

**Concordia College, Moorhead, MN - CC IRB  
Protocol Review Checklist**

<b>Title of Study:</b>	<b>IRB Reviewer(s):</b>
<b>Principal Investigator:</b>	<b>Date:</b> <b>IRB Protocol #:</b>
<b><i>Technical Review</i></b>	<b><i>Yes / No / NA / Comments</i></b>
Education requirement for PI & key researchers met?	
Review Categories Checklist filled out and attached?	
Protocol application form completely filled-out and signed?	
Description of the Study attached with 23 elements addressed?	
Consent / parental permission / child assent documents attached?	
All the instruments attached?	
Debriefing form, recruitment materials, site permission letters, grant application, etc. attached?	
Required number of protocol copies provided?	
<b><i>Substantive Review - Description of Study Document</i></b>	
Title of study provided?	
Rationale for conducting research adequately explained?	
Sponsor of study specified?	
Target population specified?	
Approximate number of subjects to be recruited specified?	
Subject inclusion/exclusion criteria equitable?	
Use of vulnerable populations justified?	
Procedures for inviting subjects into study protect privacy and confidentiality and minimize coercion?	
Extra precautions taken to minimize possible coercion due to conflictual relationships with subjects?	
Study design and all procedures to be performed (including time commitment) acceptable?	
Rationale for using deception convincing?	
Consent procedure (setting, timing, process, person obtaining consent, wording & language, documentation, storage, etc.) ensures autonomy, privacy, confidentiality?	
Request for waiver of requirement to obtain signature, to have all elements of consent on the form, or to obtain consent justified?	

Potential risks (physical, psychological, social, or legal) and procedures to minimize them described?	
Anticipated benefits (to subjects, particular group from which the subject population is drawn, discipline, and/or society) described along with a statement indicating that benefits are not guaranteed?	
Benefits outweigh risks of the research?	
Compensation to subjects reasonable?	
Added expenses (e.g. time missed from work or school) to subjects or to a third party (e.g. parent) noted, with a description of what, if any, and how compensation will be given to subjects for them?	
Whether or not subjects will be compensated for development of commercial products as a result of the research clearly stated?	
Whether the subjects will be anonymous or not clearly discussed?	
Confidentiality of participants protected (e.g. through restricted access to data, use of appropriate coding procedures, separate storage of codes and identifying information, etc.)?	
Plan for where, how, and how long data, consent documents, and other documents will be stored and what will happen to documents after storage period elapses acceptable?	
Financial interests of investigators (and those of his/her spouse, dependent children, etc.) disclosed?	
<b><i>Substantive Review - Informed Consent Document</i></b>	
<b>Study title</b> , identification of <b>investigators</b> , <b>university</b> affiliation, and names of <b>sponsors</b> provided?	
Statement that <b>study involves research</b> along with explanation of the <b>purposes</b> of the study, expected <b>duration</b> of the subject's participation, and description of <b>procedures</b> to be followed?	
Description of reasonably foreseeable <b>risks/benefits</b> to the subject or to others adequate?	
Description of extent to which <b>confidentiality</b> of records will be maintained clear?	
Statement that participation is <b>voluntary</b> , refusal to participate will involve no loss of benefits, and that subject may discontinue participation at any time without penalty provided?	
Procedures for <b>orderly termination</b> of participation by the subject clearly described?	
<b>Compensation</b> for participation accurately stated?	
<b>Contact</b> information for researchers and IRB provided?	
If subjects drawn from a classroom, statement that participation is not part of regular curriculum and will not affect class grade or standing, and an explanation of whether subject will miss regular class work or not and what non-participants will do while research is taking place?	
Signature & date line provided for participant, legally authorized person, and witness (if applicable)?	

Understandable, correct language with reference to "you" & "I" rather than "subject" & "researcher"?	
No language that implies waiver of subject's rights?	
No exculpatory language?	
Statement that subjects would be given a copy of the consent form included?	
Financial interests disclosed?	
<b><i>Other Elements of Informed Consent...if applicable</i></b>	
Appropriate alternative procedures/courses of treatment disclosed?	
A statement that treatment used in study may involve currently unforeseeable risks included?	
Information on available treatment in case of research-related injury provided?	
Circumstances under which subject's participation may be terminated clarified?	
Additional costs to the subject that may result from research participation mentioned?	
A statement that significant new findings developed during the course of the research will be revealed to subjects if they may affect their willingness to continue participation provided?	
Explanation of why subject was selected to participate provided?	
Possibility that the FDA may inspect records of the FDA regulated study mentioned?	
Request for waiver of the requirement to obtain subject's signature justified?	
If signature waived, statement that by completing the survey subject indicates consent to participate?	
Request for waiver of the requirement to obtain informed consent or some of its elements justified?	
If short consent form used, provision for a witness to sign?	
<b><i>Substantive Review - Instruments and Other Materials</i></b>	
Instruments free of typographical and grammatical errors?	
All instrument questions necessary and appropriate?	
Other materials (debriefing form, recruitment script, site permissions, grant proposal, etc.) adequate?	
<b><i>Other Issues Raised during the Review Process</i></b>	