# THE PATH OF A CLINICAL TRIAL

Principal Investigator (PI) or sponsor has an idea.

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PI/sponsor works with co-investigators, administration, sponsor and Cancer Consortium to develop a clinical trial protocol and consent(s).

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Protocol and related material submitted for:

- Scientific review (e.g., Scientific Review Committee [SRC])
- Safety review (e.g., Institutional Biosafety Committee [IBC] or Radiation Safety Committee)
- Other peer reviews (e.g., FH Clinical Investigator Meeting)

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Protocol submitted to sponsoring institution's IRB for review and approval.

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PI determines what activities/procedures of clinical trial are standard or routine care for that disease and what portions of the clinical trial are non-routine care or solely to support study data.

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Protocol submitted to SCCA Research Implementation Office to review implementation issues:

- For clinical trials going through FHCRC/Cancer Consortium Protocol Office and IRB, we are notified by Protocol Office
- For clinical trials ging through other IRB's, this is the responsibility of the study staff

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**Clinical Trial Implementation (CTI)**

- Reviews Medical Oncology, FHCRC Public Health Sciences and other non-HSCT clinical trials (both protocol and consent form)
- SCCA Medical Director is the medical advisor to this group and reviews Investigator's determination of standard/routine care and research trial/non-routine care activities and procedures as needed
- Determines if the SCCA Clinic is equipped and staffed to conduct this research
- Identifies any gaps prior to initiation of study
- Provides pricing for research-only activity
- Group includes Nurse Managers, Operational Managers (or their designee) for laboratory services, radiology, material management, IDS pharmacy, Research Billing Specialist, Compliance Analyst and Research Implementation Coordinator
- Meetings are held the 1st and 3rd Wednesday of each month from 1-2 pm (as needed)

**Protocol Implementation Meeting (PIM)**

- Reviews HSCT related trials
- HSCT Standard Practice Chair is the medical advisor to this group and reviews Investigator's determination of standard/ routine care and research trial/non-routine care activities and procedures as needed
- Determines if the SCCA is equipped and staffed to conduct this research
- Identify and gaps prior to initiation of study
- Reviews and is the approving body for study-specific pre-printed orders
- Group includes Nurse Managers, infusion nurse, pharmacists, nutritionists, mid-level provider, Standard Practice Coordinator and Research Implementation Coordinator
- Provides pricing for research-only activity (facilitated by Research Implementation Office)
- Meetings are each Wednesday from 11:30 am -12:30 pm (as needed)

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Research Implementation Office and Research Billing Office work with study investigator and staff to determine the cost of research-related activity for development of the study budget.

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Once the clinical trial is IRB approved, all grants or contracts are signed, a study budget number is assigned, a AAA account is created and the identified implementation issues are addressed, then the study accrual begins.