

### **Guidance Notes**

This document provides an overview of many potential points of inclusion in a consent form (CF). It is important to note that the content of the CF will depend on the particular research project and when creating the CF consideration should be taken as to what is required for a particular study.

Further considerations must be made for research projects that involve:

- Adults with incapacity (laws differ between the UK 4 nations)
- Child participants
- Tissue samples
- Research Databases and Tissue Banks

Research involving these types of participant groups involves greater regulation and approvals. Guidance can be found at the [Health Research Authority site \(HRA\)](#).

### Version Control

It is essential that all documents are correctly version controlled. More information regarding version control can be found in SHLS-S-004.

### Taking Consent

The person taking consent must be appropriately qualified and delegated to do so as per the protocol.

## CONSENT FORM [*Version*]

<b>Study Title:</b>	
<b>Chief Investigator:</b>	
<b>Principal Investigator at Site:</b>	
<b>IRAS ID:</b>	
<b>Centre Number:</b>	
<b>Local Study Number:</b>	
<b>Participant Identification Number for this trial:</b>	

**Please initial box**

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Health Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

5. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. / I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team.

6. (If appropriate) I understand that the information held and maintained by \_\_\_\_\_ [*enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations*] may be used to help contact me or provide information about my health status.

7. (If appropriate) I understand that data generated during the study will be sent outside of the European Economic Area where laws protecting my personal information may be different to my own country

8. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant                      Date                      Signature

\_\_\_\_\_  
Name of Person                      Date                      Signature  
taking consent

[When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.]