COUNSELING CHECKLIST: INFORMED CONSENT

Use this abbreviated guide in your sessions if you need a reminder of the main elements of informed consent.

1. **Introductions.** Welcome the client and introduce yourself. Ask, "What brings you in today?" and then validate the client's interest in HIV testing.
2. **Check in with the client about the Client Assessment Questionnaire (CAQ) or the waiting area.** Ask, "I wonder if you have any questions about the Questionnaire?" If the client discloses higher HIV risk that was not originally documented on the CAQ, then the client will need to be offered counseling from this point forward. The CAQ is not used in San Francisco; for these clients check in about their time in the waiting area.
3. **Orient the client to the session.** Describe what is going to happen during the visit. Describe health education to lower risk clients and offer counseling to higher risk clients. Ask, "What questions do you have about the testing process?" or "Let's make sure you know what your options are for the test."
4. **Confirm informed consent.**
   a. **Testing history and past results:** Ask, "Have you tested before? If so, when and what were your results?"
   b. **Rapid or conventional testing:** Ask, "What have you heard about the rapid test?"
      - Same day results in 20 minutes to 40 minutes
      - Two collection methods (oral swab or finger stick/whole blood)
      - Describe the options for waiting for results
      - HIV-negative results do not need confirmation but may involve discussion of the window period; preliminary positive results require confirmation by submitting a second sample for laboratory testing.

      Ask, "What have you heard about conventional testing?" Describe conventional testing, if offered.
   c. **Anonymous or Confidential:** Ask, "What have you heard about anonymous or confidential testing?"
      - Anonymous: no name or identifying information
      - Confidential: written result, HIV reporting by name if confirmed HIV-positive
      - Offer a referral if client prefers a different testing procedure
   d. **Counseling Information form (CIF)/ Client Information form (SFCIF):** For clients receiving counseling, introduce the CIF or SFCIF and describe the purpose of its questions: funding services, directing future HIV prevention and care, epidemiology of the epidemic. The CIF and SFCIF are not used with clients whose risk for HIV is low.
   e. **Consent forms**
   f. **Subject Information Pamphlet**
5. **Administer the test.**

COUNSELING PROTOCOL: INFORMED CONSENT

1. Introductions.

Welcome the client, introduce yourself, and establish rapport by describing what is going to happen during the session. You might begin by asking, "What brings you in today?" and then validate the client's interest in testing.

If the client will be offered counseling, you might validate by saying, "From what you've said and your responses on the questionnaire, I think I can see what motivated you to see us for a test." If a client is low risk and will not be offered counseling, you might say, "We can talk a little later about your concerns and what kind of testing you might need in the future."

2. Check in with the client about the Client Assessment Questionnaire (CAQ) or waiting area.

Other than in San Francisco, the CAQ forms the basis for the opening of the counseling session. Give the client an opportunity to disclose more than they did in the waiting room.

For example, "Before you get your HIV test today, let's check in about the questionnaire we asked you to fill out in the waiting room. The questionnaire is a very important part of your HIV test; it helps us cater our services to your needs. First, I'm wondering if you have any questions about the questionnaire. [Pause for the client to respond.] Also, now that we're in the privacy of this office and away from the waiting room, I want to give you a chance to change your answers—if you feel like that would reflect your situation more realistically."

If there are no changes to the CAQ that elevate the client's HIV risk, continue with the session.

- If the client discloses a higher level of HIV risk than initially recorded on the CAQ, seamlessly shift toward offering counseling rather than just health education.
- Check in with your supervisor on your program's approach to transitioning and how you should note this in your paperwork. Keep in mind that if a client is transitioned, a Counseling Information form (CIF) will need to be filled out.

In San Francisco, the CAQ is not used. for these clients check in about their time in the waiting area and if the client has used a PalmIt data collection device, ask about their experience, "I wonder if you have any questions about the PalmIt?"

3. Orient the client to the session.

Ask, "What questions do you have about the testing process?"

Inform the client of the basic structure and steps of the session.

Explain the role of the counselor, define the amount of time the client will be in the clinic (check with your supervisor to confirm the amount of time that the process takes at your site), and describe the content of the session (CAQ review, outside of San Francisco; informed consent; HIV test; counseling, health education or neither; and disclosure of results). If you are working with a lower-risk client, state that you will be conducting the first part of the session and that "A counselor will call you when your result is ready."

4. Confirm informed consent.

Review informed consent, answer client questions, complete paperwork. Ask questions that will involve the client in this process, confirm the client's level of knowledge before you embark on long explanations, and treat the client as a partner in the process, for example:

a. Testing history and past results: Ask the client, "Have you tested before. If so, when and what were your results?"

This question gives the counselor some information about the client's test history and frames the informed consent process, since some information may not have to be repeated, perhaps just reviewed.

b. Rapid or conventional testing: Ask, "What have you heard about the rapid and conventional HIV tests?"

Validate the client's response, and proceed with the explanation. If your site offers only one kind of HIV testing, you need only describe that testing process. for example, "Sounds like you've done this before. Let's just go over the testing process here, because it may be a little different from your last visit." If you offer both kinds of tests, it's often easiest to describe the rapid testing process in its entirety or the conventional testing process in its entirety, rather than try to go back and forth between the two.

If offering the OraQuick ADVANCE rapid test, explain the test, its accuracy, the timing of results (same day, 20 minutes to 40 minutes after starting the test), the method for collecting fluids (either oral swab or finger stick/whole blood), and the possible results.

Describe what will happen after the test has started (for rapid testing) or before the sample is collected (for conventional testing). for higher-level services with rapid testing, you might say, "After we start the test, we'll have about 20 to 40 minutes to address any concerns you have about HIV." for lower-level services, describe the site- specific low-level intervention (for example, video, brochure, or group HIV education).

Explain that HIV-negative results do not need to be confirmed, but may involve discussion of the window period, which you may need to describe briefly.

For rapid testing, explain the need for a second sample should the result return as a preliminary positive. for conventional testing, explain that the lab has already confirmed HIV-positive results before sending them to the test site.

Check in with the client, since by this point, you have offered lots of information. You may need to offer further explanation:

- **Negative results**: for either rapid or conventional testing, if the result is negative, that result is conclusive. for example, the counselor might say:

  "The test is a screening test, so it is very good at finding HIV antibodies. If the result is HIV-negative, we can rest assured that a person testing does not have HIV. The meaning of an HIV-negative result depends in part on when potential exposure happened. We'll have a chance to talk a little more about that later."

- **Preliminary positive results**: If it is a rapid test and the result is a preliminary positive, the client is very likely to be HIV-positive. As is the standard of care in the United States for the positive results of all medical screening tests, positive results on the OraQuick ADVANCE must be confirmed by a second test. During the initial informed consent, the client will need to agree to give a second sample before leaving and return to receive confirmatory results if the rapid test result is preliminary positive.

  For example, a counselor might say, "When a test result is preliminary positive, we have to confirm the result with a second, confirmatory test. The second test will tell us for certain if the preliminary positive result is truly HIV-positive. We do this because in California and the rest of the United States, we cannot tell someone that they are HIV-positive based on one screening test. The first preliminary positive result has to be confirmed by a second positive result on a different test. Currently, there is no rapid confirmatory test for HIV, so the second sample has to be sent to the lab to be tested."

  Or, "The standard of care in the United States for all medical screening tests, including HIV tests, is to perform a second test to confirm any reactive result on the first test and to rule out any chance of a false positive result."

- **HIV-positive results in conventional testing**: If it is a conventional test and the result is HIV-positive, the client is HIV-positive. The client's sample tested positive in the ELISA antibody test and a second confirmatory test.

c. **Anonymous or confidential testing:** Ask, "What have you heard about anonymous or confidential testing?" Use what you know about the client's testing history to assess the client's knowledge of the difference between anonymous and confidential testing.

   Explain HIV name-based reporting, clarifying that this occurs only in confidential test sites and only for HIV-positive results that have been confirmed. Make it clear, however, that the names of people with HIV are reported when an individual, even one who has tested anonymously, seeks medical care through a doctor or nurse. It is important to state "Your results will be forwarded to the CDC," not "Your name will be forwarded to the CDC," when referring to the last phase of the process.

   Explain that anonymous tests can be converted to confidential tests if a client result is preliminary positive or confirmed HIV-positive, to facilitate entry into medical care.

   Offer a referral to alternative testing if the client prefers a testing procedure different than the one available at your test site.

d. **Client Information form (CIF, or SFCIF in San Francisco), only for clients receiving counseling:** Introduce and describe the purpose of the CIF or SFCIF. for example, "I will also refer to this form from time to time. It will not have any identifying info about you. It helps us understand trends so that we can direct services where they're most needed. It's also how we're able to offer the test for free through the state

Department of Public Health. You can always decline answering any questions on this form." Pause and then ask, "What questions do you have about the form?"

Neither the CIF nor SFCIF is used with low-risk clients. These forms are used only with clients who have risk for HIV. Keep in mind, however, that if a client transitions to counseling (either because of disclosure of higher HIV risk or because of a preliminary positive result), the introduction and explanation of the form is required.

e. **Consent forms**: After reviewing all this material, present consent forms as a way of summarizing the informed consent discussion. Ask the client to confirm consent. If the client is choosing confidential testing, the client and counselor should now complete appropriate paperwork. In an anonymous test site, the client consents orally and only the counselor completes the paperwork.

g. **Subject Information Pamphlet:** Offer the Subject Information Pamphlet from OraSure Technologies to assist with any future questions the client may have. You may want to show the client the paragraph stating "deep, or French kissing is not advised" and note that this statement is not endorsed by the Office of AIDS or the Centers for Disease Control and Prevention.

Ask client if they have any questions before proceeding.

This interchange should facilitate the informed consent process, which must, at the very least, include informing the client of the following:

- The difference between anonymous and confidential testing in California, especially in terms of current HIV reporting laws.
- If it is a rapid test, how the OraQuick ADVANCE test will be administered, reviewing rapid test procedures, and explaining how the test result will be interpreted and disclosed during the course of this session. If it is a conventional test, how the ELISA will be administered, reviewing conventional test procedures and explaining that the test result will be disclosed in one or two weeks (depending on your test site).
- The purpose and use of the CIF or SFCIF.
- Offering a Subject Information Pamphlet from OraSure Technologies.

All clients who consent must be given a copy of the OraQuick ADVANCE Subject Information Sheet to assist with any future questions they may have. Before proceeding, address any of the client's immediate questions or concerns.

5. Administer the test.

Collect sample and begin the HIV test according to agency procedures