**Empirical Work:**
- Systematic review of published cluster trials
- Survey of and in-depth interviews with researchers
- Survey of REBs
- Focus group discussions and in-depth interviews with trial participants and gatekeepers

**Conceptual Work:**
- Evolving framework of ethical issues
- Ethical analysis of identified issues

Team produces a **Guidance Document** laying out principles, policy options and rationale

**Expert Panel (International membership):**
- Investigators (4)
- Bio-ethicists (4)
- Health lawyers (2)
- Consumer advocates (4)
- REB members (4)
- Low-middle income countries (2)

Expert Panel prepares **draft guidelines**

**Consensus Conference:**
- Invited representatives from national and international funding and regulatory agencies
- Journal editors
- Researchers

**E-consultation:**
Comments invited from researchers, policy makers, patient advocates, health lawyers

Expert Panel produces **final guidelines**

Team **disseminates results** to researchers, REBs, journal editors, funding agencies