

	AC.4.4.2
	FREE AND INFORMED CONSENT
Section:	Academic/Student (AC)
Subject:	Applied Research
Legislation:	
Effective:	January 21, 2005
Revision:	January 20, 2006; January 29, 2013; September 1, 2016 (reformatted)

APPROVED:	
	President and CEO

## **POLICY**

The policy of the Board of Governors is to establish principles that promote and facilitate the conduct of all research in ways that respect human dignity and that demonstrate concern for the welfare of living human research participants, in accordance with national human research ethics policies.

# **PROCEDURE**

### **DEFINITIONS**

Consent Free, informed and ongoing consent, and for the purposes of

this procedure, "free" and "voluntary" are used

interchangeably.

**Incidental findings** Unanticipated discoveries made in the course of research but

that are outside the scope of the research.

**Principal investigator** The lead investigator completing the research.

Research Ethics Board (REB) The board that reviews research applications to ensure that

researchers comply with this procedure.

Researcher

Any member of the SAIT community or any person external to the SAIT community who conducts or carries out research The official controlled version of this document is held in the Board of Governors Office. Procedure AC.4.4.2 Page 1 of 4



using SAIT resources and/or formally using members of the SAIT community as human participants. This includes but is not limited to researchers carrying out scholarly activity, applied research, and/or research under the terms of a Cadmus Trades Teaching Chair award or a Cisco e-Learning Chair award.

## **GOVERNING PRINCIPLES**

- Individuals who participate in research should do so voluntarily, understanding the
  purpose of the research and its risks and potential benefits, as fully as is reasonably
  possible. Where a person has the capacity to understand this information and the ability
  to act on it voluntarily, the decision to participate is generally seen as an expression of
  autonomy.
- 2. Where elements of the consent process may need to be adapted to the requirements of a particular research project, the Research Ethics Board (REB) can play an educational and consultative role in determining the appropriate process for seeking and maintaining consent.
- 3. The principal investigator is responsible for ensuring that the consent process is followed. Researchers are responsible for ensuring that all applicable legal and regulatory requirements with respect to consent are met.

#### **PROCEDURE**

- 1. Consent shall be given voluntarily and can be withdrawn at any time. Participants who withdraw their consent can also request the withdrawal of their data.
- 2. Consent must be free of undue influence and coercion. Incentives may be used, although the onus is on the researcher to justify to the REB that any proposed incentives do not constitute undue influence.
- 3. Researchers shall provide to prospective participants or authorized third parties full disclosure of all information necessary for making an informed decision to participate in a research project
- 4. Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

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Procedure AC.4.4.2 Page 2 of 4





- 5. Researchers have an obligation to disclose to the participants any material incidental findings discovered in the course of research.
- 6. Research shall begin only after the participants or their authorized third parties have provided their consent. This is the clearest demonstration that their participation is based on consideration of the risks and potential benefits of the research project. In situations where there is a teacher-student relationship between a researcher and the participants, the researcher must take special care to ensure that a participant's consent is truly voluntary and without coercion or undue influence.
- 7. Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.
- 8. The REB may approve a consent procedure which does not include, or which alters some or all of the elements of the normal requirements for informed consent or which waives the requirement to obtain informed consent, provided that the REB documents that:

- 9. Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the such research by the REB.
- 10. For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the researcher involves those participants to consent on their own behalf to the greatest extent possible in the decision-making process. The researcher should interests of the persons concerned, and the authorized third party should not be the

a) The research involves no more than minimal risk to the participants. b) The waiver or alteration is unlikely to adversely affect the welfare of the participants. c) The research could not practicably be carried out without the waiver alteration. d) Whenever possible and appropriate, the participants shall be provided with additional pertinent information after participation. e) The waived or altered consent does not involve a therapeutic intervention. individuals involved, and then only in accordance with criteria established in advance of also seek and maintain consent from authorized third parties in accordance with the best researcher of any other member of the research team. The official controlled version of this document is held in the Board of Governors Office. Page 3 of 4

Procedure AC.4.4.2



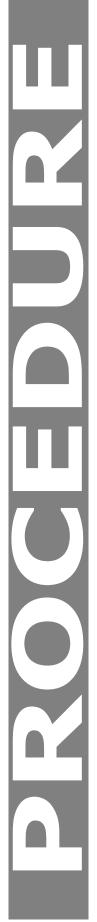
- 11. Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation.
- 12. Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.
- 13. Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for documenting the consent process. Whether or not a consent form is signed, it may be advisable to leave a written statement of the information conveyed in the consent process with the participant.

# POLICY/PROCEDURE REFERENCE

AC.4.4	Human Research policy
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AC.4.4.1 Research Requiring Ethics Review procedure

AC.4.4.3 Privacy and Confidentiality procedure



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Procedure AC.4.4.2 Page 4 of 4