

**Drexel University**  
**Institutional Review Board**

**Electronic Consent Policy**

Introduction

Informed consent is a vital part of the research process, and as such entails more than obtaining a signature on a form. Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research. Their informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves. In almost all cases, investigators must document the informed consent process by use of a written consent document (research consent form) signed and dated by the subject or his/her legally authorized representative (or surrogate) and the investigator (or study staff if approved by the Institutional Review Board (IRB)) who obtained consent.

Regulation

Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at 45 CFR 46.117(c), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects' legally authorized representatives (LAR) or the parents of subjects who are children. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can understand and retain. The Office for Human Research Protections (OHRP) would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature." If properly obtained, an electronic signature can be considered an "original" for the purposes of recordkeeping.

Recruitment Using the Internet

Passive electronic recruitment involves advertisements that are simply electronic versions of printed media advertisements residing on a website or functioning as a pop-up window ad when visiting a particular web site. In fact, electronic recruitment tools are far better than printed versions since they can be more informative like FAQs. These advertisements must be reviewed and approved by the IRB.

Recruitment tools that use email or other electronic solicitations, such as instant messaging or text messaging, to reach potential research subjects are examples of active electronic recruitment methods. This type of method requires that any list of email addresses gathered be obtained from public sources or with documented permission of the list owner.

The following guidelines pertain to these recruitment methods:

1. Electronic invitations by email, instant messaging or text messaging must allow for the recipient to "not participate" in any future contact regarding the research project simply by the click of a button and/or typing in the email address/text or instant address. The

recipient must not be asked for a reason or for their name or other contact information. It is reasonable and prudent to inform anyone using the 'opt out' feature of the approximate time that it will take for contact to be terminated.

2. Electronic invitations that allow the recipient to open a website, by hyperlink or other, must be presented to the IRB with the full text illustration of the website and its functions (additional hyperlinks, audio, video, etc.). All hyperlinks must be approved/accepted by the IRB.
3. Electronic invitations that allow the recipient to complete the informed consent process as approved by the IRB, and proceed to any research data collection tools, such as surveys or other data collection instruments as approved by the IRB, must include technology to ensure that privacy and confidentiality of participant are protected and the research subject is not contacted again with the request to participate.

#### Electronic consent process

Consent may be obtained electronically if:

1. Subjects are 18-years-of age or older.
2. The online consent form steps subjects through each consent element, one at a time.
3. Subjects can print a hard copy of the form.
4. The risks to subjects are low otherwise, and consent must be obtained with a signature on paper- and returned to the researchers via surface mail, fax or PDF versions via email.
5. To do research involving minors and others not allowed to consent for their self, consent is obtained from the parent or legal guardian and assent from the individual. Parental consent may be obtained on paper sent to the researcher via paper mail, fax or by telephone if the research is low risk. Parental consent should be obtained in a face to face to interview with the parent/guardian if the research is not low risk.
6. The technology ensures safeguards of protection of privacy and confidentiality.
7. If waiver of consent is requested by the PI, the PI must submit the "Application form for "Waiver or Alteration of Informed Consent" which must be approved by the IRB. This approval must have been discussed and recorded by the IRB.