Section 17. Qualitative

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17.1 Overview

The purpose of this SSP is to provide guidance on the implementation of the qualitative components of the HPTN 083-01 Study, as described in Sections 2.3, 7.1, 7.7.5, and 7.9 of the study protocol. Timing is indicated in Appendices II, III, and IV.

In-depth qualitative interviews will be conducted after the exposure period to study product (Week 34) with up to 9 adolescent participants (total, across all sites) and up to 9 parent/caregivers (total, across all sites). For the adolescent participants, the aim is to provide more holistic and contextualized information on motivations, attitudes and experiences using injectable PrEP, experiences with contraception, reasons for and circumstances related to product and/or study discontinuation, and future intentions related to PrEP use. For the parent/caregivers, the aim is to provide information about their experiences with having their child using injectable PrEP and contraception and the support they received from the study team.

Please note: This SSP Section is not intended to be a comprehensive explanation of qualitative methods. Staff involved in this component of the study are expected to have the knowledge and skills necessary to successfully implement qualitative research and should follow the HPTN 083-01 protocol, Study Specific Procedures (SSP) manual, this manual and site study operating procedures (SOPs) as needed. If at any time any of these materials conflict with the protocol, the protocol should be followed. Any questions regarding the qualitative component of the study should be directed to the protocol team.

17.2 Qualitative Interview Recruitment

The following section outlines the process for identifying participants for the qualitative component.

17.2.1 Identifying Participants for Interview

For this study, we will utilize a purposive sampling strategy. Site Interviewers should liaise with their study team to identify suitable potential participants as well as parents/caregivers who would be interested in and comfortable with sharing their experiences with the study product as well as study procedures. Each site may attempt to interview all willing adolescents and all willing parent/guardians, for a total of up to 9 each, across all 4 HPTN 083-01 sites.

17.2.2 Informed Consent Procedures and Documentation (All Participants)

Staff should complete the qualitative informed consent procedure using the appropriate language IRB-approved consent and assent forms. Written consent and assent must be obtained prior to participation in the interview.

17.2.3 Interviews with Participants

At completion of the interviews, sites should begin transcription and translation into English (as needed). All analyses will be completed through collaboration between the protocol team and the site qualitative teams. The HPTN 083-01 protocol team will coordinate collaboration between the sites working with their qualitative data from the interviews.

17.3 Interview Procedures

17.4 Interview Guides

Interview Guides can be found in Appendix A of this manual. Sites are responsible for making sure that all appropriate IRB approvals have been obtained *prior* to use of these guides.

17.5 Interview Set-Up and Materials

All interviews should take place in a location identified by staff that assures adequate privacy and confidentiality. Site Interviewers may choose to use other members of the study team who interact frequently with the participants, for example counsellors or

nurses, to assist them build good rapport with the adolescent girl before the interview. Only the participant and the Interviewer should be present for the actual interview, however. Appropriate infection prevention and control procedures must be followed throughout the interview process, to reduce the spread of COVID-19.

In an effort to streamline study procedures on the day of the actual interview, staff should make sure that they have all necessary materials prepared in advance. A suggested materials list can be found in Appendix B and should be modified for site specific needs.

17.6 Documentation Requirements for Interviews and Focus Groups

As with other study visits, the qualitative component should follow the guidelines for source and essential documentation as outlined in the HPTN 083-01 SSP and in site specific SOPs. Source documentation for interviews may consist of chart notes, checklists, and transcripts.

17.7 Qualitative Interview Data Collection

17.7.1 Qualitative Interviewer

All interviews should be conducted by someone who has training and/or experience in qualitative methods. All staff conducting or attending the interviews should not have a role of influence with a participant.

17.7.2 Recording

All interviews will be audio-recorded using digital recorders which provide very detailed, high fidelity reproduction of the interview/focus group for transcription and analysis. Study staff are encouraged to always have extra batteries, and when possible, an extra digital recorder on hand. Staff should test the recording device and external microphone (if applicable) prior to the beginning of each interview. Prior to initiating the interview, staff should record at the beginning of the digital file the date and study PTID, indicating whether the interview is being conducted with the adolescent participant herself or with a parent/guardian. This information should also be documented on checklists, participant chart notes, and other forms as required by the site.

Once the interview has been completed, the digital recordings should be reviewed and backed-up by the local qualitative team within 48 hours of the interview. Backup to a secure computer should use the following labeling approach – the participant's ID number and the date of the interview (e.g. 1234567Adolescent_12NOV21). "Adolescent" or "ParentGuardian" should be used to indicate which type of interviewee was interviewed. No other identifying information, such as participant name, should be included in the file name. All audio files should be maintained until after analysis is complete.

17.7.3 Transcription and Translation

For the participant interviews, sites are responsible for transcription and translation to English (if needed). Sites may elect to use a commercial service for this and/or use of internal resources. Once transcripts have been completed, they should be reviewed and corrected as needed by the appropriate staff person for accuracy against the source documentation (recordings, notes) within 2 working days of receipt. During the transcription process, transcribers should not transcribe any participant identifiers. Translated transcripts should not include numbering for each line, as the numbering does not necessarily convert properly with the software used during the coding and analysis process. Timeline for transcription is determined by the sites.

17.7.3.1 De-identification of Transcripts

Any identifying information should be removed at the time of transcription. Identifying information should be replaced with a description holder indicating what type of information was removed.

Examples of text with identifying information, as well as the de-identified version are included below. The identifiable information, as well as the corresponding de-identified description holder are indicated in bold.

a) Identifiers
Participant: I don't use the tablets with **Sean**, my boyfriend.
Participant: I've been living at the corner of **Park and Vine** for 5 years.

b) De-identified
Participant: I don't use the condoms with **[name of boyfriend]**, my boyfriend.
Participant: I've been living at the corner of **[name of intersection]** for 5 years.

17.7.4 Interview Transcript File Format

Save transcript file names in the following format:

PTID_Date
For example: 1234567Adolescent__12NOV21
(Use "Adolescent" or "ParentGuardian" at end of file name to distinguish types of interviewees.)

17.7.5 Interview Confidentiality and Privacy

Audio files will be saved on a password-protected, access-limited computer and any physical copies of the file (e.g. burned onto compact disc for transcription) will be kept in a locked, limited-access storage location like a file cabinet when not in use. Any other files related to the qualitative component, including, but not limited to, hard copies of transcriptions, written consent forms, and link logs will be handled and stored according to the study protocol and SSP.

17.7.6 Data Transfer

Electronic recordings, transcriptions, and translation files should be transferred using secure methods, such as SharePoint. Upload de-identified transcripts to the HPTN 083-01 Qualitative Data SharePoint site when they are ready for team review.

Link: HPTN 083-01/HPTN 084-01 External - Qualitative - All Documents (sharepoint.com)

17.8 Data Management and Analysis

Data Management and Analysis will be led by the protocol team in collaboration with local qualitative teams.

Appendices
Appendix A: Qualitative Interview Guides
Appendix B: Materials Checklist
Appendix C: Qualitative Interview Checklist

Appendix A: HPTN 083-01 Qualitative In-depth Interview Guide for Trial Participants

Introduction: Hello. My name is _____, and I will be conducting this interview today. I would first like to thank you for taking the time to talk with me today. Your thoughts and opinions are very valuable, and I appreciate your willingness to help in our efforts to understand young people's needs for and experiences using injectable pre-exposure prophylaxis – medication that can be taken to prevent getting HIV.

As I ask you to describe your opinions and experiences, please keep in mind that there are no right or wrong answers to these questions. People have a lot of different views on these topics. I'm simply interested in your experiences. I am looking forward to learning more about these experiences from you. You are in the role of a teacher today and I am here to learn from you since you are an expert in your own life experiences, opinions, and viewpoints. Thank you for giving me your time. This interview should take less than an hour to complete. If, at any time, you have questions or something I say is not clear, please let me know and I will try to clarify. Also, if, at any time, you need to take a break, please let me know.

Please silence your mobile phone during the interview.

May I turn on the digital recorder now?

STATE FOR THE RECORDER: I am [INTERVIEWER NAME] interviewing participant [PARTICIPANT ID#] on [DATE AND TIME] at [SITE NAME].

I'd like to start today by just getting to know you a little. For example, it would be helpful to know more about your home life, who you live with and how you spend your time when you are not involved in clinic visits or trial-related activities.

<u>Household and Family Context</u>

1. Could you tell me a little about your home life?
    a. Where is your home located? (How far away from the clinic is it?)
    b. How long have you lived there?
    c. Who are all the people you live with?
    d. Are your caregiver(s) your parents, legal guardian(s), or something else?
        i. i. How would you like us to refer to them through out this interview?

2. What kind of school, work or leisure activities do you do, when not involved in study activities?
    a. What does your day-to-day schedule look like?
    b. If working, how long have you been working in this job?
    c. If a student, what grade are you in?
        i. What do you hope to do after you finish your studies?

<u>Motivations for Trial Participation</u>

3. How did you hear about this study prior to joining it?

4. Please tell me about your reasons for joining this trial?
    a. (If knowledgeable about other trials) Why did you choose to join this trial that is testing a new long-acting, injectable prevention method instead of another one?
    b. In what ways did you think you might benefit from being in the trial?
        i. How much was your decision based on getting additional HIV testing?

ii. What about other medical tests or exams?
iii. How important were the payments for trial participation?
iv. What other reasons made you decide to join the trial?

c. In what ways, if any, did you think you might *not* benefit from being in the trial?

5. What, if any, experiences have you had with HIV prevention trial participation in the past?
    a. What kind of a study was it? (What products were being tested?)
    b. What did you like best about the study?
    c. What did you like least about it?

6. How easy or difficult would it be for you to access PrEP on your own, if you did not choose to join this trial?

Disclosure of Trial Participation/Product Use

7. Who among your family or friends have you talked to about participating in this trial?
    a. How did you talk to your parents (or guardians) about this study? If self-consented, what (if anything) have you told your parents about this study?
        i. If you haven't spoken with your parents, what were some of the barriers that prevented you from doing so?
        ii. If you have spoken to them, what were some of the reasons you did so?
    b. What, if anything, have you told your sexual or romantic partner(s) about this study?
    c. What about other family members?
    d. How do they feel about your participation in the trial?
        i. What do others in the community where you live think about involving young people in research studies?
        ii. What do others in the community where you live think about involving sexual and gender minority youth in research studies?

8. Do you know other young people who are participating in this trial?
    a. What role did they play in your decision to participate?
    b. How do they support you (or not) in study participation?

Sexual Relationships

We are going to spend a little time now talking about relationships.

9. (If a partner mentioned above) Can you tell me about your sexual or romantic partner(s)?
    a. *OR* Is there someone you consider to be your main or steady partner? Can you tell me about him/them?
    b. How long have you known him/them?
    c. How did you meet?
    d. What kind of person is he/they?
    e. How would you describe your relationship?
        iii. How do you spend time together?
        iv. What kinds of interests do the two of you share?
        v. In what ways are you different from each other?
    f. If you have differences of opinion, how easy or difficult is it to resolve your differences?
    g. Do you ever feel afraid of your partner? Has your partner ever hurt you physically or emotionally?

h. How do you see your future together?

10. Have you had other sexual partners recently?
    a. How would you describe this/these other relationship(s)?

EMOJI CARDS

Note to Interviewer: Show pages of different emojis. Ask participant one that shows how they feel about their risk of getting HIV. First ask them to tell you about why they selected the image. Then, use the card they have selected to probe more into the topics below on HIV risk.

HIV/STI Risk Perception

11. Before your participation in this trial, how much did you worry about HIV or other sexually transmitted infections?
    a. Have you ever been diagnosed with an STI in the past? If so, how did you find out about it?
    b. How similar or different do you believe your risk is compared to other young people like you?
    c. How much do your partner's (partners') behaviors put you at risk?
        i. Have you ever worried that your partner has other partners? What are the reasons you say that?
    d. How about your own behaviors?

12. Before joining this study, what have you done, if anything, to reduce your risk of HIV or other STIs?
    a. How easy or difficult has it been for you to use condoms?
    b. How frequently have you used condoms with your current partner or partners?
    c. How frequently have you tested for HIV?
    d. What about your current partner/s – do you know his/their HIV status? Have you tested together?
    e. Have you ever been prescribed PEP –a short course of anti-HIV medications to prevent HIV after you may have been exposed to HIV?
        i. What were the circumstances?

13. Since joining this trial, how much have you worried about your risk of getting HIV?
    a. Would you say that you are more worried, less worried – or you feel about the same as you did before joining the trial?
    b. How has the trial influenced your use of condoms - has it increased, decreased or stayed the same? Why?

14. *(Note to interviewer: this question is only relevant if the participant previously stated they have a current regular partner.)*
    Since joining the trial, have you and you partner had any arguments that made you afraid?
    a. Were any of these arguments related to your trial participation?
    b. What were the circumstances?

15. Have you experienced anything else while in the trial that affected how you think about HIV? What?

Understanding of Trial Context

To end our discussion today, I'd like to ask you some questions about the trial and your experience using different products in the study. Let's start by talking about the study itself. Then, I'd like to move on to your experience with the oral pills, and finally the injections – or shot.

16. From your perspective, what do you think the main reason is for conducting this trial?
    a. Can you describe the different phases of the trial?
    b. Why are you being asked to use two different products – first a pill and then an injectable?
    c. Truvada (or Descovy) for oral PrEP is available for young people in many places. What have you heard about Truvada?

17. Is there anything you would like to share about your experiences in this trial thus far?

EMOJI CARDS

Note to Interviewer: Show pages of different emojis. Ask participant to choose one that shows how they feel about the study overall. Ask them to tell you about why they selected the image.

18. Since joining this trial, how would you describe your experiences overall?
    a. What have you liked the most about being in the trial?
    b. What have you found the most difficult about being in the trial?

19. What could we do differently to make the study better for you?

Oral Pill Adherence

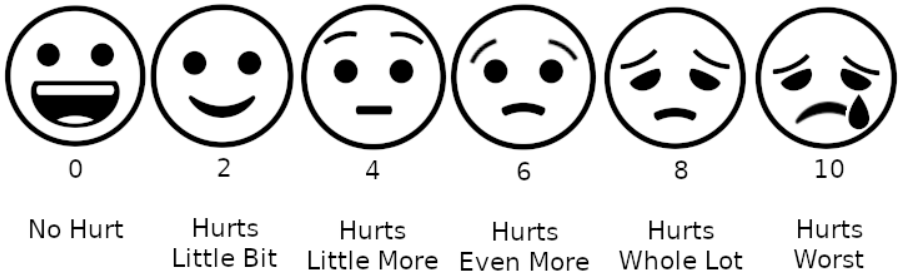
20. During the first month, you were first asked to take a daily oral pill. How did you feel about the first phase?
    a. How easy or difficult was it to take the pill every day?
    b. What were your experiences taking the pill?

21. When taking oral medications, most people miss taking a pill from time to time. What are the different reasons you have missed taking a study pill?
    a. How easy or difficult is it to remember to take your pills?
        i. If easy, what do you do to remember to take it?
        ii. What makes it difficult to remember?
    b. What do you think about the pill size and taste?
    c. How much do you worry about other people seeing you take the study pills?
    d. Where do you store your pills?

22. What, if any, side effects have you experienced from taking the pill?
    a. If any experienced, how quickly did they resolve?
    b. What, if anything, did you tell the clinic staff?
    c. How did they respond to your concerns?
    d. How did these experiences affect your product use?

Injectable Experience

23. What was it like when you got the first injection?
    a. What concerns did you have prior to getting the injection?
    b. How would you describe the insertion process?
    c. How did you feel just after the injection – before leaving the clinic?
    d. What about in the following days?



24. Using the emojis above, how painless or painful would you describe the injectable?
    a. Has your experience with the injection changed over time?
    b. What about in comparison with other types of injections?

25. How do you feel about these different aspects of the injectable:
    a. Size of the needle
    b. Location of injection on your body
    c. Receiving an injection every two months

26. Have you experienced any other side effects from the study injectable?
    a. If any experienced, how quickly did they resolve?
    b. What, if anything, did you tell the clinic staff?
    c. How did they respond to your concerns?

<u>HIV Prevention Preferences</u>

27. What kind of PrEP services are available to you outside of this trial?

28. Once your participation in this trial is finished, how likely are you to use an HIV prevention method?
    a. Why do you say that?

29. Now that you have taken both pills and injections as a way to prevent HIV, which option would you prefer to use in the future?
    a. What would be the reasons for preferring pills? For not liking pills?
    b. What would be the reasons for preferring injections? For not liking injections?
    c. Are there other HIV prevention options you'd like to try in the future?

30. If you could change anything about the long-acting injectable, what would you change?

31. Now that the FDA has approved injectable PrEP for adolescents and adults, does this change the likelihood that you'll use it when the study is done?

Future Implementation

32. Now that that injections for HIV prevention are approved in the US to everyone, along with daily pills, young people can choose what method best suits their personal needs. We would like to hear your thoughts on how we can successfully get these HIV prevention strategies into the community.

33. How can we best reach adolescents, including sexual and gender minority youth, who might benefit from HIV prevention?

34. How can we support people who want to use injectable PrEP?
    a. What specific support will adolescents need?
    b. Who should provide that support?
    c. How and where should that support be provided?

35. In what type of place would you most like to go to get injectable PrEP? (probe for type of clinic; mobile vs. standard) Why?
    a. What kind of provider should give the injections? Why?

36. What will be most challenging about introducing injectable HIV prevention to adolescents?

Thank you so very much for your time today and for participating in this interview. Your answers and your commitment to this study will help us improve our HIV prevention efforts for young people.

HPTN 083-01 Qualitative In-depth Interview Guide
for Parents/Caregivers

Introduction: Hello. My name is _____, and I will be conducting this interview today. I would first like to thank you for taking the time to talk with me today. Your thoughts and opinions are very valuable, and I appreciate your willingness to help in our efforts to understand the parent/caregiver opinions about teenagers using injectable pre-exposure prophylaxis – medication that can be taken to prevent getting HIV.

As I ask you to describe your opinions and experiences, please keep in mind that there are no right or wrong answers to these questions. People have a lot of different views on these topics. I'm simply interested in your views. I am looking forward to learning more from you. Thank you for giving me your time. This interview should take less than an hour to complete. If, at any time, you have questions or something I say is not clear, please let me know and I will try to clarify. Also, if, at any time, you need to take a break, please let me know.

Please silence your mobile phone during the interview.

May I turn on the digital recorder now?

STATE FOR THE RECORDER: I am [INTERVIEWER NAME] interviewing parent of participant [PARTICIPANT ID#] on [DATE AND TIME] at [SITE NAME].
I'd like to start today by just getting to know you a little. For example, it would be helpful to know more about your home life, who you live with and how you spend your time. Note that, if you are a legal guardian/representative or caregiver, we will refer to the participant as "your child" throughout.
<u>Household and Family Context</u>

37. Could you tell me a little about your home life?
    a. Where is your home located? (How far away from the clinic is it?)
    b. How long have you lived there?
    c. Who are all the people you live with?
        i. Does the participant live with you or elsewhere?

38. What kind of work or activities do you do?
    a. What does your day-to-day schedule look like?
    b. If working, how long have you been working in this job?
    c. What social groups are you involved in?

<u>Motivations for Trial Participation</u>

39. How did you hear about this study? (probe for who approached the parent/caregiver to request permission)

40. What were your first thoughts when you heard about the study?
    a. Were you inclined to agree or disagree about your child's enrollment?

41. Please tell me about all of your reasons for allowing your child to join this trial? [Probe for reasons relating to sexual activity, sexual and gender identity, HIV risk, health care access, incentives. Be careful to avoid unintentional disclosure of sexual or gender identity.]
    d. In what ways did you think your child might benefit from being in the trial?
        i. Getting additional HIV testing?

ii. Other medical tests or exams?
iii. How important were the reimbursements for trial participation?
iv. What other reasons made you decide to allow your child to join the trial?

e. In what ways, if any, did you think your child might *not* benefit from being in the trial?

42. Did you seek counsel or advice from anyone before deciding to consent to the trial? [Probe for other family members, clergy, community leaders, healthcare professionals]

43. What, if any, experience do you have with HIV prevention, or other types of clinical trials, yourself?
    a. What kind of a study was it? (What products were being tested?)
    b. What did you like best about the study?
    c. What did you like least about it?
    d. What previous experience do you have with this research site?

44. How easy or difficult do you think it would be for your child to access PrEP on their own, if they did not choose to join this trial?

Disclosure of Trial Participation/Product Use

45. Who among your family or friends have you talked to about your child's participation in this trial?
    e. How do they feel about their participation in the trial?
        i. What do others in the community where you live think about involving young people in research studies?

46. Do you know other young people who are participating in this trial?
    a. What role did they play in your decision to allow participation?

EMOJI CARDS

Note to Interviewer: Show pages of different emojis. Ask parent to choose one that shows how they feel about their child's risk of getting HIV. First ask them to tell you about why they selected the image. Then, use the card they have selected to probe more into the topics below on HIV risk.

HIV/STI Risk Perception

47. How much do you worry about your child's chances of contracting HIV?
    a. Would you say that you are more worried, less worried – or you feel about the same as you did before they joined the trial?
    b. How similar or different do you believe their risk is compared to older people like you?
    c. Have you ever worried about your own risk for HIV?
        i. If yes, did your own concerns play a role in allowing your child to participate?

Understanding of Trial Context

Note to interviewer: To end our discussion today, I'd like to ask you some questions about the trial and your understanding of the different products in the study.

48. From your perspective, what do you think the main reason is for conducting this trial?

d. Can you describe the different phases of the trial?
e. Why are we asking the participants to use two different products – first a pill and then an injectable?
f. Truvada for oral PrEP is available for young people in many places. What have you heard about Truvada?
g. Now that FDA has approved CAB LA – the shot being given in this study – for young people, how likely do you think it would be for your child to want to use it outside of the study?

49. Is there anything you would like to share about your child's experiences in this trial thus far?

HIV Prevention Locally

50. What kind of PrEP services are you aware of locally that are available to teenagers outside of this trial?
51. Once this trial is finished, how likely are you to encourage your child to use an HIV prevention method?
    a. What prevention options would you encourage them to try in the future [probe for pills, injections]

After this study ends, we hope that injections for HIV prevention will be available to everyone, along with daily pills, so young people can choose what method best suits their personal needs. We would like to hear your thoughts on how we can successfully get these HIV prevention strategies into your community.

52. How can we best reach adolescents who might benefit from HIV prevention?

53. In this country, young people can access HIV prevention without parental/guardian consent at age [INSERT AGE BASED ON LOCAL REGULATIONS]. What are your feelings about that? Should they be able to access it when they are younger without a parent/guardian?

54. What do you think will be most challenging about introducing injectable HIV prevention to adolescents?

Thank you so very much for your time today and for participating in this interview. Your answers and your commitment to this study will help us improve our HIV prevention efforts for young people.

Appendix B: Materials Checklist

Interviews

☐ Participant Interview ICF

☐ Interview guide

☐ Digital recorder

☐ Back-up digital recorder

☐ Extra batteries for digital recorders

☐ Pad of paper and a pen

☐ Interviewee reimbursement

☐ Appropriate PPE supplies

☐ Additional items to be added, per site

Appendix C: Qualitative Interview Checklist

Participant Interview Checklist

…….

Interviewer Code:_____ Interview Location:_____

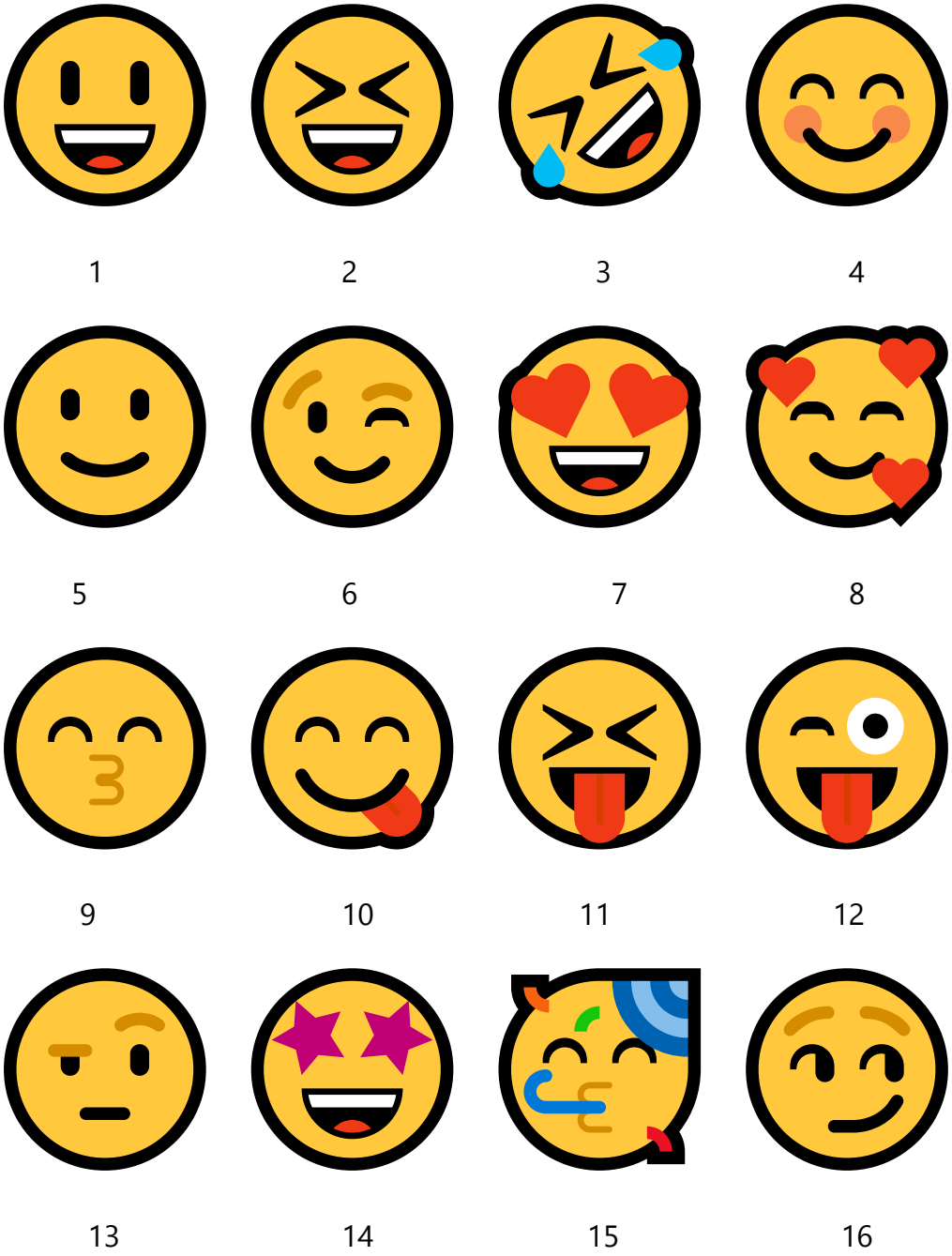
Interview Date:_____ Time:_____

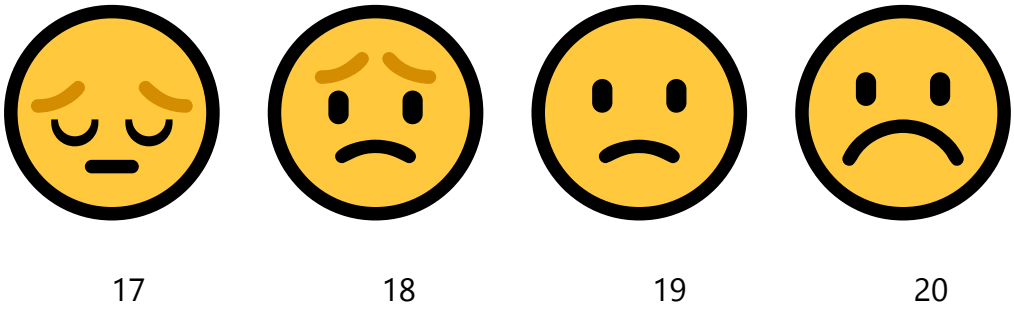
PTID: □□□-□□□□-□-□ (Adolescent or ParentGuardian)

Note: If this form is to be used as a source document, initial and date each item. For any procedures conducted after the initial contact date, initial and date the corresponding item. For any procedures not completed, either mark as "N/A" (not applicable) or "N/D" (not done). If interview is with a participant note:

Initials	Date	
BEFORE THE INTERVIEW		
_____		Verify identity of participant or parent and record study PTID + indicate whether adolescent participant or parent/guardian
_____		Obtain Informed Consent and assent
_____	_____	Prepare materials for Interview (see Appendix B Materials Checklist)
_____	_____	Check that digital recorder and batteries are in working order
_____	_____	Review purpose/provide introduction for the interview
_____	_____	Begin Recording: At the beginning of the digital file, staff should record the date, study PTID, and whether adolescent or parent/guardian (qualifier)
AFTER THE INTERVIEW		
_____	_____	Provide interviewee reimbursement
_____	_____	Transfer digital recording to a secure computer, and label with PTID and qualifier within 2 business days of interview
_____	_____	Securely transfer digital file to transcription/translation service
_____	_____	Transcription service sends completed transcript
_____	_____	Site reviews transcript within 2 business days of receipt from transcription service, removing all identifying information
_____	_____	Upload final transcript in required format
_____	_____	Update tracking log, as necessary

Appendix D: Emojis for Feeling Assessment





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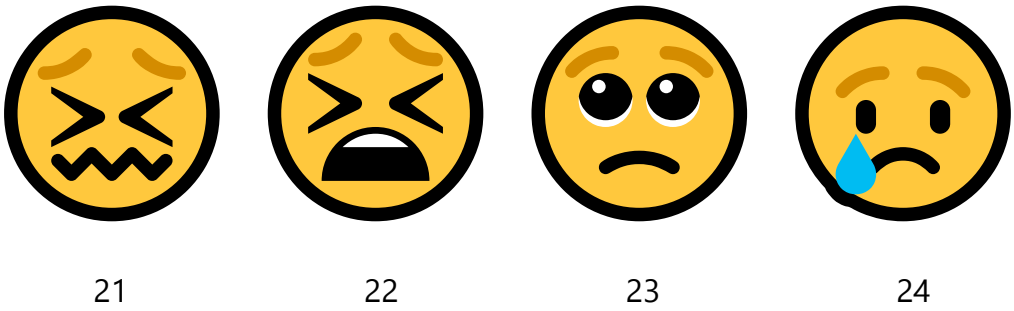

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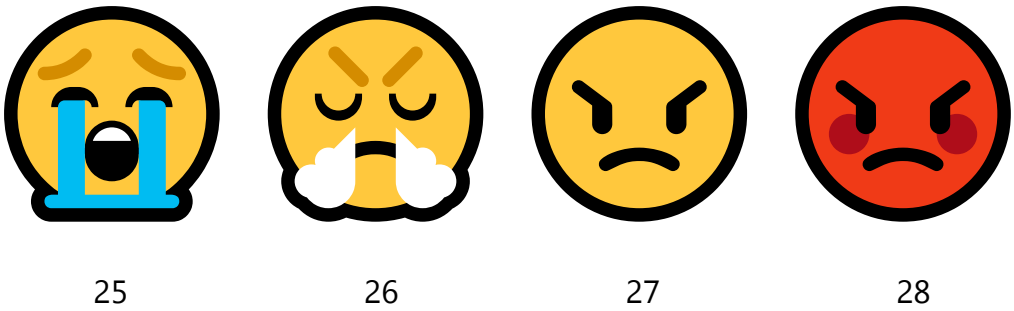

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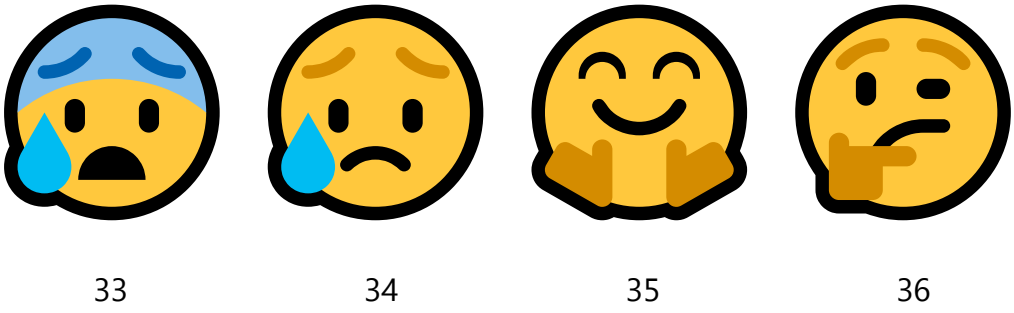

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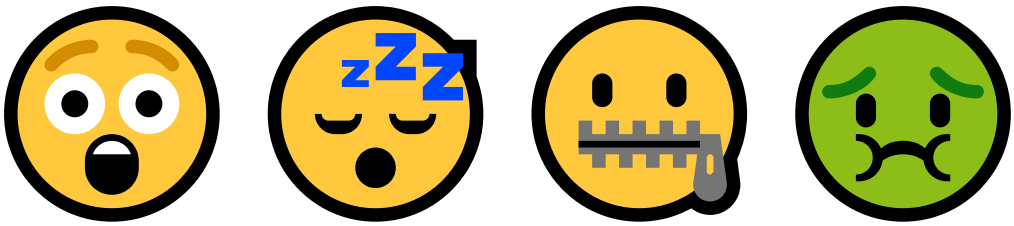

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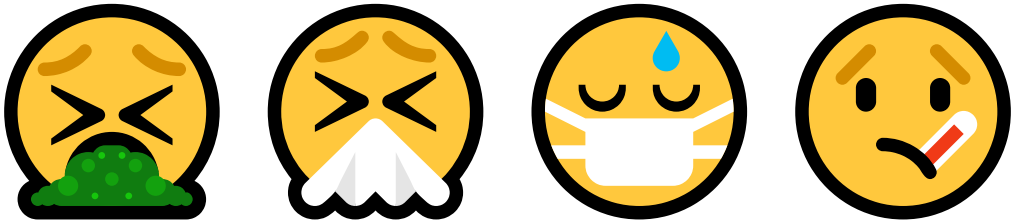

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53 54