€ CASE   € CONTROL

Attachment D: Pediatric Case and Control Screening Forms

Community-associated *Clostridium difficile* Infection (CDI) Risk Factor Study Call Log

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

PHONE NUMBER:_____

PHONE TYPE: ☐ Home ☐ Office ☐ Cell

STATUS OF PHONE NUMBER:_____

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**

€ CASE   € CONTROL
Patient ID:_____
State ID:_____

REFERENCE Date _____/_____/_____

Attachment D: Pediatric Case and Control Screening Forms

CASE SUBJECT

INITIAL CALL INTRODUCTION

1. [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 [*parent/ guardian of potential enrollee*]?"

___Yes: person who answered is parent or guardian of enrollee; [go to case patient call script]

___Yes: coming to the phone; [go to case patient call script]

___No: person is unavailable – *record call back time on phone log if given*

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

- IF SPANISH SPEAKING: "We will try to call back with someone who speaks Spanish, thank you."
- IF OTHER LANGUAGE: "Thank you for your time. Have a nice day" [If case speaks a language other than English or Spanish, he/she is not eligible. Record on tracking log as "No English or Spanish." =stop=]

CASE PARTICIPANTS Call Script:

2. "I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [*State Health Dept.*] because your child 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 your child had an infection with a germ called *Clostridium difficile;* sometimes it is also called *C. diff*. The <state health department> routinely tracks how often people in your area get sick from *C.difficile* infections and is notified whenever a person develops this infection. Participation is voluntary and involves completing a 30 minute interview over the phone. It will include questions about your child's illness, healthcare visits, medical history, 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 $20 gift card as a token of appreciation. May I tell you more about the study?"

___Yes; [go to Case Subject Screening]

___No; [go to Q3]

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3. "Your participation in this study is very important. We are trying to better understand why people develop *Clostridium difficile* 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."]

*******BEFORE YOU PROCEED INTERVIEW, HAVE A CALENDAR IN FRONT OF YOU******

CASE **S**UBJECT **S**CREENING **Q**UESTIONS

I will ask you questions about your child's illness, healthcare contacts, household contacts, other exposures, and medical history. It may be difficult to remember, but I would like your best guess for each question. Because I will be asking about specific dates around the time your child's illness began, it may be helpful for you to have a calendar or datebook in front of you. I can hold while you get these things. The dates we are interested in are between [12 weeks *before* positive specimen collection Date_____/_____/_____] to [positive specimen collection date _____/_____/_____]. Do you need a minute to go get any of these items?

When Participant returns say "I would like to begin with a few questions to be sure you are eligible to participate in the study"

1. Today, what is your child's health status? I will read some choices:

Well………………………………………….1
Ill or sick…………………………………..2
Deceased………………………………..5
 " If deceased say : "I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you and we do not need to continue with the interview. Thank you for your time."

Don't know/Not sure................................7
Refused...9
If Don't know / refused say "We are only interviewing parents if the child's health status is known. Thank you for your time"

€ CASE   € CONTROL

Patient ID:_____

State ID:_____

REFERENCE Date _____/_____/_____

2. Has your child been diagnosed with *C. difficile* **before** the collection of your child's stool specimen on [specimen collection date_____/_____/_____]?

        Yes...1

      (If Yes –STOP Interview and say "We are only interviewing people who have not had a previous C. difficle diagnosis. Thank you for your time.)

        No..2

        Don't know/Not sure...................7

        Refused....................................9

3. Did your child stay overnight in a hospital, long term care facility, or nursing home in the 12 weeks **before** [Reference Date _____/_____/_____]?

        Yes...1

      (If Yes –STOP Interview and say "We are only interviewing people who did not stay in a hospital during that time." Thank you for your time.)

        No..2

        Don't know/Not sure...................7

        Refused....................................9

4. Did your child have diarrhea at the time your child's stool specimen was collected on [specimen collection date_____/_____/_____]? We define diarrhea as 3 or more loose stools in a 24 hour period.

        Yes...1 **(Go to Q. 5)**

        No..2

        Don't know/Not sure...................7

        Refused....................................9

      (IF NO, DON'T KNOW, REFUSE- STOP Interview and say "We are only interviewing people who had diarrhea with their C. difficile diagnosis. Thank you for your time.)

5.A. Do [you] remember when your child's diarrhea began?

        Yes...1 **(If Yes –fill in date diarrhea began and use as reference date)**

        No..2 **(fill in date of specimen collection and use as reference date.)**

        Don't know/Not sure...................7 **(fill in date of specimen collection and use as reference date.)**

        Refused....................................9 **(fill in date of specimen collection and use as reference date.)**

€ REFERENCE DATE: _____/_____/_____
(mm/dd/yyyy)

2 week before _____/_____/_____

4 weeks before _____/_____/_____

12 weeks before _____/_____/_____

€ CASE　　€ CONTROL

Patient ID:_____

State ID:_____

REFERENCE Date _____/_____/_____

GO TO CASE CONSENT AND SAY "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." [<u>AFTER CONSENT COMPLETE CONTINUE WITH INTERVIEW</u>]

CONTROL SUBJECTS

INITIAL CALL INTRODUCTION

1. [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.*]. I am calling about a public health study on an infection called *Clostridium difficile.* For this study we are looking for children who are [insert sex / age group]. Is there a parent or guardian of a child in this group who I can speak with?"

___Yes: person who answered is parent or guardian of enrollee; [go to control patient call script]

___Yes: coming to the phone; [go to control patient call script]

___No: person is unavailable – *record call back time on phone log if given*

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

- IF SPANISH SPEAKING: "We will try to call back with someone who speaks Spanish, thank you."
- IF OTHER LANGUAGE: "Thank you for your time. Have a nice day" [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=]

CONTROL PARTICIPANTS Call Script:

2. "I am calling on behalf of the Centers for Disease Control and Prevention (CDC) and the [*State Health Dept.*] because your child may be eligible to participate in a public health study. This study looks at how people living in the community get an illness caused by a germ called *Clostridium difficile* (also called *C. diff*). As part of our study, we need to talk to the parents of children who **did not** become ill with *C.diff*, but live in the same area as someone who did and who is around the same age as the ill person. The study is voluntary

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and involves completing a 30 minute interview over the phone. It will include questions about your child's

healthcare visits, medical history, 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 $20 gift card

as a token of appreciation. May I tell you more about the study?"

___Yes; [go to CONTROL SCREENING QUESTIONS]
___No; [go to Q 3].

3. "Your participation in this study is very important. We are trying to better understand why people develop

Clostridium difficile 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."]

*******BEFORE YOU PROCEED, HAVE A CALENDAR IN FRONT OF YOU******

Control Subject Screening Questions

I will ask you questions about your child's healthcare contacts, household contacts, other exposures, and medical history. It may be difficult to remember, but I would like your best guess for each question. Because I will be asking about specific dates, it may be helpful for you to have a calendar or datebook in front of you. The dates we are interested in are between [12 weeks *before Matched CASE participant's* Reference Date_____/_____/_____] to [matched *case participant's* Reference Date_____/_____/_____]. I can hold while you get these things. Do you need a minute to go get any of these items?

When Participant returns say "I would like to begin with a few questions to be sure you are eligible to participate in the study"

1. Today, what is your child's health status? I will read some choices:

Well………………………………………1
Ill or sick…………………………………..2
Deceased…………………………………..5
 " If deceased say : "I would like to offer my condolences and apologize for any inconvenience that this call may have caused to you and we do not need to continue with the interview. Thank you for your time."
Don't know/Not sure...............................7
Refused...9
If Don't know / refused say "We are only interviewing parents if the child's health status is known. Thank you for your time"

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€ CASE   € CONTROL

Patient ID:_____

State ID:_____

REFERENCE Date _____/_____/_____

1. Was your child between the ages of [matched case patient age group_____] on [REFERENCE Date

_____/_____/_____]?

      Yes..1 (**Go to Q.2)**

      No...2
      Don't know/Not sure...................7
      Refused.....................................9
      (If No, Don't know / Refuse STOP Interview and say:" We are only interviewing patients in that age

group. Thank you for your time".)

2. Did your child live in [EIP catchment area counties] on [REFERENCE Date _____/_____/_____]?

      Yes..1 (**Go to Q.3)**

      No...2
      Don't know/Not sure...................7
      Refused.....................................9
      (If No, Don't know / Refuse STOP Interview and say:" We are only interviewing patients who lived

in that area. Thank you for your time".)

3. Did your child stay overnight in a hospital, long term care facility, or nursing home in the 12 weeks *before*

[Reference Date _____/_____/_____]?

      Yes..1
        **(*If Yes –STOP Interview and say "We are only interviewing people who did not stay in a hospital*
        during that time." Thank you for your time.)
      No...2 (**Go to Q.4)**
      Don't know/Not sure...................7
      Refused.....................................9
      (If Don't know / Refuse STOP Interview and say "We are only interviewing people who did not
stay in a hospital during that time. Thank you for your time")

4. Has your child ever been diagnosed with *C. difficile* in the past?
      Yes..1
        **(*If Yes –STOP Interview and say "We are only interviewing people who have not had a previous*
        C. difficle diagnosis. Thank you for your time.)
      No...2 (**Go to Q. 5)**
      Don't know/Not sure...................7
      Refused.....................................9
      (If Don't know / Refuse STOP Interview and say "We are only interviewing people who did not
have C.   difficile in the past. Thank you for your time")

5. Did your child have diarrhea within the 12-weeks before [REFERENCE date_____/_____/_____]? We define
diarrhea as 3 or more loose stools in a 24 hour period.

€ CASE   € CONTROL

Patient ID:_____

State ID:_____

REFERENCE Date _____/_____/_____

      Yes..1
        (IF YES- STOP Interview and say "We are only interviewing people who did not have diarrhea.
        Thank you for your time.)
      No..2 *(GO TO CONSENT SCRIPT BELOW)*
      Don't know/Not sure...................7
      Refused.....................................9
      (If Don't know / Refuse STOP Interview and say "We are only interviewing people who did not
have   *diarrhea. Thank you for your time")*

CONTROL CONSENT SCRIPT: GO TO CONTROL CONSENT AND SAY "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."

[AFTER CONSENT COMPLETE CONTINUE WITH INTERVIEW