**Guidance on the content of the Informed Consent Form**

1. This document should be read in conjunction with *GD\_032 Guidance on content of a Patient Information Sheet for UHBW sponsored studies*
2. The *TMPL\_117 ICF template* should be used for UHBW sponsored studies which are not managed through a trials unit which uses its own template. Each paragraph in the template which states (if applicable) is optional depending on requirements for the study. The paragraphs without this must be retained and used.
3. If a trials unit is using its own ICF template, it should be checked against UHBW’s template to ensure that all applicable items have been addressed and that there are no inconsistencies in the wording. It is recommended that where the study ICF differs in substance from the UHBW ICF template that this is documented in a File Note with an explanation of why this decision was made.
4. For studies involving children, vulnerable adults, genetics studies and rare diseases (where patients may be identifiable), additional clauses may be required or the text may need to be adapted so that it is appropriate for the readership. Please refer to the HRA website for templates and additional guidance.
5. It is not necessary to seek explicit permission in the consent form for obtaining personal data (including special category data) if arrangements for processing of this information are fully covered in the Patient Information Sheet. However, where identifiable personal data is being shared with a third party or sent outside the UK, explicit consent must be sought.
6. Check with the study team what types of personal data are being collected and make sure that they are clearly identified in the PIS. The PIS should also be explicit about storage and archiving arrangements, including use of link keys.
7. Consent does not need to be sought in anticipation of a participant withdrawing from the study and use of their data and samples. It is expected that the PIS will clearly explain what happens to the data and samples when a participant withdraws from the study and whether they are able to request what happens to data/samples already collected and, where applicable, continued collection of their routine data.
8. If adding additional paragraphs to the ICT, note that there is a difference between ‘giving permission’ and ‘understanding’ e.g., the participant may give permission for their identifiable information to be shared with other parties, whereas they understand that they cannot be identified from their CT scans.
9. It is not necessary to seek separate permission in the consent form for procedures and tests to be carried out, although consent may be required for what happens to them (see paragraphs 10 and 12 below). Exceptionally, agreement should be sought for photographs. If photographs are required for the study, the following wording may be used: ‘I agree to having photographs taken of my [identify body area]. Photographs will only be taken of [part of body photographed] which are being taken because [explanation]. You will not be identifiable in the photographs.’
10. Paragraph 8 of the ICF refers to situations where identifiable data is shared with another organisation for the purpose of the study e.g. a pharmaceutical supplier delivering the study drug directly to patients requires patient contact details. It is not necessary to include this paragraph where the participant would not be identifiable to the organisation receiving the data (ie pseudonymised or anonymised data).
11. Paragraph 9 of the ICF is applicable where routine health data held by the NHS (eg NHS Digital) is accessed by the study team to gain additional information about the patient or use of health resources (eg for health economics analysis).
12. Paragraph 10 of the ICF is applicable where study data is held on a data platform outside the UK or where a labs facility outside the UK is processing samples and also needs clinical data to assist the samples analysis. Arrangements must be clearly stated in the PIS.
13. With reference to paragraphs 7, 18,19 and 20 of the ICF, the Research Management Facilitator/Research Project Manager should discuss with the study team whether consent for tissue sample collection and DNA/RNA analysis is optional or mandatory for the study. A similar discussion is needed about storage and analysis of samples and consent for DNA/RNA analysis for future studies. And finally, consideration should be given as to whether permission for DNA/RNA analysis and long-term storage of DNA/RNA samples and sharing with other researchers needs a separate paragraph in the consent form. Arrangements for the management of samples should be clearly set out in the PIS.