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

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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

Massett, 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 (ie biopsies)