Appendix II

Focus Group – Discussion Guide

Introduction (5 minutes)

Thank them for coming
Aim of discussion – hear people's views, there are no right or wrong opinions, disagreement OK
Participation voluntary
Confidentiality – all info anonymous, personal details will not be passed on to any third party
Get permission for recording to be taped – no names or identifying features used when typed up
Guidelines – talk one at a time; am interested in everyone's views so will try and give everyone equal 'airtime'; no wrong answers – be honest and open.
Turn mobile phones off
Go round room. Ask everyone to say their name and one of their favourite foods.

Research (30 minutes)

On the information sheet you've been given, there is some general information about donating samples for research. Has everybody had a chance to read this information? (if not give participants a few minutes to read document). So, to summarise….*give a brief overview of information on the document.*

1. So to start off, does anyone have any questions about anything I've said so far?

So I'd like us to think now about the different types of samples someone might donate to medical research. Human biological samples can mean a variety of different things including body fluid such as blood, saliva and sperm, and human tissue such as fat, cancer tumours or muscle or even whole organs.

2. Do you think there are some types of samples which are more sensitive to give than others? Which ones? Why?

There are also various different ways that samples can be collected. They might be

- left over from routine procedures such as surgery;
- left over after a medical test such as a blood test;
- donated specifically for medical research, for example a cheek swab or an extra blood sample;
- donated after a person's death;
- a person's organs e.g. heart or kidneys, which would have been donated for transplant, may be used for research if they are not suitable for transplant or a suitable recipient is not available. The relevant clinical data may also be included and reviewed after death.

3. I'd like us to go through each of these in turn and discuss whether you have concerns about any of these ways that samples might be collected and why. GO THROUGH AND PROBE EACH POINT SPECIFICALLY (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

4. Do you see donation of human samples for medical research and organ donation for transplant similarly or do you think they are different?

5. Thinking specifically about donating tissue or organs after one's death, do you think if someone has indicated in writing that they are willing to donate these for research in the event of their death, their wishes can be overridden by their relatives?

Samples may be used for a variety of different types of research. This might include looking at how the body works to fight disease; testing new treatments for conditions such as heart disease and diabetes or developing ways of diagnosing earlier different types of cancer.

6. Are there any types of research you would not be happy for your sample to be used for? Why?
   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

There are many places where research is performed, such as universities, NHS, charities such as cancer research, government labs and pharmaceutical companies. These are all groups that do research & sometimes they collaborate with each other in order to make medical progress.

7. Do you have any concerns about any particular types of organisations using donated samples. Which if any, and why?

   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

8. What do you think about the organisations that conduct research on samples? Do you think they are generally doing a good thing for society? Do you have any concerns about what they do?

9. Institutions such as the government and ethics review committees make decisions about what research can and can't be done on human samples. Ethics review committees are usually made up of different experts such as of doctors, scientists, ethics experts and patients Do you generally trust these types of institutions to make decisions about what research can and can't be done using human tissue samples?

Consent (40 minutes)

I'd like to now talk about getting permission, also known as consent, to use a person's sample for medical research. Most of us have probably had blood taken at some point and some of us will have had an operation. If we have blood taken for a test, there might be some blood left over after the test has been done. Similarly, tissue may be removed during an operation and there may be some left over after any necessary tests have been done on the tissue. So you would not have any additional tissue taken just for research purposes unless you had specifically given permission for this at the time it was going to be taken. In most cases, it is just the leftover blood or tissue that you might agree to donate to medical research.

10. Thinking about leftover blood or tissue being used for medical research, do you think a person needs to be asked for their consent? FOR EACH RESPONSE: Why/why not? How important is this to you?

11. What would you expect to happen to samples that are left over from clinical procedures?

12. The majority of the time, tissue that is left over is destroyed. How do you feel about that?

There are a number of different ways that a person could give their permission or consent for their sample to be used for medical research. I'd like us to think about some of these now and discuss what we like and what we dislike about these different types of consent.

I'd like us to start by thinking about whether we prefer what is known as an **opt-in** system, or whether we prefer an **opt-out** system of sample donation.

Opt-in means that a person has to say that, after they turn 18, they are willing to and actively agree to donate their sample for research. This is how the current system for organ donation works in the UK.

The other approach is an opt-out approach. In this system, it is assumed that a person is happy, after they turn 18, for their sample to be used for research unless they specifically say otherwise. However, there is a mechanism in place for a person who is not willing to donate to opt out.

So, to start with, lets think about the first option, OPT-IN.

13. What do you think are the pros and cons about this approach? Why?

14. Thinking now about the OPT-OUT approach, what you think are the pros and cons? Why?

15. Which do you prefer? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

The current system is an opt-in one, so I want us to think about this type of consent now. If you were going to be asked to donate any leftover blood or tissue for medical research there are two ways this could be done. You could be asked to give consent **every time** you have an operation or blood test, or you could give consent just **once for life for all your samples,** with the option of withdrawing at a later point if you wanted to.

16. Thinking about **consent every time**, what do you think are the advantages and disadvantages of this approach?

17. Thinking about **consent once for life**, what do you think are the advantages and disadvantages of this approach?

18. Can you think of any happy medium which might be better?

19. Which would you prefer? Why? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

20. If people gave consent just once, when and where do you think the best place would be to give consent?

21. If someone wanted to consent to donate their tissue or organs for medical research in the event of their death, do you think it should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register?

In front of you, you have 3 different scenarios. In each one the story is essentially the same, however there are some slight differences and these are highlighted in bold. I'd like to discuss what you think of each of these in turn.

Read all 3 scenarios out loud highlighting the key differences between the three. Then go back and discuss each one in turn.

Scenario 1: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what kinds of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the left over tissue for a range of future unknown uses
- Lisa is given some general information about the kind of research the tissue might be used for but nothing specific.
- This type of consent is known as GENERIC CONSENT

22. What do you think about this type of consent?

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

24. Do you have **any concerns** about this approach?

Scenario 2: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what types of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. Lisa is asked to sign a consent form. The surgeon explains that **Lisa can indicate on the consent form whether there are any particular kinds of research which she doesn't want the tissue to be used for, for example research involving animals or research conducted outside the UK.** He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the tissue for a range of future unknown uses;
- Lisa is given some general information about the kind of research the tissue might be used for;
- **Lisa can say if there are any particular kinds of research which she doesn't want the tissue to be used for.**
- This type of consent is known as TIERED CONSENT

25. What do you think about this type of consent?

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

27. Do you have any **concerns** about this approach?

Scenario 3: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not

donated for medical research it will be destroyed. The surgeon explains that **the hospital are currently involved in a study looking at the growth of tumours. He informs her that if she gives permission for the left over tissue to be used, it would only be for this particular study.** He also explains that the study has been approved by an independent ethics committee.

So, in this scenario:

- **Lisa is only asked to give consent to a particular study and is given information about that study.**
- This type of consent is known as SPECIFIC CONSENT

28. What do you think about this type of consent?

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

30. Do you have any **concerns** about this approach?

31. In this exercise we have discussed three different types of consent. Which do you prefer and why? GO ROUND AND ASK PEOPLE (AFTER GROUP DISCUSSION: ask participants to complete associated question 6 & 7 on questionnaire)

32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where they cannot do this with confidence, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If your first choice wasn´t generic consent, does this information change your preference? (AFTER GROUP DISCUSSION: ask participants to complete question 8.

33. So, we've discussed which type of consent you would like for left over samples. Would your preference be any different for samples that you might donate specifically for research, e.g. if you volunteered to took part in a study and had to give a saliva or blood sample?

34. Would your preference be any different if you were donating what you might consider to be more sensitive samples e.g. genetic data, stem cells?

35. If you decide to withdraw consent would you be happy for researchers to use the data that had already been generated up to that point using your sample?

36. Do you think a central website where you can find out about general research that your sample might be used for would be useful and something you would use?

Information (10 minutes)

Researchers often need to have access to the donor's medical records in order to be able to meaningfully interpret the results of the scientific research. However, information, such as names or addresses are always removed and not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary.

37. Would you be happy with your medical records being linked to your sample or would you have concerns? Why?

38. Are there any types of information you would not want to be associated with your sample?

Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoked, drank alcohol, how often they exercised etc. This information might help them to better understand the particular condition they are investigating.

39. Would you be happy for this information to be made available or would you have concerns about your lifestyle information being associated with your sample? Why?

Ownership of sample (5 minutes)

40. What significance do you attach to a biological sample once it has been removed from your body? Do you still see it as yours or part of you in some way? Are you owed money if a drug is developed using your sample?