OPPERA-II CATI SCRIPT: SCREENING AND VERBAL CONSENT FOR ACUTE->CHRONIC TMD (PROTOCOL 12-049) & CHRONIC TMD GWAS REPLICATION (PROTOCOL 12-052)

I.   LIST-ASSISTED CONTACT SCRIPT

IF PHONE IS ANSWERED WITH RECOGNIZED BUSINESS NAME, APOLOGIZE FOR CALLING WRONG NUMBER, HANG-UP, AND CODE BUSINESS.

IF BUSINESS NAME IS NOT RECOGNIZED OR NO BUSINESS NAME IS GIVEN, INTERVIEWER READS SCRIPT BELOW.

CS1   Hello, this is [FULL NAME] calling on behalf of researchers at the University of [STUDY SITE]. We're conducting an important research survey to better understand causes of facial pain in adults aged 18 to 54 living around [STUDY SITE]. This phone number was randomly selected for an interview. Can you please tell me, do any adults aged 18 to 54 currently live in this household?

(IF NEEDED: Do not include adults who usually live somewhere else.)

(IF NEEDED: Must be 18 to 54 as of today.)

(IF RESPONDENT SOUNDS LIKE A CHILD, ASK FOR AN ADULT. IF NEEDED, REASSURE THAT THIS IS NOT A MARKETING CALL.)

YES [GOTO CS2] 1

NO [INELIGIBLE, GOTO Q28] 2

YES, BUT CAN'T TALK NOW (ASK FOR TIME TO CALL BACK. END INTERVIEW.) 3

SPEAKING WITH CHILD. NO ADULT AVAILABLE (ASK FOR TIME TO CALL BACK. END INTERVIEW.) 4

BUSINESS. (I'm sorry, we're interviewing residences only. Thank you for your time. INELIGIBLE. END INTERVIEW.) 5

REFUSED [INELIGIBLE, GOTO Q28] 97

DON'T KNOW [INELIGIBLE, GOTO Q28] 98

CS1a   Hello, this is [FULL NAME] calling on behalf of researchers at the University of [STUDY SITE]. We're conducting an important research survey to better understand causes of facial pain in adults aged 18 to 54 living around [STUDY SITE]. Can you please tell me if any adults aged 18 to 54 currently live in this household?

(IF NEEDED: Do not include adults who usually live somewhere else.)

(IF NEEDED: Must be 18 to 54 as of today.)

YES...1

NO [INELIGIBLE, GOTO Q28] 2

YES, BUT CAN'T TALK NOW (ASK FOR TIME TO CALL BACK. END INTERVIEW.) 3

SPEAKING WITH CHILD. NO ADULT AVAILABLE (ASK FOR TIME TO CALL BACK. END INTERVIEW.)...............4

BUSINESS. (I'm sorry, we're interviewing residences only. Thank you for your time. INELIGIBLE. END INTERVIEW.)...5

REFUSED [INELIGIBLE, GOTO Q28]............................97

DON'T KNOW [INELIGIBLE, GOTO Q28]......................98

CS2   Please tell me how many adults aged 18 to 54 currently live in this household.

(IF NEEDED: Do not include adults who usually live somewhere else.)

(IF NEEDED: Must be 18 to 54 as of today.)

Thank you.

[CAI SPECS: IF CS2=1, GOTO CS3a; ELSE, GOTO CS3.]

.... 1-20

REFUSED [INELIGIBLE, GOTO Q28] 97

DON'T KNOW [INELIGIBLE, GOTO Q28] 98

CS3   Next, I'd like to ask for the initials of each adult. This information will help us determine which person may be eligible to complete a short interview.

ENTER INITIALS

REFUSES TO GIVE INITIALS

DK INITIALS OR DK IF SHOULD GIVE INITIALS

IF REFUSED OR DK: Do you have any questions that I may be able to answer for you?

(IF NEEDED: ANSWER QX. FROM ELECTRONIC Q&A.)

　　IF STILL NO: Is there another adult in the household that I would be able to speak with?

　　　　IF YES: GOTO CS1a AND REPEAT SERIES AS REQUIRED

[CAI SPECS: ADD "RETURN" OPTION TO SCREEN; GOTO CS1a AND REPEAT SERIES AS REQUIRED.]

　　　　IF NO: [INELIGIBLE, GOTO Q28a.]

[CAI SPECS: MAY ALSO ACCEPT FIRST/MIDDLE/LAST INITIAL; IF SAME INITIALS FOR MULTIPLE PERSONS, LABEL INITIALS WITH "1", "2", ETC. TO DISTINGUISH EACH PERSON; LOOP THROUGH A MAX OF 10 HH MEMBERS.]

CS3a   What are the initials of the [(IF CS2=1, person)/(ELSE, first person)] aged 18 to 54 who currently lives in this household?

(IF R REFUSES, ASK: Do you have any questions that I may be able to answer for you?)

PERSON 1 INITIALS: _____

REFUSED [INELIGIBLE, GOTO Q28a] 97

DON'T KNOW [INELIGIBLE, GOTO Q28a] 98

[CAI SPECS: IF CS2=1, GOTO CS3d. IF ADDITIONAL PERSONS AGED 18 TO 54 CURRENTLY RESIDE IN THE HH, CONTINUE LOOP UNTIL ALL PERSONS ARE RECORDED.]

CS3b   What are the initials of the next person aged 18 to 54 who currently lives in this household?

(INTERVIEWER NOTE: ONCE FINAL HH MEMBER RECORDED, SELECT "ROSTER COMPLETE" TO CONTINUE.)

(INTERVIEWER CONFIRMS HH ROSTER LIST WITH RESPONDENT; MAKES CORRECTIONS OR ADDITIONS AS REQUIRED.)

PERSON 2-10 INITIALS: _____

REFUSED [INELIGIBLE, GOTO Q28a] 97

DON'T KNOW [INELIGIBLE, GOTO Q28a] 98

[CAI SPECS: DISPLAY HH ROSTER LIST TO INTERVIEWER IN TABLE FORMAT; EDITABLE; ADD "ROSTER COMPLETE" SELECTION OPTION TO INTERVIEWER SCREEN.]

[CAI SPECS: DISPLAY "FINALIZE LIST" BUTTON ON ROSTER SCREEN; INTERVIEWER SELECTS THIS OPTION TO FINALIZE THE HH ROSTER AND INITIATE RANDOMIZATION OF ELIGIBLE HH MEMBER TO COMPLETE SCREENER.]

CS3c   Thank you. Next, the computer will randomly select one of the adults from the list.

[CAI SPECS: DISPLAY RANDOMLY SELECTED INITIAL SET.]

CS3d   The computer has selected [INSERT INITIALS SET FOR SELECTED HH MEMBER] to complete the survey. Would you please give me [INSERT INITIALS SET FOR SELECTED HH MEMBER]'s first name?

IF YES:

RECORD HH SELECTION NAME:

FIRST NAME_____

IF NO: CONTINUE TO USE INITIALS.

[CAI SPECS: DISPLAY OPTION SUCH AS "CURRENT RESPONDENT IS SELECTED HH MEMBER"; ONCE SELECTED INTERVIEW IS DIRECTED TO GOTO Q3a.]

[CAI SPECS: IF RESPONDENT SELF IDENTIFIES AS THE SELECTED HH MEMBER, MARK THIS OPTION AND MOVE TO Q3a.]

[CAI SPECS: DISPLAY FIRST NAME OF SELECTED RESPONDENT ON ALL SCREENS (PREFERABLY IN SAME PLACE AT TOP OF SCREEN) FROM CS3d OR CS3e THROUGH END OF INTERVIEW.]

CS3e   Thank you. Is [INSERT NAME PROVIDED FOR SELECTED HH MEMBER] available to come to the phone?

SUBJECT IS SAME PERSON WHO ROSTERED HOUSEHOLD [GOTO Q3A]...1

SUBJECT COMES TO PHONE [GOTO Q3] 2

SUBJECT NOT AVAILABLE...3

RESP. WILL NOT ASK SUBJECT TO COME TO PHONE ...4

CS3f   We'd like to review the study with [INSERT NAME]. Could you please give me [INSERT NAME]'s full name, phone number, and the best times to reach [INSERT NAME] so we can call [INSERT NAME] directly?

(INTERVIEWER: RECORD BEST DAYS OF WEEK AND RECORD TIMES FOR CONTACTING HH MEMBER.)

IF NO: Thank you for your time. [INELIGIBLE. GO TO Q28b]

IF YES: Thank you. What is [INSERT NAME]'s:

First name: _____

Last name: _____

Telephone number: (xxx) xxx-xxxx

Telephone type: Is this [INSERT NAME]'s cell, home, work, or another type of phone number?

[CAI SPECS: LIST CELL, HOME, WORK, OR OTHER + OTHER SPECIFY FIELDS AS REQUIRED; INTERVIEWER SELECTS ONE.]

And what are the best days and times for us to reach [INSERT F NAME]?

[Thank you for this information. Please let [INSERT NAME] know that we'll be calling about this survey. Thank you for your time today. Goodbye.]

II.   SELF IDENTIFIED VOLUNTEER CONTACT SCRIPT

ES1w   Hello, may I speak with [SELF IDENTIFIED VOLUNTEER] please?

This is [FULL NAME] calling about the survey of facial pain (OPPERA) being conducted by researchers at the University of [STUDY SITE]. You asked to be contacted about the survey. Thank you very much for your interest. If this is a good time, I'd like to ask you some questions that take about 8 minutes to answer. Is this a convenient time to talk?

YES[GOTO Q3c]..1

NO[CALL BACK LATER]...2

III.   SUBJECT SELECTION AND VERBAL CONSENT

[CAI SPECS: USE Q3 IF PERSON SELECTED FOR INTERVIEW IS NOT THE PERSON WHO ROSTERED THE HOUSEHOLD.]

Q3   Hello, this is [FULL NAME] calling on behalf of researchers at the University [STUDY SITE]. We're conducting an important research survey to better understand causes of facial pain in adults aged 18 to 54 living around [STUDY SITE]. This phone number was randomly selected for an interview. I'd like to ask you some questions that take about 8 minutes to answer. Is this a good time to speak with you?

(IF R REFUSES, ASK: Do you have any questions that I may be able to answer for you? RESPOND USING FAQ. IF R DECLINES STUDY PARTICIPATION, BREAKOFF AND CODE REFUSAL.)

YES [GOTO Q3d]..1

NO [SET CALLBACK] 2

[CAI SPECS: USE Q3a IF PERSON IS ONLY HH MEMBER 18 to 54 OR IF PERSON SELECTED FOR INTERVIEW IS SAME PERSON WHO ROSTERED THE HOUSEHOLD.]

Q3a   Thank you. I'd like to ask you some questions that take about 8 minutes to answer.

Q3b   [IF Q3=YES, Thank you.] Is this a good time to speak with you?

(IF R REFUSES, ASK: Do you have any questions that I may be able to answer for you? (RESPOND USING FAQ. IF R DECLINES STUDY PARTICIPATION, BREAKOFF AND CODE REFUSAL.))

[ASK Q3c ONLY IF SELF-IDENTIFIED VOLUNTEER.]

YES [GOTO Q4]..1

NO [CALL BACK LATER] 2

Q3c   [IF SKIPPING FROM ES1W, Thank you.] First, how did you hear about this study?

[CHECK ONE (I.E., HOW FIRST HEARD)]

POSTER/BROCHURE/FLYER/OTHER POSTED

MATERIAL 1

E-MAIL 2

FRIENDS, FAMILY, ACQUAINTANCES, OR SOMEONE

ELSE YOU KNOW..3

NEWSPAPER ADVERTISEMENT 4

REFERRED BY RESEARCH CLINIC 5

MY HOUSEHOLD RECEIVED CALL ABOUT SURVEY........6

OTHER [SPECIFY_____]............................7

REFUSED 97

DON'T KNOW 98

Q3d   [IF SKIPPING FROM Q3b, Thank you. First]   YES 1

Could you please tell me, are you aged 18 to 54?   NO [INELIGIBLE, GOTO Q28] 2

REFUSED [INELIGIBLE, GOTO Q28] 97

DON'T KNOW [INELIGIBLE, GOTO Q28] 98

Q4   [IF SKIP FROM Q3b, Thank you. First,] please tell me, do you live or work in one of the following areas? (INTERVIEWER: READ **STUDY-SITE** SPECIFIC LIST)   YES .... CLICK ON SELECTED COUNTY OR CITY

NO [INELIGIBLE, GOTO Q28c] 2

[CAI SPECS: DISPLAY CHART OF COUNTIES FOR THE SUBJECT'S STATE ONLY. STATE WILL COME FROM LISTING SERVICE, OR SELF-REPORTED INFORMATION FROM EMAIL OR PHONE CALL.]   REFUSED [INELIGIBLE, GOTO Q28c] 97

DON'T KNOW [INELIGIBLE, GOTO Q28c] 98

ELIGIBLE: STATE, COUNTIES & 1 CITY

#	NC	#	FL	#	NY	#	MD
10	Chatham County	20	Alachua County	30	Erie County	40	Anne Arundel County
11	Durham County	21	Columbia County	31	Niagara County	41	Baltimore City
12	Orange County	22	Marion County			42	Baltimore County
13	Wake County	23	Putnam County			43	Howard County

Q5   Great, let me tell you a little more about the study. This is a research study directed by Dr. [SITE PI] at [STUDY SITE.] We would like to ask you questions about facial pain, your health and your background. You do not have to answer any questions you do not want to, and you can end the interview at any time. Any information you give me will be confidential. This study has been awarded a Certificate of Confidentiality by the National Institutes of Health which means we cannot be forced to share your information with anyone. At the end of this interview, depending on your answers, I might ask if you would be willing to visit the research clinic at [*STUDY SITE*] **or** complete two surveys and provide a saliva sample. If you are asked to participate in these activities and complete them, you will receive an incentive in thanks for your participation. Would you like to continue with the interview?

(INTERVIEWER: PAUSE & ANSWER QUESTIONS.)   YES 1

NO [INELIGIBLE, GOTO Q28b] 2

REFUSED [INELIGIBLE, GOTO Q28b] 97

DON'T KNOW [INELIGIBLE, GOTO Q28b] 98

Q6   If you have any questions about this research, you may   YES, QUESTIONS ASKED 1
      call the principal investigator, [SITE PI] toll-free at [xxx-
      xxx-xxxx]. If you have any questions about your rights   NO QUESTIONS 2
      as a study participant, you may call the Institutional
      Review Board for the [STUDY SITE] at [INSERT STUDY
      SITE LOCAL IRB NUMBER].

      (INTERVIEWER: PAUSE & ANSWER QUESTIONS;
      REFERENCE FAQ.)

Q7   To make sure I'm doing the best job possible, this call   CONCERN(S) RAISED 1
      may be monitored by my supervisor.
                                                                      NO CONCERN(S) OR COMMENT(S) 2
      (INTERVIEWER: PAUSE & ANSWER QUESTIONS.)

Q8   Do you have any questions before we begin the   YES, QUESTIONS ASKED 1
      interview?
                                                                      NO QUESTIONS 2
      (INTERVIEWER: PAUSE & ANSWER QUESTIONS.)

IV.   FACIAL PAIN

Q9   The first questions are about pain in your face and jaw.   YES 1
      During the last 30 days, have you had: [READ EACH
      ITEM]   NO 2
      Q9a. pain in your face?
      Q9b. pain in your jaw?   REFUSED 97
      Q9c. pain in your ear?
      Q9d. pain in front of your ear?   DON'T KNOW 98
      Q9e. headaches in your temples?
      Q9f. pain in your temples other than headaches?   [CAI SPECS:

                                                                     RESPONSES FOR EACH ITEM ARE Y/N/RF/DK.
                                                                     COMPLETE Q9a THOUGH Q9f.
      (STOP FOR ANSWER AFTER EACH CONDITION.)
                                                                     THEN, IF Y TO ONE OR MORE OF Q9A THROUGH Q9F,
      (IF RESPONDENT ASKS FOR DEFINITIONS OF THESE   GOTO Q10.
      LOCATIONS, STATE "Please answer this question based   ELSE, IF N TO ALL OF Q9A THROUGH Q9F, GOTO Q13.
      on what these locations mean to you.")   ELSE, CODE AS INELIGIBLE (GOTO Q23).]
      (REPEAT 'during the last 30 days' AS NEEDED.)

      [CAI SPECS: STORE BLUE TEXT OF POSITIVE RESPONSE AS MACRO VARIABLE Q9PAIN. IF ≥2 LOCATIONS REPORTED,
      CREATE COMBINED DESCRIPTION AS FOLLOWS: Q9A="FACE", Q9B="JAW", Q9C OR Q9D="EAR", Q9E OR
      Q9F="TEMPLES"

      [CAI SPECS: DISPLAY "During the last 30 days, have you had:" ON SCREEN FOR EACH QUESTION SO INTERVIEWER
      CAN REPEAT AS NEEDED.]

Q10   Was the pain caused by toothache or ear infection?   YES [INELIGIBLE, GOTO Q23].......................................1

      IF NECESSARY, PROMPT "Did toothache or ear infection   NO [GOTO Q12] 2
      cause any of the pain that you just mentioned?"
                                                                     REFUSED [INELIGIBLE, Q23] 97
      IF NECESSARY: CLARIFY (IF FIRST YES AT Q9 WAS TO
      Q9a-c, The pain in your [Q9PAIN])/(IF FIRST YES WAS   DON'T KNOW [GOTO Q12] 98

TO Q9d, The pain [Q9PAIN])/(IF FIRST YES WAS TO Q9e, Pain in your [Q9PAIN])/(IF THE FIRST YES WAS TO Q9f, The [Q9PAIN]

IF NECESSARY, PROMPT "I WANT TO KNOW IF THE &Q9PAIN WAS CAUSED BY TOOTHACHE OR EAR INFECTION"

[CAI SPECS: DISPLAY BLUE TEXT OF POSITIVE RESPONSE FROM Q9 AS MACRO VARIABLE [Q9PAIN]. IF ≥2 LOCATIONS REPORTED, CREATE COMBINED DESCRIPTION AS FOLLOWS: Q9A="FACE", Q9B="JAW", Q9C OR Q9D="EAR", Q9E OR Q9F="TEMPLES"]

Q12 Would you say you had this type of pain for five or more days in the last 30 days?

YES [GOTO Q13]...1

NO [INELIGIBLE, GOTO Q23] 2

REFUSED [INELIGIBLE, GOTO Q23] 97

DON'T KNOW [INELIGIBLE, GOTO Q23] 98

[IF NECESSARY PROMPT: "HAVE YOU HAD THE &Q9PAIN FOR FIVE OR MORE DAYS IN THE LAST 30 DAYS"

(IF FIRST YES AT Q9 WAS TO Q9a-c, The pain in your [Q9PAIN])/(IF FIRST YES WAS TO Q9d, The pain [Q9PAIN])/(IF FIRST YES WAS TO Q9e, Pain in your [Q9PAIN])/(IF THE FIRST YES WAS TO Q9f, The [Q9PAIN]

(IF NUMBER OF DAYS HAS VARIED ACCORDING TO LOCATION: We mean the number of days you had pain at any of these locations.)

[CAI SPECS: DISPLAY BLUE TEXT OF POSITIVE RESPONSE FROM Q9 AS MACRO VARIABLE [Q9PAIN]. IF ≥2 LOCATIONS REPORTED, CREATE COMBINED DESCRIPTION AS FOLLOWS: Q9A="FACE", Q9B="JAW", Q9C OR Q9D="EAR", Q9E OR Q9F="TEMPLES"]

Q13 Prior to [sysdate minus 30 days] did you have:
Q13a. pain in your face?
Q13b. pain in your jaw?
Q13c. pain in your ear?
Q13d. pain in front of your ear?
Q13e. headaches in your temples?
Q13f. pain in your temples other than headaches?

(STOP FOR ANSWER AFTER EACH CONDITION.)

(IF RESPONDENT ASKS FOR DEFINITIONS OF THESE LOCATIONS: "Please answer this question based on what these locations mean to you.")

(REPEAT IF NECESSARY: Before SYSDATE MINUS 30], have you had:")

Yes 1

No 2

REFUSED 97

DON'T KNOW 98

RESPONSES FOR EACH ITEM ARE Y/N/ RF/DK.

[IF Y TO ONE OR MORE, GOTO Q14.
ELSE IF N TO ALL OF Q13A TO Q13F, GOTO Q16.
ELSE CODE AS INELIGIBLE (GOTO Q23).]

[CAI SPECS: STORE BLUE TEXT OF POSITIVE RESPONSES AS MACRO VARIABLE Q13PAIN. IF ≥2 LOCATIONS REPORTED, CREATE COMBINED DESCRIPTION AS FOLLOWS: Q13A="FACE", Q13B="JAW", Q13C OR Q13D="EAR", Q13E OR Q13F="TEMPLES"]

Q14 Was the pain caused by toothache or ear infection?

Yes [GOTO Q23] 1

IF NECESSARY, PROMPT "Did toothache or ear infection cause any of the pain that you just mentioned?" IF NECESSARY: CLARIFY :(IF FIRST YES AT Q13 WAS TO Q13a-c, The pain in your [Q13PAIN])/(IF FIRST YES WAS TO Q13d, The pain [Q13PAIN])/(IF FIRST YES WAS TO Q13e, Pain in your [Q13PAIN])/(IF THE FIRST YES WAS TO Q13f, The [Q13PAIN]

No [GOTO Q15] 2

REFUSED [INELIGIBLE, GOTO Q23]............................ 97

DON'T KNOW [GOTO Q15] 98

[CAI SPECS: DISPLAY BLUE TEXT OF POSITIVE RESPONSES FROM Q13 AS MACRO VARIABLE [Q13PAIN]. IF ≥2 LOCATIONS REPORTED, CREATE COMBINED DESCRIPTION AS FOLLOWS: Q13A="FACE", Q13B="JAW", Q13C OR Q13D="EAR", Q13E OR Q13F="TEMPLES"]

IF NECESSARY, PROMPT "I WANT TO KNOW IF THE &Q13PAIN WAS CAUSED BY TOOTHACHE OR EAR INFECTION"

Q15 For how many months during the 12 months before [SYSMONTH MINUS ONE MONTH] did you have this type of pain for five days or more per month?

(IF NECESSARY PROMPT: "that is from [SYSMONTH MINUS 13 MONTHS] to [SYSMONTH MINUS 1 MONTH])?")

(IF NUMBER OF DAYS HAS VARIED ACCORDING TO LOCATION: We mean the number of days you had pain at any of these locations.)

{Note to Interviewer: if "don't know", probe with: "During the 12 months before [SYSMONTH MINUS ONE MONTH] were there ANY months when you had at least five days of pain? If N, record 0; if Y prompt further with "Would you have had at least five months when you had experienced pain for at least five days per month? If Y, record 5.}

.... 0-12

REFUSED [INELIGIBLE, GOTO Q23] 97

DON'T KNOW [INELIGIBLE, GOTO Q23] 98

IF Q15 ≥ 5, GOTO Q16 (*potential chronic TMD case*)

IF Q15=1-4, [INELIGIBLE, GOTO Q23]

IF Q15=0, GO TO Q16 (*potential acute case*)

[CAI SPECS: EXAMPLE: IF DATE OF INTERVIEW IS FEBRUARY 12, 2013, [SYSMONTH MINUS 13 MONTHS] to [SYSMONTH MINUS 1 MONTH])? READS JANUARY 2012 TO JANUARY 2013]

Q16 [CAI SPECS: SYSTEM ALGORITHM: NO TEXT]

- [IF NO TO EACH OF Q9A THROUGH Q9F AND (NO TO EACH OF Q13A THROUGH Q13F), DETERMINE WHETHER OR NOT QUARTERLY QUOTA HAS BEEN ACHIEVED FOR ENROLLMENT OF CONTROLS AT [STUDY SITE]. IF QUOTA HAS BEEN ACHIEVED, FLAG AS INELIGIBLE AND GOTO Q23; OTHERWISE, FLAG AS POTENTIAL CONTROL AND GOTO Q17.]
- [IF (YES TO ≥1 OF Q9A THROUGH Q9F) AND Q10= (NO OR DON'T KNOW) AND Q12=YES AND (YES TO ONE OR MORE OF Q13A THROUGH Q13F) AND Q14= (NO OR DON'T KNOW) AND Q15 ≥ 5, THEN FLAG AS POTENTIAL CHRONIC TMD: GOTO Q19.]
- [IF (YES TO ≥1 OF Q9A THROUGH Q9F) AND Q10= (NO OR DON'T KNOW) AND Q12=YES AND (NO TO EACH OF Q13A THROUGH Q13F), THEN FLAG AS **POTENTIAL ACUTE CASE**] GOTO Q21
- [IF (YES TO ≥1 OF Q9A THROUGH Q9F) AND Q10= (NO OR DON'T KNOW) AND Q12=YES AND (YES TO ≥1 OF Q13A THROUGH Q13F) AND Q14=(NO OR DON'T KNOW) AND Q15=0, FLAG AS **POTENTIAL ACUTE CASE**] GOTO Q21
- [OTHERWISE FLAG AS INELIGIBLE AND GOTO Q23.]
- [QUOTA: PER THE UNC PIs AND DCC PI, WE ENVISION THE SCENERIO IN WHICH THE 3 BINS {A) ACUTE->CHRONIC TMD, B) CHRONIC TMD GWAS REPLICATION, AND/OR C) CONTROLS} MAY BE TOO STAGGERED IN TERMS OF RECRUIMENT AND ENROLLMENT. WE WILL NEED TO BE ABLE TO MAKE THESE ELIGIBILITY BINS, STRATFIED BY SITE, BE AUTOMATICALLY FLAGGED AS TEMPORARILY INELIGIBLE OR COMPLETED AT ANY POINT DURING THE RECRUITMENT PERIOD. WE WILL NEED TO HANDLE BY LANDMARKING SUCH A VARIABLE. IF SO, INELIGIBLE, GOT0 Q23.]

Q17   Have you ever been diagnosed with Temporomandibular Muscle and Joint Disorder, TMJD, TMD, or TMJ, that was causing you pain?

Yes [INELIGIBLE, GOTO Q23] 1

No 2

REFUSED [INELIGIBLE, GOTO Q23] 97

DON'T KNOW [INELIGIBLE, GOTO Q23] 98

Q18   Do you wear a night guard? Please do not include sports mouth guards.

(IF ASKED: A night guard is a plastic cover for your teeth that you wear during the day and/or at night.)

Yes [INELIGIBLE, GOTO Q23] 1

No 2

REFUSED [INELIGIBLE, GOTO Q23] 97

DON'T KNOW [INELIGIBLE, GOTO Q23] 98

[CAI SPECS: IF NO TO Q17 AND Q18, FLAG AS POTENTIAL CONTROL: GOTO Q22 OTHERWISE, FLAG AS INELIGIBLE: GOTO Q23.]

Q19   Next, please think again about the last 30 days when you reported(IF FIRST YES AT Q9 WAS TO Q9a-c, the pain in your [Q9PAIN])/(IF FIRST YES WAS TO Q9d, the pain [Q9PAIN])/(IF FIRST YES WAS TO Q9e, pain in your [Q9PAIN])/(IF THE FIRST YES WAS TO Q9f, the [Q9PAIN]. In the last 30 days, did [THE FOLLOWING ACTIVITIES] change the pain?

Yes 1

No 2

REFUSED 97

DON'T KNOW 98

Q19a. Chewing hard or tough food
Q19b. Opening your mouth or moving your jaw forward or to the side
Q19c. Jaw habits such as holding teeth together, clenching, grinding or chewing gum
Q19d. Other jaw activities such as talking, kissing, or yawning

RESPONSES FOR EACH ITEM ARE Y/N/RF/DK

(STOP FOR ANSWER AFTER EACH CONDITION.)

(IF NECESSARY, CLARIFY: :(IF FIRST YES AT Q9 WAS TO Q9a-c, The pain in your [Q9PAIN])/(IF FIRST YES WAS TO Q9d, The pain [Q9PAIN])/(IF FIRST YES WAS TO Q9e, Pain in your [Q9PAIN])/(IF THE FIRST YES WAS TO Q9f, The [Q9PAIN]

(IF NECESSARY, CLARIFY: 'Change' means that the pain got better or worse because of the activity.)

[CAI SPECS: IF ≥ 1 AFFIRMATIVE RESPONSE, FLAG AS POTENTIAL CHRONIC TMD; GOTO Q22. OTHERWISE FLAG AS INELIGIBLE AND GOTO Q23.]

[CAI SPECS: DISPLAY BLUE TEXT OF POSITIVE RESPONSES FROM Q13 AS MACRO VARIABLE [Q9PAIN]. IF ≥2 LOCATIONS REPORTED, CREATE COMBINED DESCRIPTION AS FOLLOWS: Q9A="FACE", Q9B="JAW", Q9C OR Q9D="EAR", Q9E OR Q9F="TEMPLES"]

Q21   Next, please think again about the last 30 days when
       you reported &Q9PAIN   Did [THE FOLLOWING
       ACTIVITIES] change the pain?

    Yes 1

    No 2

    REFUSED 97

    DON'T KNOW 98

       Q21a. Chewing hard or tough food
       Q21b. Opening your mouth or moving your jaw
           forward or to the side
       Q21c. Jaw habits such as holding teeth together,
           clenching, grinding or chewing gum
       Q21d. Other jaw activities such as talking, kissing, or
           yawning

RESPONSES FOR EACH ITEM ARE Y/N/RF/DK

       (STOP FOR ANSWER AFTER EACH CONDITION.)(IF
       NECESSARY, CLARIFY: 'Change' means that the pain got
       better or worse because of the activity.)

       (IF NECESSARY, REPEAT: :(IF FIRST YES AT Q9 WAS TO
       Q9a-c, The pain in your [Q9PAIN])/(IF FIRST YES WAS
       TO Q9d, The pain [Q9PAIN])/(IF FIRST YES WAS TO Q9e,
       Pain in your [Q9PAIN])/(IF THE FIRST YES WAS TO Q9f,
       The [Q9PAIN]

       [CAI SPECS: DISPLAY BLUE TEXT OF POSITIVE RESPONSE
       FROM Q9 AS MACRO VARIABLE [Q9PAIN]. IF ≥2
       LOCATIONS REPORTED, CREATE COMBINED
       DESCRIPTION AS FOLLOWS: Q9A="FACE", Q9B="JAW",
       Q9C OR Q9D="EAR", Q9E OR Q9F="TEMPLES"]

       [CAI SPECS: IF ≥ 1 AFFIRMATIVE RESPONSE, FLAG AS **POTENTIAL ACUTE TMD**; GOTO Q22 OTHERWISE FLAG AS
       INELIGIBLE AND GOTO Q23.]

V.   HEALTH STATUS

Q22   Has a doctor told you that you <u>currently</u> have:

       Q22a. Kidney failure or do you undergo dialysis?

       Q22b. Heart disease that is <u>not</u> controlled by
           medication?

    Yes 1

    No 2

    REFUSED 97

    DON'T KNOW 98

       Q22c. Chronic respiratory disease that is <u>not</u> controlled
           with medication?

RESPONSES FOR EACH ITEM ARE Y/N/RF/DK

       Q22d. Hypertension or high blood pressure that is <u>not</u>
           controlled with medication?

       Q22e. Epilepsy or do you take medication to control
           grand mal seizures?

       Q22f. Diabetes that is <u>not</u> controlled with medication
           or diet?

       Q22g. Psychiatric disorders or conditions that have
           required hospitalization over the <u>last 6
           months?</u>

       (STOP FOR ANSWER AFTER EACH CONDITION.)

       [CAI SPECS: IF ≥1 POSITIVE RESPONSE, FLAG AS
       INELIGIBLE AND GOTO Q23. ELSE, GO TO QVa]

Va   **PRIOR/CURRENT OPPERA PARTICIPANT**

Have you ever enrolled in the research project called OPPERA?

YES [INELIGIBLE; GO TO Q28d] 1

NO 2

REFUSED [INELIGIBLE; GO TO Q28d] 97

DON'T KNOW [INELIGIBLE; GO TO Q28d] 98

VI.   **DEMOGRAPHICS**

Q23   (INTERVIEWER: ASK ONLY IF NECESSARY)

I'm required to ask, are you male or female?

MALE 1

FEMALE 2

REFUSED 97

DON'T KNOW 98

Q24   What is your age (in years)?

....｜＿｜＿｜＿｜

96 AND OLDER 96

[CAI SPECS: IF AGE<18 OR AGE > 54 FLAG AS INELIGIBLE.]

REFUSED [INELIGIBLE, GOTO Q25] 97

DON'T KNOW [INELIGIBLE, GOTO Q25] 98

Q24a   What is your date of birth?

MM/DD/YYYY ....｜＿｜＿｜/｜＿｜＿｜/｜＿｜＿｜＿｜＿｜

[CAI SPECS: DISPLAY Q24a ONLY IF 12-049-E ELIGIBLE; OTHERWISE DO NOT DISPLAY]

REFUSED [CONTINUE] 97

DON'T KNOW [CONTINUE] 98

[CAI SPECS: CALCULATE AGE FROM DOB; IF AGE<18 OR AGE > 54 AND/OR IF DOB AGE DOES NOT MATCH AGE IN YEARS @ Q24 DISPLAY ERROR MESSAGE TO INTERVIEWER WITH AGE IN YEARS VS. DOB AGE REPORTED; ADD INTERVIEWER INSTRUCTION BELOW.]

[INTERVIEWER INSTRUCTION: NOTE DISCREPANCY TO RESPONDENT; CONFIRM IF AGE IN YEARS AND OR DOB NEED CORRECTIONS; MAKE CORRECTIONS AS REQUIRED]

Q25   Are you Hispanic or Latino?

YES 1

NO 2

REFUSED 97

DON'T KNOW 98

Q26   Which one or more of the following would you say is your race?

(INTERVIEWER: READ CATEGORIES; RECORD ALL THAT APPLY.)

White 1

Black or African American 2

Asian 3

Native Hawaiian or Other Pacific Islander 4

American Indian or Alaska Native 5

Other 6

REFUSED 97

DON'T KNOW 98

VII.   CONSENT FOR FURTHER STUDY ACTIVITIES

Q27   [CAI SPECS: *SYSTEM ALGORITHM* --

IF ELIGIBLE AS ACUTE TMD: EXPLAIN NATURE AND DURATION OF INTENDED CLINIC VISITS; REQUEST PERMISSION TO FORWARD NAME AND CONTACT INFORMATION TO [STUDY SITE] TO SCHEDULE APPOINTMENT.

IF ELIGIBLE AS CHRONIC TMD OR CONTROL: EXPLAIN NATURE AND DURATION OF INTENDED IN-HOME QUESTIONNAIRES/SALIVA SAMPLE. REQUEST NAME AND CONTACT INFORMATION TO SCHEDULE MAILOUT.]

We'd like to invite you to take part in this important study. The study will give clinicians, researchers, and participants a better understanding of the factors that cause facial pain in adults.

Q27a   [**ACUTE-> CHRONIC TMD**: We would also like to give your name and phone number to the clinic at [STUDY SITE]. They will call you to schedule a clinic visit including an exam and drawing a small amount of blood. At the beginning of your clinic visit, the staff will review these activities with you, answer any questions, and get your permission before proceeding with the exam or blood sample. We would also like to send you a series of questionnaires for you to complete in the privacy of your home. Once completed, we ask you to bring your completed surveys with you to your clinic visit. Or, if you prefer, you can complete these questionnaires on the web. We will provide a unique username and password for you to access the web. Please complete either the hardcopy surveys or the web surveys **but not both**. You will receive $80 for completing the clinic visit and an additional $20 for providing a blood sample. At the clinic visit, the staff will review additional study activities with you. Do I have your permission to give your phone number to the clinic and to mail you a packet containing an introductory letter, the surveys, and instructions for completing the surveys?]

Yes [CONSENT TO RECEIVE STUDY MATERIALS] 1

No [DECLINED PARTICIPATION: Thank you for taking the time to talk to me.] 2

[**CHRONIC TMD GWAS REPLICATION**: We would like to send you a survey for you to complete in the privacy of your home and return it in the prepaid postage envelope. Or, if you prefer, you can complete this survey on the web. We will provide a unique username and password for you to access the web. Please complete either the hardcopy survey or the web survey **but not both**. We are also requesting 5 minutes of your time to provide a saliva sample. If you complete all surveys and provide a saliva sample, you will receive $25. Do I have your permission to mail you a packet containing an introductory letter, the survey, and saliva kit, and instructions?]

[CAI SPECS: NEED YES/NO TO INDICATE ORAL CONSENT GIVEN TO RECEIVE STUDY MATERIALS VIA MAIL.]

Q27b [**ACUTE-> CHRONIC TMD:** Are there some times that are better than others for the clinic to call you?]

[**CHRONIC TMD GWAS REPLICATION:** If we need to follow-up with you regarding the packet, are there some times that are better than others for us to call you?]

DATE .... ⎿__⎟__⏌ - ⎿__⎟__⏌ - ⎿__⎟__⎟__⏌

DAY OF THE WEEK:

MONDAY.. 1

TUESDAY 2

WEDNESDAY 3

THURSDAY 4

FRIDAY 5

SATURDAY.. 6

SUNDAY 7

TIME... ⎿__⎟__⏌ : ⎿__⎟__⏌ AM

.... PM

Q27c What is the best telephone number we should use when calling you?

PHONE ....⎿__⎟__⎟__⏌ - ⎿__⎟__⎟__⏌ - ⎿__⎟__⎟__⎟__⏌

[CAI SPECS: DISPLAY CURRENT PHONE IF WE DIALED OUT; LINK ALL PERSONAL IDENTIFIERS TO SEPARATE & SECURE DATA BASE.]

[CAI SPECS: PROMPT INTERVIEWER TO ASK FOR BEST CONTACT METHOD IF "NO PHONE" IN Q27c.]

Q27d In order for us to mail surveys and material to you, please provide your name and mailing address.

VERIFY SPELLINGS.

[CAI SPECS: LINK ALL PERSONAL IDENTIFIERS TO SEPARATE & SECURE DATA BASE.]

FIRST NAME: _____

MIDDLE NAME: _____

LAST NAME: _____

STREET ADDRESS: _____

CITY: _____

STATE: _____

ZIP CODE: _____

Q27e May we email study reminders and/or forms to you?

YES 1

NO EMAIL (DONE).. 2

HAVE EMAIL, NO (DONE) 3

Q27f What is your email address?

[VERIFY SPELLING]

_____@_____

_____@_____

DONE:

[ACUTE-> CHRONIC TMD: I want to thank you for your time and for volunteering to take part in this important study. Within a few days you should receive your study materials. The clinic will call you (*in about 2 weeks OR about one week later to give you time to read the materials*. If at any time you have questions about the materials or how they should be completed, please feel free to call our study hotline at [SITE NUMBER (UNC 1-919-966-1060); UB (716-829-

2984): UFL (1-352-392-0769); UMD (1-443-740-5452)]. Someone from our research staff will be available to help you. Again, thank you for volunteering to help us find out more about the causes of facial pain. Goodbye. END CALL.]

[**CHRONIC TMD GWAS REPLICATION**: I want to thank you for your time and for volunteering to take part in this important study. Within a few days you should receive your study materials. If at any time you have questions about the materials or how they should be completed, please feel free to call our study hotline at [SITE NUMBER (DCC 1-919-XXX-XXXX)]. Someone from our research staff will be available to help you. We look forward to receiving your completed survey and the saliva samples and again, thank you for volunteering to help us find out more about the causes of facial pain. Goodbye. END CALL.]

VIII.   EXIT SCRIPT FOR INELIGIBLE SUBJECTS

Q28   Thank you for having an interest in our project. Because we need to enroll participants aged 18 to 54, we will not be able to invite you to be part of this study. Thank you for taking the time to talk with me.

Q28a   I'm sorry. Because we need to list adults in order to randomly select a participant, we will not be able to invite someone from your household to be part of this study.   Thank you for talking with me.

Q28b   Thank you for talking with me. Goodbye. END CALL.

Q28c   Thank you for having an interest in our project. Because we need to enroll participants who live around certain study sites, we will not be able to invite you to be part of this study. Thank you for taking the time to talk with me.

Q28d   Thank you for having an interest in our project. At this time we have completed recruitment for this part of the study. Thank you for taking the time to talk with me.

Q28e   Thank you for having an interest in our project. Because we need to enroll participants with very specific health histories, we will not be able to invite you to be part of this study. Thank you for taking the time to talk with me.

VIa.   [CAI SPECS: IF INELIGIBLE AT ANY POINT IN THE SCREENER DIRECT TO HERE AFTER SYSTEM DISPLAY OF INELIGIBLE EXIT SCRIPT] [INELIGIBLE EXIT SCRIPT SELECTION PREVIOUSLY DETERMINED BY SYSTEM]

Are you interested in other studies in the future?

YES [DISPLAY Q27c, Q27d, Q27f]................................ 1

NO; DISPLAY "Thank you. Goodbye"]......................... 2

REFUSED [INELIGIBLE; DISPLAY

"Thank you. Goodbye"].. 97

DON'T KNOW [INELIGIBLE;

"Thank you. Goodbye"]].. 98

[CAI SPECS: IF YES; DISPLAY Q27c/Q27d/Q27f FOR NAME AND CONTACT INFORMATION; ALSO COLLECT BASIC DEMOGRAPHICS BY ASKING Q23, Q24, Q25, AND Q26. *(COUNTY SURROGATE AVAILABLE FROM AREA CODE)*]

[INTERVIEWER: WILL COLLECT CONTACT INFORMATION]

INSERT SCRIPT BELOW ONCE CONTACT INFORAMTION FOR INTEREST IN OTHER STUDIES IS COLLECTED:

Thank you. Goodbye. END CALL.

[CAI SPECS: IF INELIGIBLE AT Q9-Q15 OR Q17-Q22, GOTO Q28E (HEALTH INELIGIBILITY CLOSING). IF INELIGIBLE AT Q16 AND QUOTA HAS BEEN MET, GOTO Q28D (CLOSING FOR RECRUITMENT COMPLETED). IF INELIGIBLE AT Q16 AND QUOTA HAS NOT BEEN MET, GOTO Q28E. IF INELIGIBLE AT Q24, GOTO Q28.

Date filled out (mm-dd-yyyy)

| | | - | | | - | | | |

ITERATION

RESPONDENT ID LABEL

Mark(☒) one response for each item and do not skip any items unless instructed to do so. If you change your mind, fill the incorrect mark completely and then mark (☒) the new response.

1. During the last **three months,** have you had any aches or pains anywhere in the body that have lasted for one day or longer?

☐ Yes   ☐ No   ☐ Don't know

If "No" or "Don't Know" to question 1, skip to question 3.

2. In which parts of your body did the aches or pains occur? Mark (☒) all that apply.

Head
☐ Head

Neck
☐ Neck

Right Shoulder
☐ R Shoulder

Left Shoulder
☐ L Shoulder

Right Upper Limb
☐ R Upper Arm
☐ R Elbow
☐ R Lower Arm
☐ R Wrist
☐ R Hand

Left Upper Limb
☐ L Upper Arm
☐ L Elbow
☐ L Lower Arm
☐ L Wrist
☐ L Hand

Right Lower Limb
☐ R Hip & buttock
☐ R Upper Leg
☐ R Knee
☐ R Lower Leg
☐ R Ankle
☐ R Foot

Left Lower Limb
☐ L Hip & buttock
☐ L Upper Leg
☐ L Knee
☐ L Lower Leg
☐ L Ankle
☐ L Foot

Trunk
☐ Chest
☐ Abdomen
☐ Pelvis

Trunk
☐ Spine
☐ Upper Back (not including spine)
☐ Lower Back (not including spine)

☐ None of the above

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Mark(☒) one response for each item and do not skip any items unless instructed to do so. If you change your mind, fill the incorrect mark completely and then mark (☒) the new response.

3. In the last **30 days**, how many headaches of any type have you had?

Number of headaches

☐ Don't know

4. In the last **30 days**, have you had any of the following symptoms in your face or jaw?
Mark (☒) all that apply.

☐ Stiffness or tightness
☐ Cramping
☐ Fatigue or weakness
☐ Pressure
☐ Soreness or tenderness
☐ Ache or dull ache
☐ None of the above

5. Do you have or has your doctor or other health care provider told you that you currently have any of the following health conditions?   Mark (☒) all that apply

☐ Arthritis or other joint diseases
☐ Ringing in your ears
☐ Repeated trouble with neck, back, or spine
☐ Depression
☐ Anxiety disorder
☐ Acid Reflux
☐ Chronic Pelvic Pain
☐ Sleep Apnea
☐ None of the above

6. Have you smoked at least 100 cigarettes in your entire life?   ☐ Yes   ☐ No   ☐ Don't know

If "No" or "Don't Know" to question 6, skip to question 8.

7. Do you now smoke cigarettes every day, some days, or not at all?   ☐ Every day   ☐ Some days   ☐ Not at all

Below is a list of problems people sometimes have. Please read each one carefully, and check the response that best describes how much that problem has distressed or bothered you during the past **7 days** including today.

	Not at all	A little bit	Moderately	Quite a bit	Extremely
8. Faintness or dizziness.	☐	☐	☐	☐	☐
9. Trouble getting your breath.	☐	☐	☐	☐	☐
10. Hot or cold spells.	☐	☐	☐	☐	☐
11. Numbness or tingling in parts of your body.	☐	☐	☐	☐	☐
12. A lump in your throat.	☐	☐	☐	☐	☐
13. Feeling weak in parts of your body.	☐	☐	☐	☐	☐
14. Heavy feelings in your arms or legs.	☐	☐	☐	☐	☐

Mark(☒) one response for each item and do not skip any items unless instructed to do so. If you change your mind, fill the incorrect mark completely and then mark (☒) the new response.

15. Please rate your average level of stress over the **last three months** on a scale from 0-10 where 0 is no stress and 10 is the highest stress imaginable.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No Stress										Highest Stress Imaginable

16. Please rate the quality of your sleep on average over the **last three months** on a scale from 0-10 where 0 is worst sleep imaginable and 10 is the best sleep imaginable.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
Worst Sleep Imaginable										Best Sleep Imaginable

17. Please rate your average mood over the **last three months** on a scale from -10 to +10 where -10 is the most negative mood imaginable, 0 is a neutral mood, and 10 is the most positive mood imaginable.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10
Most Negative Mood Imaginable										Neutral Mood										Most Positive Mood Imaginable

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