Ethics Considerations Regarding Phase I Oncology Clinical Trials

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Major Issues to be Addressed

• What are the Objectives of Phase I Oncology Trials
• Barriers to Enrolling in Clinical Trials—patient and physicians' perspective
• Risk/Benefit of Participation
Phase I Oncology Trials

• **Primary Objective**: Determine an acceptable range of dose(s) & schedule(s) for a new drug
  – Determine toxicities (dose-limiting and others)
• **Secondary Objectives**: Pharmacokinetics, Pharmacodynamics and Anti-tumor Activity
• Dose based on pre-clinical exposure to ide
  – Maximum Tolerated dose
  – Maximum biological dose

• Participants have often failed other treatments but **Not** an alternative to Hospice Care
Phase I Design Strategy

• Designs often based on tradition
• Typically do some sort of dose escalation to reach targeted endpoint
• Has been shown to be safe and reasonably effective
Potential Accrual Barriers – Patients Perspective

- Awareness of trials as an option
- Understanding of what trial participation involves
- Concerns around side effects
- Education about trial phase and treatment
- Fear of distrust instead of trust in physician recommendations
- History of discrimination in medical research
- Inconvenience of trial logistics: travel, times, number of visits
- Financial burden

Masset, et al., Clin Can Res, November 2016
Barriers to Enrollment – Physician Perspective

• Concerns about potential toxicity from study treatment
• Concerns about comorbid conditions of patients
• Lack of awareness of accessible clinical trials
• Lack of access to clinical trials
• Physicians’ own perceptions about the relevance of the questions being addressed in the available trials
• Lack of time in busy practices to discuss trial options
Risks of Phase I Clinical Trials

- incremental burdens of receiving care within a trial instead of standard approaches
- risks from study drugs
- risks from research procedures for scientific purposes (i.e., biopsies)