the study then say:

- “Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3. Even though we were not able to enroll you in this study, we appreciate your time and willingness to participate. Do you have any questions for me?” [EXCLUDE THIS CASE FROM STUDY = STOP=]

___ If facility is participating in the study then [Go to 1C; this patient is eligible]

1C. “What was the date that you left this hospital where you stayed for 3 or more nights?” ____/____/____ [NOTE: you should use this date as the date of discharge from the hospitalization of interest. MRRF with this new hospitalization of interest date will need to be filled out for this patient]

1D. “Now that I know you are eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at any time.” [GO TO Appendix 5: Consent Form]

SECTION C: PROXY INTRODUCTION

Q4. “I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [STATE HEALTH DEPT] because [POTENTIAL ENROLLEE] may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. We are calling you because [POTENTIAL ENROLLEE] was hospitalized and then developed an infection with a germ called MRSA. Participation is voluntary and involves completing a 15-20 minute interview over the phone. It will include questions about [POTENTIAL ENROLLEE]’s visits to hospitals, illnesses, and recent medications. Please know that your answers will be kept secure and you may choose not to answer any question. If you agree to participate we will send you a \$10 Target gift card for the time you give us. ”

“Are you legally qualified to answer questions about [POTENTIAL ENROLLEE]?”

 Yes; [IF DECEASED, GO TO Q4.1]

 No; [Go to Q4.1]

Q4.1 “Are you considered [POTENTIAL ENROLLEE]’s next of kin?”

 YES: [RECORD PROXY NAME ON ENROLLEE INTERVIEW COVERSHEET; GO TO Q4.2.]

 NO:

- **“Do you have the name and phone number of the person who may be legally qualified to answer question about [POTENTIAL ENROLLEE] or who is [POTENTIAL ENROLLEE]’s next of kin?” [RECORD PROXY NAME AND PHONE NUMBER ON ENROLLEE INTERVIEW COVERSHEET]” Thank you for your time.”**

 DON’T KNOW OR UNSURE:

- **“Thank you but we need to talk with the person who is legally qualified to answer question about [POTENTIAL ENROLLEE] OR WHO IS THE NEXT OF KIN. Thank you for your time.” [= STOP =]**

Q4.2 “What is your relationship to [POTENTIAL ENROLLEE]?”

 Husband, wife, widow/er; [GO TO Q4.3]

 Legal guardian; [GO TO Q4.3]

 Son or daughter; [GO TO Q4.3]

 Power of attorney; [GO TO Q4.3]

 Parent; [GO TO Q4.3]

 Caregiver; [GO TO Q4.3]

 Sister or brother; [GO TO Q4.3]

 Other, please specify _____; [GO TO Q4.3]

Q4.3 . “May I tell you more about the study?”

 Yes; [GO TO SECTION D] No; [GO TO Q5.]

Q5 “Participation in this study is very important. We are trying to better understand why people develop severe MRSA infection. What would be a better time to call you back?”

 Yes [RECORD DAY/TIME TO CALL ON PHONE LOG].

- **“Thank you very much for your time, I will call you back later. Good-bye.” [=STOP=and call back at requested day and time.]**

 No; “Sorry to have disturbed you. Good-bye.” [=STOP=]

SECTION D: ELIGIBILITY OF CASE FOR PROXY

“Before I proceed, I would like to ask you a few questions about the time after his/her hospitalization at _____ [Name of hospital] to make sure s/he is eligible to participate in this study. Do you have a calendar? Many of our questions are going to refer to the time period after his/her discharge on ____/____/____ [Date of discharge from hospitalization of interest], and it might be helpful for you to look at a calendar. I can hold if you want to get a calendar.

CASE ELIGIBILITY:

1. "Between the time when s/he left _____ [Hospital name] on ___/___/___ [Date of discharge from hospitalization of interest] and the date of his/her MRSA infection on ___/___/___, [Date of initial HACO MRSA culture] did s/he make any other visits to any hospital where s/he had to stay overnight?"

- ___ Yes.....1 [Go to Q.1A]
- ___ No.....2 [Go to Q.1D]

1A. "During this overnight stay at the hospital, did s/he sleep there for 3 or more nights?"

- ___ Yes.....1 [Go to Q.1B]
- ___ No.....2 [Go to Q.1D]
- ___ Don't know/Not sure.....7

- "Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll [POTENTIAL ENROLLEE] in this study, we appreciate your time and willingness to participate. Do you have any questions for me?" [STOP! EXCLUDE THIS CASE FROM STUDY]

1B. "What is the name of this hospital where s/he stayed in for 3 or more nights between the time s/he left _____ [First hospital name] and the date of his/her MRSA infection on ___/___/___ [Date of initial HACO MRSA culture]?"

___ Not Sure/Don't Know then say:

- "Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll [POTENTIAL ENROLLEE] in the study, we appreciate your time and willingness to participate. Do you have any questions for me?" [EXCLUDE THIS CASE FROM STUDY = STOP=]

___ If facility is not participating in the study then say:

- "Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3. Even though we were not able to enroll [POTENTIAL ENROLLEE] in this study, we appreciate your time and willingness to participate. Do you have any questions for me?" [EXCLUDE THIS CASE FROM STUDY = STOP=]

___ If facility is participating in the study then [Go to 1C; this patient is eligible]

1C. "What was the date that s/he left this hospital where he/she stayed for 3 or more nights?"

___/___/___

[Please NOTE: you should use this date as the date of discharge from the hospitalization of interest. New MRRF will need to be filled out for this patient]

1D. "Now that I know s/he are eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at any time." [Go to Appendix 5: Consent Form]

START TIME: _____

TELEPHONE SCRIPT/SCREENING - FOR CONTROLS

Screening Questions for control-patients

[Note: if the respondent indicates at any point in the interview that s/he is driving, end the interview and schedule a call back.]

Q1. [To the person who answers the phone, IF ADULT, otherwise ask to speak to an adult]: “Hello, my name is _____ . I am calling from the [State health dept]. May I please speak to [Potential enrollee]?”

___ Yes: person who answered is potential enrollee; [go to Section A: Q2.]

___ Yes: coming to the phone; [go to Section A: Q2]

___ No: person is deceased:

- “I am sorry. I was not aware of your loss. When did s/he pass away?” ___/___/___
[Record date of death and proceed.]
 - [If date of death was before date of matched-case's initial HACO MRSA culture
[Date: ___/___/___] stop and say:]
 - “I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you. Thank you for your time.” [Do not conduct interview- control not eligible]
 - [If date of death is after date of matched-case's case's initial HACO MRSA culture
[Date: ___/___/___], please say:]
 - “I would like to offer my condolences to you and your family. Would this be a good time to talk to you about a public health study about a severe infection caused by “MRSA” or “mersa”; or should I call back another time?”
 - Not Now
 - [Record person's name to ask for, and day/time to call on phone log and say thank-you.]
 - Now is a good time
 - [If now is a better time, go to Section C:]

___ No: person is incapacitated; [go to Section C: Q4]

___ Does not speak English; [record language in comment section of phone log.]

- “We will try to call back with someone who speaks Spanish, thank you.” [If control speaks a language other than English or Spanish, he/she is not eligible. Record on tracking log as “No English or Spanish.” =stop=]

SECTION A: INTRODUCTION FOR CONTROLS

Q2. “I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [STATE HEALTH DEPT] because you may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. We are calling you because someone who was hospitalized at the same time as you has developed an infection with a germ called MRSA. Participation is voluntary and involves completing a 15-20 minute interview over the phone. It will include questions about your visits to hospitals, illnesses, and recent medications. Please know that your answers will be kept secure and you may choose not to answer any question. If you agree to participate we will send you a \$10 Target gift card for the time you give us. May I tell you more about the study?”

___ YES; [GO TO SECTION B].

___ NO; [GO TO Q3].

Q3. “Your participation in this study is very important. We are trying to better understand why people develop severe MRSA infection. May I schedule a time to talk that would be better for you?”

___ YES; [RECORD DAY/TIME ON PHONE LOG].

- “Thank you very much for your time.” [=STOP= and call back at requested day and time.]

___ No;

- “Sorry to have disturbed you. Good-bye.” [=STOP= and record on interview tracking log as “Refused to participate.”]

SECTION B: ELIGIBILITY OF LIVING CONTROL

“Before I proceed, I would like to ask you a few questions about the time after your hospitalization at _____ [Name of hospital] to make sure you are eligible to participate in this study. Do you have a calendar? Many of our questions are going to refer to the time period after your discharge on ____/____/____ [Date of discharge from hospitalization of interest] and it might be helpful for you to look at a calendar. I can hold if you want to get a calendar.”

CONTROL ELIGIBILITY:

1. “After you left _____ [hospital name] on ____/____/____ [date of discharge from hospitalization of interest], were you told by your doctor that you had “MRSA” or “MERSA”?

- ___ Yes.....1 [Go to Q.1A]
- ___ No.....2 [Go to Q.2]

1A. [If yes], “Do you remember what part of the body were you told you had MRSA?”

- a ___ Blood [Go to Q.1B]
- b ___ Joint [Go to Q.1B]
- c ___ Bone [Go to Q.1B]
- d ___ Heart [Go to Q.1B]
- e ___ Other sterile site, Specify: _____ [Go to Q.1B]
- f ___ Unknown [Go To Q.2]
- g ___ Told it was not an infection; list the site: _____ [Go to Q.2]

[NOTE: If the MRSA infection was not INVASIVE (MRSA not isolated from a sterile site; e.g. sputum, lung, wound, skin, nose) or answers f-g were checked skip to Q. 2.]

1B. “Did this MRSA infection occur between the date you left the hospital on ____/____/____ [date of discharge from hospitalization of interest] and ____/____/____ [look on the calendar and determine the date 12 weeks later]?”

- ___ Yes.....1 [If yes], What date did it occur?: ____/____/____
 - “Thank you for taking the time to answer my questions. We are only interviewing people who did not get sick with the MRSA germ within 12 weeks after leaving the hospital. Even though we were not able to enroll you in this important study, we appreciate your time and willingness to participate in the study. Do you have any questions for me?” [EXCLUDE THIS CONTROL = STOP=]
- ___ No.....2 [Go to Q. 2]

2. “Between ____/____/____ [date of discharge from hospital of interest] and ____/____/____ [date of matched-case invasive HACO MRSA culture], did you make any other visits to a hospital where you had to stay overnight?”

- ___ Yes 1 [Go to Q. 2A]
- ___ No..... 2 [Go to Q. 2B]

2A. “During this overnight stay at the hospital, did you sleep there for 3 or more nights?”

- ___ Yes.....1
 - “Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll you in this study, we appreciate your time and willingness to participate. Do you have any questions for me?” [STOP! EXCLUDE THIS CONTROL]
- ___ No.....2 [Go to 2B]
- ___ Don't know/Not sure.....7
 - “Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll you in this study, we appreciate your time and

willingness to participate. Do you have any questions for me?" [STOP! EXCLUDE THIS CONTROL]

2B. "Now that I know you are eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at any time." [Go To Appendix 5: Consent Form]

SECTION C- PROXY INTRODUCTION FOR CONTROLS:

Q4. "I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [STATE HEALTH DEPT] because [POTENTIAL ENROLLEE] may be eligible to participate in a public health study. This study is being performed by CDC and your State Health Department. We are calling [Potential Enrollee] was hospitalized at the same time as someone who developed an infection with a germ called MRSA. Participation is voluntary and involves completing a 15-20 minute interview over the phone. It will include questions about [POTENTIAL ENROLLEE]'S visits to hospitals, illnesses, and recent medications. Please know that answers will be kept secure and you may choose not to answer any question. If you agree to participate we will send you a \$10 Target gift card for the time you give us. "
"Are you legally qualified to answer questions about [POTENTIAL ENROLLEE]?"

Yes; [IF DECEASED, GO TO Q4.1]

No; [Go TO Q4.1]

4.1 "Are you considered [POTENTIAL ENROLLEE]'s next of kin?"

YES: [RECORD PROXY NAME ON ENROLLEE INTERVIEW COVERSHEET; GO TO Q4.2.]

NO:

- "Do you have the name and phone number of the person who may be legally qualified to answer question about [POTENTIAL ENROLLEE] or who is [POTENTIAL ENROLLEE]'s next of kin?" [RECORD PROXY NAME ON ENROLLEE INTERVIEW COVERSHEET]" Thank you for your time."

DON'T KNOW OR UNSURE:

- "Thank you but we need to talk with the person who is legally qualified to answer question about [POTENTIAL ENROLLEE] OR WHO IS THE NEXT OF KIN. Thank you for your time." [= STOP =]

Q4.2 "What is your relationship to [POTENTIAL ENROLLEE]?"

Husband, wife, widow/er; [GO TO Q4.3]

Legal guardian; [GO TO Q4.3]

Son or daughter; [GO TO Q4.3]

Power of attorney; [GO TO Q4.3]

Parent; [GO TO Q4.3]

Caregiver; [GO TO Q4.3]

Sister or brother; [GO TO Q4.3]

Other, please specify _____; [GO TO Q4.3]

Q4.3. "May I tell you more about the study?"

Yes; [GO TO SECTION D] No; [GO TO Q5.]

Q5 "Participation in this study is very important. We are trying to better understand why people develop severe MRSA infection. What would be a better time to call you back?"

Gives another time [RECORD DAY/TIME TO CALL ON PHONE LOG].

- "Thank you very much for your time. Good-bye." [=STOP= and call back at requested day and time.]

No/None; "Sorry to have disturbed you. Good-bye." [=STOP=]

SECTION D: ELIGIBILITY OF CONTROL FOR PROXY

"Before I proceed, I would like to ask you a few questions about the time after his/her hospitalization at _____ [Name of hospital] to make sure s/he is eligible to participate in this study. Do you have a calendar? Many of our questions are going to refer to the time period after his/her discharge on ____/____/____ [Date of

discharge from hospitalization of interest], and it might be helpful for you to look at a calendar. I can hold if you want to get a calendar.

CONTROL ELIGIBILITY:

1. "After s/he left _____ [Hospital name] on ____/____/____ [Date of discharge from hospitalization of interest], was s/he told by his/her doctor that s/he had "MRSA" or "MERSA" inside of his/her body?"

- ___ Yes.....1 [Go to Q.1A]
- ___ No.....2 [Go to Q.2]

1A. [If yes], "Do you remember in what part of the body s/he had MRSA?"

- a. ___ Blood [GO To Q.1B]
- b. ___ Joint [GO To Q.1B]
- c. ___ Bone [GO To Q.1B]
- d. ___ Heart [GO To Q.1B]
- e. ___ Other sterile site, Specify: _____ [GO To Q.1B]
- f. ___ Unknown [GO To Q.2]
- g. ___ Told it was not an infection; list the site: _____ [GO To Q.2]

[NOTE: If the MRSA infection was NOT INVASIVE (MRSA isolated from a non-sterile site; such as sputum, lung, wound, skin, nose skip to Question 2.)

1B. "Did this MRSA infection occur between the date s/he left the hospital on ____/____/____ [Date of discharge from hospitalization of interest] and ____/____/____ [look on the calendar and determine the date 12 weeks later]?"

- ___ Yes.....1 [If yes] what date was it: ____/____/____
 - "Thank you for taking the time to answer my questions. We are only interviewing people who did not get sick with the MRSA germ within 12 weeks after leaving the hospital. Even though we were not able to enroll [POTENTIAL ENROLLEE] in this study, we appreciate your time and willingness to participate. Do you have any questions for me?" [EXCLUDE THIS CONTROL = STOP=]
- ___ No.....2 [Go to Q.2]

2. "Between ____/____/____ [date of discharge from hospital of interest] and ____/____/____ [date of matched-case initial HACO MRSA culture], did s/he make any other visits to a hospital where s/he had to stay overnight?"

- ___ Yes 1 [Go to Q.2A]
- ___ No 2 [Go to Q.2B]

2A. "During this overnight stay at the hospital, did s/he sleep there for 3 or more nights?"

- ___ Yes.....1
 - "Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll [POTENTIAL ENROLLEE] in this study, we appreciate your time and willingness to participate. Do you have any questions for me?" [STOP! EXCLUDE THIS CONTROL]
- ___ No.....2 [Go to 2B]
- ___ Don't know/Not sure.....7
 - "Thank you very much for taking time to answer my questions. We are only interviewing people who did not stay in the hospital overnight for more than 3 nights. Even though we were not able to enroll [POTENTIAL ENROLLEE] in this study, we appreciate your time and willingness to participate. Do you have any questions for me?" [STOP! EXCLUDE THIS CONTROL]

2B. **“Now that I know s/he is eligible to participate, I would like to share some additional details about the study and obtain your verbal permission for participation. Feel free to stop me and ask questions at any time.”** [[GO TO Appendix 5: Consent Form](#)]