

UNIVERSITY OF MAINE AT FORT KENT

HUMAN SUBJECT RESEARCH

CAUTIONS

1. Investigate procedures must often be distinctly impersonal, in order to avoid contamination of data. Where the method is impersonal, exaggerated care must be taken to ensure that the well-being of the subject as a person is protected. For this reason, statistical error-rates may fail as indices of the importance of injury; even a single lasting injury to any individual subject, in body, capacity, or dignity, is important. Additionally, because redress through legal means is almost always awarded in terms of dollars, and not in terms of kind, it may at times be apparent that available redress cannot begin to approach the importance of an injury.
2. Consent by the state, by some corporate body, by some individual acting in an impersonal capacity, such as a lawyer, or by some relative not of the immediate family should not be interpreted as a guarantee of ethical informed consent. Where the only concern for the well-being of the subject is a legal concern, the IRB should independently determine the subject's best interest.
3. Certain kinds of research may be inadvisable in an institution which maintains close connections with the community and with community values. For example, studies in radioactivity, psychoactive substances, physiological pain, and extraordinary psychological stress, or investigations utilizing subjects near, at, or apparently just beyond the point of death may be especially sensitive to criticism. Prior education of the public may be helpful in such cases; in others, the research may be judged unsuitable for institutional support.
4. In research proposals, and in the consent form signed by the subject, the proposed use and disposal of identifiable records, such as photographs, video-tapes, or voice-tapes should be clearly indicated.
5. Assurance of access to professional attention and facilities should be provided by the University or by some insuring body, and should include the provision of appropriate specialized care and expertise over an indefinite time and distance. It is unreasonable to assume that the investigator will be responsible for such care and cost, since few investigators will have sufficient net worth to satisfy all the legitimate claims which might result from accident or negligence.