BIOBANK FOCUS GROUP STUDY

Introduction (5 Minutes)

Hello. I'd first like to welcome everyone and thank you all for coming today and for fitting this session into your schedules. My name is __________, and I'm the moderator for today's focus group discussion.

- Our purpose today is to get a better *understanding of how you feel about the storage and use of biological samples and medical information for research purposes.*
- Before we get started, I'd like to take care of a few housekeeping items that are required by the university. First of all, your participation in this focus group is completely voluntary and you may discontinue your participation at any time. Please also feel free to pass on answering any questions that you deem necessary. Secondly, all discussion that takes place today will be kept confidential by all researchers, and I ask that you as participants keep all discussion confidential as well.

Today's focus group is being audio recorded, and the audio recorder is located here in the center of the table. This is done so that I can get an accurate report of, not who said what, but "what was said."

At any time during the course of the focus group, please feel free to excuse yourself to go to the restroom. The restrooms are located (direct participants to restroom). Do not feel like you need to wait to be excused to do so. The only thing that I would ask is that only one person be up and about at a time.

Finally, a few guidelines for today's focus group.

1) Please talk one at a time. Important so that everyone has an opportunity to have their opinion heard by the group.
2) Talk in a voice at least as loud as mine.
3) Avoid side conversations with your neighbors.
4) I'm interested in what everyone in the group has to say, so please make sure that we try to provide everyone with equal "air time".
5) There are no wrong answers in a focus group, so please share your opinions openly and honestly, regardless if others in the group have just shared a different opinion. There are many other people in the world that share your opinion, and you are here to represent not only yourself, but those people as well.
6) Out of respect for your schedules and in order to end on time this evening, I may need to interrupt conversation at various points. This is also necessary to make sure that we can cover a broad array of topics tonight.

Participant Introductions (5 Minutes)

- First Name
- What is one of your favorite foods?

__Questions (90 minutes)__

A. GENERAL IMPRESSIONS – [Note, 5 minutes max on the first 3 questions]

1. **What comes to mind (if anything) when you hear the word, "biobank?"**
2. **Had you heard of the word, "biobank," before this focus group?**
3. **Now I'd like to provide you with a little more information about biobanks for the purposes of our discussion today. [NOTE: Show Visual]**

   Biobanks are typically managed by a medical center and…

   - **Store biological samples such as blood or tissue. These samples could be left over from either inpatient or outpatient medical procedures such as blood draws, surgeries or biopsies. Or they could come from procedures like blood draws that need to be done specifically to get the sample for the purposes of the biobank.**
   - **Store a patient's medical records along with their samples.**
   - **Provide samples and medical records to scientists to conduct medical research.**
   - **Keep people's samples and information for many years, so research can be done on them well into the future.**

   In other words, biobanks are a little like libraries. But instead of books, they contain biological samples and medical records. And instead of just anybody being able to access these samples and records, only researchers with special approval can get at them and use them for research.

4. **So based on this information, what initial thoughts or questions do you have about biobanks?**

   (Probe: What makes you say that? What are some reasons for that? What did you consider when determining this to be something you would want answered?)

Now I want to tell you a bit more about the kinds of research that could be done through a biobank. Here are four examples: [SHOW VISUAL]

- ♦ Researchers could use DNA from cancer tissue that was stored in biobanks to better understand the genetics of cancer;
- ♦ Researchers could use blood samples stored in biobanks to study the genetics of mental illnesses such as bipolar disorder or schizophrenia;

- Researchers could use urine samples stored in biobanks to improve how diabetes is managed;
- Researchers could use samples from an infected wound that are stored in a biobank to learn more about the bacteria that caused the infection.

5. **Overall, how useful or important do you think this kind of research is? Please explain…**

6. **Do you think some of this research is more or less important than other types? Please explain….**

7. **What, if anything, concerns you about any of this research?**

8. **What difference, if any, does it make to you knowing that some biobank research involves genetic or DNA research?**

B. FORMAT FOR CONSENT

Now let's talk about how a biobank should get permission from patients to store their biological samples and make them available for researchers to use.

First of all, do you think a biobank needs to get permission from patients to use any material that may be left over from their medical procedures? Why? Why not?

> **One way a biobank could get permission is to say to patients, "Your samples will be included unless you explicitly ask that they <u>not</u> be included." This approach is also called an opt-out approach. In an opt-out approach, patients would get some information about the biobank to read. Then the patient would need to sign a document if they did <u>not want</u> their biological sample or personal information included in the biobank.**

9. **What are your initial thoughts about opt out?**
10. **What do you like about this approach?**
11. **What concerns, if any, do you have about this approach?**

Another way a biobank could get permission to collect samples from patients is to essentially say to patients, "Your samples will NOT be included unless you explicitly ask that they be included." This is a called an opt-<u>in</u> approach. In this approach patients would also get something to read about the biobank, but this time they would sign on the dotted line only if they want their sample included in the biobank.

12. **What are your initial thoughts about this approach?**

13. What do you like about this approach?

14. What concerns, if any, do you have about this approach?

Now I'd like to give you a chance to think about your preferences regarding these approaches. I'm going to hand out a card to each of you and ask you to mark on the card whether you personally would prefer the opt-out, opt-in, or whether you have no particular preference. I will then collect the cards from you. There is no need to put your name on the card.

[Hand out cards and have people complete them]

15. Thank you for doing that. Now that you have had the opportunity to state your preference, what do you view as some of the overall advantages and disadvantages of these two approaches?

C. PERMISSION

Now, I mentioned earlier that samples in biobanks could be used for many years in different kinds of research. It may not even be possible to say exactly what kind of research the samples could be used for at the time they are collected. So there are a few options for dealing with this uncertainty.

[SHOW VISUAL]

One option is for biobanks to ask patients for what is called "blanket permission." In this case, a patient would agree that their samples and medical records can be used in any and all research that is done through the biobank. Researchers will need to get approval from the hospital research review board to do this research and to follow the policies of the biobank. So blanket permission means that your samples could be used in any approved research in the near or distant future.

16. What are your initial thoughts on blanket permission?

17. What do you like about this approach?

18. What concerns, if any, do you have about this approach?

Since patients who give biobanks blanket permission may have little control over what happens to their samples down the line, some people suggest that biobanks should have an advisory board to help monitor what kinds of research is done. This advisory board could include members of the public, community leaders, and patients whose samples are included in the biobank.

19. What do you think are the advantages, if any, of having an advisory board like this?

20. **What do you think are the disadvantages, if any, of having an advisory board like this?**

21. **How much of a difference do you think having an advisory board like this would have on your community's attitudes towards a biobank?**

    [SHOW VISUAL]

Another option is for patients to be given something similar to a menu that lists different kinds of research. The patient can then pick the kinds of research they would allow on their samples and medical records. The biobank would then make sure that only research picked by the patient is allowed.

22. **What are your initial thoughts on this menu-like approach?**

23. **What do you like about this approach?**

24. **What concerns, if any, do you have about this approach?**

[SHOW VISUAL]

A third option is for biobanks to contact patients on a case-by-case basis. In other words, the biobank would contact you and ask for your permission every time a researcher wanted to include your sample and medical records in a research study.

25. **What are your initial thoughts on this case-by-case approach?**

26. **What do you like about this approach?**

27. **What concerns, if any, do you have about this approach?**

    One way this case-by-case approach could work is if biobanks create websites that patients can visit to check what research studies they qualify for. Patients could then review the research studies and pick which ones, if any, they want their samples or medical records included in.

28. **What are your thoughts about this website option?**

29. **What do you like about this option?**

30. **What concerns, if any, do you have about this option?**

31. **Are there any other options for obtaining permission from patients that you believe should be considered?**

    Now I'd like to give you a chance to think about your preferences regarding these approaches. I'm going to hand out a card to each of you and ask you to mark on the card whether you personally would prefer blanket permission,

menu-type permission, case-by-case permission, or whether you have no particular preference. I will then collect the cards from you. There is no need to put your name on the card.

[Hand out cards and have people complete them]

32. **Thank you for doing that. Now that you have had the opportunity to state your preference, what do you view as some of the overall advantages and disadvantages of these approaches?**

D. PATIENT MEDICAL INFORMATION

As we've already talked about, biobanks can store information from people's medical records as well as their biological samples. Some biobanks also include identifying information like patient names, addresses, and so on. [REFER TO VISUAL HERE] Some people have concerns about the confidentiality of their health information in the biobank, while for others this is not a concern.

33. **How do you feel about this?**

Identifying information can be handled differently from one biobank to the next. One reason researchers may want identifying information is because they may be able to learn more about the genetics of a disease if they know things like people's age, gender, and factors like whether they smoke and where the live. I want to ask you about 3 possible options for handling identifying information: [SHOW VISUAL]

Option #1: The first option is for both biobank staff and researchers to have access to your identifying information.

Option #2: A second option is for biobank staff to have access to identifying information about you but <u>not</u> the researchers.

Option #3: A third option is for <u>neither</u> the biobank staff <u>nor</u> the researchers to have access to any identifying information about you.

34. **What are your initial reactions to these approaches?**
35. **What are some advantages to each of these approaches?**
36. **What are some disadvantages to each of these approaches?**

Now I'd like to give you a chance to think about your preferences regarding these three options. I'm going to hand out a card to each of you and ask you to mark on the card which option you'd prefer or whether you have no particular

preference. I will then collect the cards from you. There is no need to put your name on the card.

[Hand out cards and have people complete them]

37. **Thank you for doing that. Now that you have had the opportunity to state your preference, what do you view as some of the overall advantages and disadvantages of these three options?**

E. INFORMING PATIENTS OF RESEARCH RESULTS

One way that a biobank or researchers may use identifiers is to contact patients regarding specific results of research that was done on their biobanked samples.

38. **What are the advantages of researchers returning to participants results of research that was done on their samples?**

39. **What are the disadvantages?**

(Probes: Please help me understand your thinking. What did you consider when determining that to be an advantage/disadvantage? What influenced you to consider that to be an advantage/disadvantage?)

40. **If you agreed to participate in a biobank, would you want researchers to contact you regarding results of research that was done on your sample?**

(Probes: Help me understand your thinking. What makes you say that?)

41. **Would your desire to be contacted depend on the type of research that was done?**

F. SAMPLE COLLECTION

Another difference between various biobanks is how they obtain biological samples. Biobanks can get samples in two main ways. I'd like to get your feedback on these.

1. **One potential way is to use samples that are left over from a routine procedure such as a blood draw or surgery. These samples would only be used with your consent. If these left-over samples don't go into a biobank, they would be destroyed.**

42. **What are some of the advantages to this approach?**

43. **What are some of the disadvantages to this approach?**

Another approach would be to draw blood from patients solely for the purpose of the biobank. In this case, the samples are not left over from a procedure, but instead, patients are asked for their permission to do a blood draw specifically for the biobank.

44. **What are some of the advantages to this approach?**
45. **What are some of the disadvantages to this approach?**
46. **Now that we have explored the advantages and disadvantages of these two options, what are your overall perceptions of these two approaches for obtaining biological samples?**

G. THOUGHTS ON A LOCAL BIOBANK

Now that we have discussed several different issues related to biobanks, I'd like to get your thoughts on the development of a biobank in or near your community.

47. **Imagine that a biobank was going to be developed in or near your community. Would this be mostly positive, mostly negative, of consequence?**

(Probes: What influenced your ideas? What makes you say that? Please tell me more about that.)

48. **Of the issues we've discussed today, what are some of the most important things that should be taken into consideration in the development of this biobank?**
49. **Of the issues we've discussed today, what issues would have the greatest impact on whether you decided to allow your biological samples to be used in this biobank?**

H. CLOSE

Unfortunately we're out of time for today. Discussions are currently underway about developing a local biobank, and your input will be extremely helpful in this consideration process. For those of you who are interested, we have put together some information that you may consult to learn a bit more about biobanks and some of the issues we have discussed today.