Items that should be included in the **Participant Information Sheet**:-

1. The Title of the study – *This should correspond with the Title given in other documents submitted as part of the Ethics Application*.
2. Introduction to the investigator(s) – *I/We are ……at Queen’s University Belfast*.
3. Brief statement of the purpose of the study (where possible) – *This study is being conducted to ……*.
4. What will be expected of those taking part in the study – *For example, this study will involve …. {completion of a questionnaire/taking part in a focus group/an eye-tracking experiment/measures of balance/the donation of a saliva sample/etc.}*.
5. The time commitment involved in the study – *For example, two questionnaires requiring five minutes each/three one hour visits to the laboratory/a thirty minute focus group meeting followed by a forty minute focus group meeting after six months/etc*.
6. Possible risks or discomforts – *For example, some of the questions asked might be distressing/you will be asked to place your hand in a bowl of ice water for thirty seconds/etc*.
7. Being in the study is voluntary – *It must be made ABSOLUTELY CLEAR that participation in the study is voluntary and that any potential participant can refuse to participate*.
8. The procedure for anonymity – *The safeguards ensuring anonymity of the data provided by any specific participant must be fully and unambiguously explained*.
9. The procedure for withdrawal – *The procedure for withdrawal from the study,* ***including timelines and points beyond which withdrawal is no longer possible****, must be stated clearly and unambiguously explained*.
10. The procedure to ensure confidentiality – *How the data from any specific participant will be made confidential, and any limits to this confidentiality, for example if a participant discloses information that indicates a risk of harm to themselves or to another, must be fully explained to the participants*.
11. The procedure for data sharing – *How the data will be shared, either between research groups, through standard scientific publication practices, or using modern internet data sharing vehicles*.
12. The person to contact with questions about the study – *The key point for further information on the study, normally the principal investigator, or supervisor of a student, must be clearly stated*.

Items that should be included in a **Written Consent Form:-**

1. Must include the Title of the study - *Which should correspond with the Title given in other documents submitted as part of the Ethics Application*.
2. Must obtain a clear statement confirming that the participant has read and understood the content of the Participant Information Sheet.
3. Must obtain a clear statement that the participant has had time to consider the information provided on the study, and can contact the researcher with any questions.
4. Must obtain a clear statement that participation is voluntary.
5. Must obtain a clear statement indicating understanding of the withdrawal procedure, timeline, and any restrictions to withdrawal.
6. Must contain clear statements informing the participant about ***anonymity*** and ***confidentiality*** of any information/data provided by the participant.
7. Must obtain unambiguous confirmation that after having read and understood the Participant Information Sheet and the Consent Form, the participant agrees to take part in the study.