SWARTHMORE

Institutional Review Board

Informed Consent Options for Research Involving Human Participants

Informed Consent is an ongoing process by which a participant, their parent or their legal representative voluntarily confirms willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the decision to participate. All research proposals involving human participants or the collection of private data linked to individuals, must address informed consent. The following options are available per federal regulations (OHRP and FDA) and Swarthmore IRB policy.

Standard for Adult Research		Research Involving Minors		Waivers		Non-English Speaking Participants	
Informed Consent with Signature*	Research Information Sheet* (No signature required)	Assent for Minors*	Parental Permission for Minors*	Waiver or Alteration to Elements of Consent*	Waiver of Consent	Short Form with Oral Translation*	Long Form Translations*
The default for all studies. The basic elements for informed consent are required for any participant enrolled in research unless some or all of the elements are waived. Different consents may be required for different participant types, e.g. teachers vs student participants, prisoner vs non-prisoner participants, etc.	Use of an Research Information Sheet with elements for informed consent but without a signature line for participants. Only allowed if : (1) the only identifier is the signature on the consent and the principal risk would be breach of confidentiality OR (2) the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Each person should be asked if they want documentation linking them to the research.	Minors of age 7-13 requires obtaining oral assent unless waived. Minors of age 13-17 requires obtaining written adolescent assent (the minor signs) unless waived.	PI must address parental permission when enrolling participants under the age of 18. Parents or legal guardian with parental rights must provide consent for child unless waived or unless the child is legally emancipated.	The IRB may approve a consent procedure which does not include, or alters, some or all of elements of informed consent, so long as the research meets the criteria for approving research, and the research meets the criteria specified in the regulations for leaving out or altering those elements. An alteration of consent can apply to all consent types and there must be an appropriate justification for the alteration.	The IRB may approve a waiver of the requirement to obtain and document consent provided the criteria in the regulations are met under: 1. Public benefit or service programs (45 CFR 46.116(c)), or 2. Conditions are met under 45 CFR 46.116 (d), or 3. Emergency Research (45 CFR 46.101(i).	The Short Form and oral translation of the English consent is required if an individual is not fluent in English and this was not anticipated. This process requires a witness who understand both languages and who is not the oral translator. General (Short Form) research consents are available on the IRB website in 18 languages.	The IRB approved English versions of a research consent must be translated if it is known in advance that non- English speaking individuals are likely to be approached for consent or if more than 5 participants speaking one foreign language have been consented using the short form.

*Copies of the consent document(s) should always be provided to the participant, a LAR or a legal guardian.