**Southeastern Community College**
**Institutional Review Board**

## ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2) A description of any reasonably foreseeable risks or discomforts to the subject;
3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116

### Implied Consent

By sending back a completed survey the recipient has implied that he or she consents to participate but has not signed an informed consent document. Although some might call this "implied informed consent," OHRP would consider this to be a permissible informed consent process if the IRB has approved the informed consent alteration and waived the requirement for documentation of informed consent.

http://www.hhs.gov/ohrp/informconsfaq.html

**SAMPLE STATEMENT OF PURPOSE TO BE READ TO RESEARCH PARTICIPANTS**

FRANCHISING, MANAGERS, AND SELF-EMPLOYMENT

DAVID B. BILLS

The purpose of this research is to learn how franchising in the United States is changing. I am particularly interested in the movement into this sector of individuals who have previous management experience in other parts of the American economy. Your participation will help us to understand the nature of franchising, its changing structure, and its effect on workplace relationships. You will be interviewed for about an hour. If you agree, our conversations may be tape-recorded, however your name, place of employment, and others to whom you may refer will be identified either by pseudonyms or case numbers. Cross-references between you and the pseudonyms or case numbers will be destroyed at the conclusion of transcription. The recordings of these interviews will be kept confidential; only I and my research team will have access to them. Your specific comments may be used in my completed report, but we will be unable to link those comments specifically to you or your workplace.

Your participation in this research is voluntary, and you will not be paid for it. Our interview is the only method by which you may participate in this research. There are no risks to your participation. You may ask questions and/or discontinue participation at any time with no consequences. If you have additional questions concerning the research and/or your rights as a research subject, you may write to the principal investigator, David Bills, at N491 Lindquist Center, The University of Iowa, Iowa City IA 52242 or call him at 319 335-5366, or you may contact Professor Ray Muston, Chair of Committee D of Policy, Planning, and Leadership Studies, N473 Lindquist Center, The University of Iowa, Iowa City, IA, 319 335-6413.

**SAMPLE CONSENT FORM FOR RESEARCH PARTICIPANTS**

CERTIFICATION OF SUBJECT CONSENT

FRANCHISING, MANAGERS, AND SELF-EMPLOYMENT
DAVID B. BILLS

I, _____, hereby certify that I have been told by
(subject's name)

David B. Bills or his representative, of The University of Iowa, about the research on franchising and its purposes. I have been told about the procedures to be followed and how much time is involved. I understand there are minimal risks and discomforts associated with my participation, and I have been told of the possible benefits from the research. I have also been told the extent to which any records which may identify me will be kept confidential.

A written summary of what I have been told is attached. I have been given adequate opportunity to read it and have been given a copy of my own.

I understand that I have the right to ask questions at any time and that I may contact the investigator or The Human Subjects Coordinator at The University of Iowa at 319 335-6413 for answers to questions about the research and my rights.

I understand that my participation is voluntary, that I may refuse to participate or withdraw my consent and stop taking part at any time.

I hereby freely consent to take part in this research project.

_____ _____
Signature of Subject Date

I freely consent to my identification being revealed in this research.

_____ _____
Signature of Subject Date

I, the undersigned, certify that I was present during the oral presentation of the written summary attached when it was given to the above subject.

_____ _____
Signature of Subject Date