CRITERIA FOR IRB APPROVAL
Proposal Checklist

In compliance with federal regulations (45 CFR Part 46.111) and internal policy, all research proposals reviewed by Augustana’s IRB must meet the following criteria to receive approval. (Criteria directly from CFR 45 are marked with an asterisk; criteria in italics may not apply to every study.)

- In all sections, the PI has explained the research plans in sufficient detail to allow for review.

Objectives
- The importance of the knowledge expected to result has been made clear, and the research is likely to achieve its proposed aims.
- Research staff/investigators have appropriate expertise with the topic and population of interest.

Procedure/Time required
- Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.*
- The research setting supports adequate safeguards for protection of human subjects.
- Where possible, any physiological procedures used are already being performed on the subjects for diagnostic/treatment purposes.*
- It is clear which procedures are exclusive to study participation, as opposed to any normal educational practice or medical treatment which subjects and nonsubjects alike would already be receiving.

Participants
- Subject selection is equitable in relation to the objectives of the research, the setting in which the research is to take place, and any special problems of research involving special populations.*
- Inclusion/exclusion criteria are reasonable for the study aims (equity is maintained wherever possible).

Recruitment
- Informed consent, containing all required elements [see the Informed Consent Checklist], will be sought from all subjects (or their legally authorized representatives).*
- Subjects (or their representatives) are allowed sufficient opportunity to consider whether to participate.*
- The possibility of coercion or undue influence has been minimized (including special safeguards for vulnerable populations).*
- The language used in consent and all recruiting materials is understandable to the subjects (or representatives).*
- The provisions for documenting informed consent/assent are appropriate.*
- If PI/research staff conflict of interest (COI) is identified, the COI in relation to subject protections is appropriately minimized or managed.

Compensation
- Proposed payment to subjects and/or costs to subjects for participation (if any) are appropriate (compensation is sufficient for time required but not large enough to be coercive; costs are minimized).

Risks & Benefits

Revised December, 2010
 Likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, and/or economic risks to the subjects) are addressed in research proposal.

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.*

Direct benefits to subjects are clearly distinguished from benefits to the broader population from knowledge obtained through research.

**Risk Reduction**

- Appropriate steps have been taken to minimize all identified risks.*
- Additional safeguards for vulnerable populations are included.*
- For greater than minimal risk, clinical research, or NIH funded/FDA regulated clinical trials, adequate provisions are in place for monitoring the data collected to insure safety of subjects.*
- If the proposal is a multicenter study in which the lead PI or Augustana is the coordinating institution, communication among sites is adequate.

**Deception**

- Convincing rationale is provided for any inclusion of deception (mere withholding of information is used unless active misleading is necessary).
- Adequate debriefing procedures are in place to satisfy any postponed elements of informed consent.

**Confidentiality**

- The research proposal describes adequate provisions for protecting the privacy of subjects.*
- The research proposal describes adequate provisions for maintaining confidentiality of the data* (including the location/procedure for data storage and date for destruction of personal information).
- Any audio/video recording of subjects is justified, and a media release has been included if the recordings are to be used for purposes beyond data analysis.

**Other Approvals**

- If the proposal involves cross-institution collaboration, procedures are in place to seek approval from other IRBs, and any approvals already received are disclosed.
- Procedures are laid out for obtaining and documenting approval from an authorized official at any external institutions to be involved (schools, businesses, etc.).