REVIEW GUIDANCE FOR REB MEMBERS

Criteria for Approval of Research

Refer to the criteria below to guide your review. All criteria must be met in order to approve the research.

1. risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the participants to risk, and, whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes;
2. risks to participants, and the burden of participation (e.g., QL (loss of work, disruption of daily life, family impact), participant materials (diaries, Qs, etc.), are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits the REB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive if not participating in the research). Long term effects of applying knowledge gained in the research should not be considered;
3. selection of participants is equitable, with attention to the special problems of research that includes individuals or groups whose circumstances may make them vulnerable in the context of research;
4. free and informed consent will be sought from each prospective participant or their legally authorized representative and withdrawal procedures are appropriate;
5. Assent will be sought from each prospective participant, as appropriate.
6. informed consent (including all of the required elements for consent) will be documented;
7. Assent will be documented (written or verbal);
8. when appropriate, the research plan includes adequate provision for monitoring the data to ensure the safety of the participants;
9. when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
10. when some or all of the participants are likely to be vulnerable to coercion or undue influence as a result of their participation, additional safeguards are included to protect their rights, safety and welfare;
11. confirmation that the research will improve health and well-being and/or increase knowledge; potential, perceived and actual COI (including budget considerations) has been addressed; recruitment and retention of participants is acceptable; and the reporting of results has been considered.