Figure 1: Component Analysis

Protocol

Therapeutic procedures
  - Clinical equipoise
  - Consistent with competent care
  - Risks reasonable in relation to potential benefits

Distinguish therapeutic and non therapeutic procedures
  - Both therapeutic and non therapeutic procedure pass
    - Yes: Acceptable
    - No: Nontherapeutic procedures

Nontherapeutic procedures
  - Risks minimized consistent with sound scientific design
  - Risks reasonable in relation to knowledge to be gained
    - Yes: No more than minor increase over minimal risk
      - Yes: Acceptable
      - No: Vulnerable population?
    - No: Unacceptable