

Study Title:			ENTER SCORE
PI:			
I. Experimental Treatment			
Low Risk	No experimental treatment in study	1 point	
Moderate Risk	Treatment effects documented from studies with similar and/or different populations and/or settings. No serious adverse events expected. Specific plans to monitor AE's detailed in DSMP	2 points	
High Risk	Experimental treatment. (e.g. investigational drug, device, or biologic)	4 points	
II. Procedures, Measurements, and Data Collection Methods			
Low Risk	Minimally invasive with low degree of emotional and/or physical discomfort. Probability of adverse events is low. Severity (magnitude) of adverse events is low. (Procedure may be rated low risk if probability of AE is moderate to high so long as the severity is low, as in the case of a bruise from phlebotomy) (e.g. procedures that meet IRB criteria for expedited review)	1 point	
Moderate Risk	Moderate degree of emotional and/or physical discomfort. Probability of adverse events is low. Severity of adverse events is moderate to high. (e.g. PET scan, lumbar puncture, arterial lines)	2 points	
High Risk	Moderate to high degree of emotional and/or physical discomfort. Probability of adverse events is moderate to high. Severity of adverse events is high. (e.g. heart muscle biopsy, insulin infusion)	4 points	
III. Decision-making Capability			
Non-vulnerable	Adult who 1) demonstrates decision-making capacity and 2) demonstrates no perception of undue influence or coercion to participate.	1 point	
Vulnerable	Any minor. Adult who 1) demonstrates limitations in decision-making capacity and/or 2) is prone to perception of undue influence or coercion to participate.	2 points	
Review completed by: _____ Signature: _____ Date: _____ TOTAL:			

The Level of Overall Risk of the Study is:

Low: 3 or 4 points

Moderate: 5 points

High: 6 to 10 points

Monitoring Requirements:

3-5 points: may be monitored by the PI who provides an annual review of data and safety information.

6 points: may be monitored by the PI who provides a quarterly review of data and safety information.

7-10 points: must have an independent monitor or DSMB, who conducts a regular review of data and safety information

(Risk assessment form source - University of Alberta)