Consent checklist for investigators (OPTIONAL)

St Patrick's Mental Health Services

In order to document consent, investigators might wish to complete the following checklist for each participant who agrees to take part in the research study.

Research project title: _____

Protocol No.: _____ Date: _____

Participant name: _____ Sex: M/F DOB: _____/_____/_____

Name of investigator obtaining consent: _____

1.	Have you given the participant an oral explanation of the proposed research project?		Yes/No
	1.2.	Have you given the information sheet to the participant?	Yes/No
	1.3	Have you told the participant that he/she will be kept informed of all relevant information that becomes available during the course of the study?	Yes/No
2.	Did your oral explanation to the participant include:		
	2.1	that this is a research project?	Yes/No
	2.2	that participation is voluntary?	Yes/No
	2.3	the aims of the project?	Yes/No
	2.4	the likely duration of the participant's involvement?	Yes/No
	2.5	the expected benefits to the participant and/or others?	Yes/No
	2.6	the expected nature of the drug, device or intervention being tested?	Yes/No
	2.7	the procedures which will be involved in participation?	Yes/No
	2.8	that the participant may instead receive a reference treatment or placebo?*	Yes/No
	2.9	what alternative standard medical therapy is available?*	Yes/No
	2.10	what risks, inconvenience, discomfort or distress may reasonably be anticipated for this participant: the level and the likelihood?	Yes/No
	2.11	that there may be some unforeseen risks?	Yes/No
	2.12	that a refusal to participate may be given without reasons and will not affect the participant's rights or their right to care?	Yes/No
	2.13	that the participant may be withdrawn from the study if the study investigator considers this is necessary in the best interests of the participant?	Yes/No
	2.14	that personal information may be scrutinised during audit by competent authorities and properly authorised people, but all personal information will be treated as strictly confidential and will not be made publicly available?	Yes/No
	2.15	that information generated by the study may be published but that no details will be divulged from which the participant could be identified?	Yes/No
	2.16	that some such information will be retained for a period after the end of the trial?	Yes/No
	2.17	what compensation arrangements are available?	Yes/No
	2.18	whom to contact in an emergency and how?	Yes/No
	2.19	what activities, if any, must be avoided during participation (e.g. driving, operating machinery, drinking alcohol, sport, pregnancy, breast feeding), after participation (e.g. blood donation, participation in another trial) and for what period?	Yes/No

3.	Has the participant given authorisation to you to inform his/her GP of the participants involvement in this study?	Yes/No
	3.1 Has the participant given permission for their GP to disclose medical information?*	Yes/No
4.	Is or has the participant been involved in any other research studies relevant to the present one?	Yes/No
5.	Is or has the participant recently been taking, or does he/she intend to take, any other medicines or preparations?*	Yes/No
6.	Have you allowed the participant sufficient time to consider the matter on his/her own, to discuss with others if wished, or ask you questions?	Yes/No
7.	In your opinion, has the participant understood and consented to take part in this research?	Yes/No

* Relevant to medical research only.