NRG ONCOLOGY *Advancing Research. Improving Lives.™*	**PROTOCOL DEVELOPMENT REVIEW PROCESS & FLOW CHART** **Research Center Contacts:** Francy Fonzi fonzif@nrgoncology.org, Kia Neff neffk@nrgoncology.org, Nancy Soto soton@nrgoncology.org

Protocol development begins when the LOI/concept has been approved by both NRG Research Strategy Committee followed by the NCI (CTEP/DCP).

Role of the Protocol Administrator:

- Inserts the text from the NCI-approved LOI or concept into the current NRG protocol template
    - The NRG protocol template includes standardized language to help Chairs develop certain sections, including eligibility, study assessments, radiation therapy, and biospecimen collection.
- Circulates the study-specific protocol template to the NRG study team including all Study Chairs, Disease Site Chair, Scientific Core Committees, and NRG departments
- Edits the master protocol documents and coordinates submission and responses to CTEP/DCP/CIRB through Activation
    - Includes coordinating working calls to finalize protocol
    - Works through any protocol logistics prior to activation
    - Works with PI and NRG Communications on study promotion materials (PI toolkit), such as patient brochure and study overview slides
- Manages the NCI required timelines

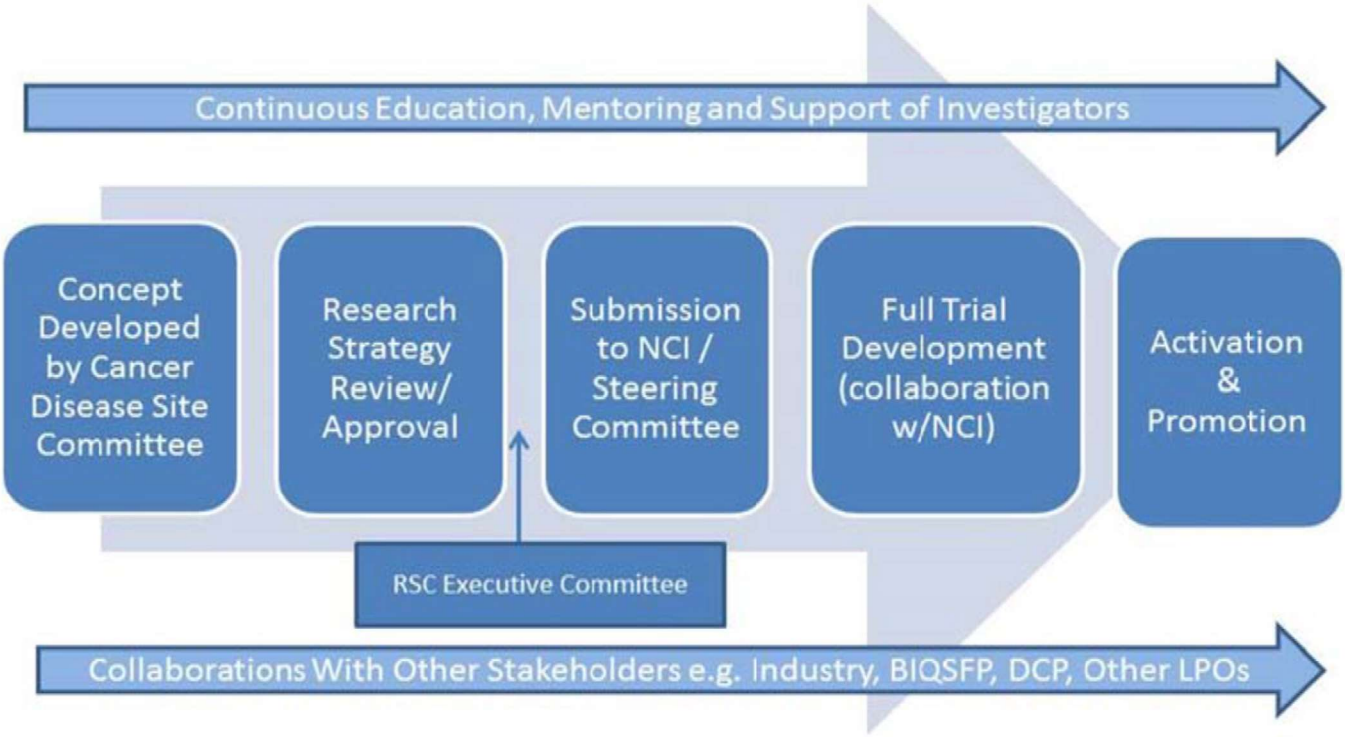
Role of the Study Chair*:

- Writes the relevant sections of the protocol (e.g., background, objectives, eligibility, treatment), including initial submissions and subsequent amendments to NCI, FDA, and industry collaborators as applicable.
- Implements promotional activities outlined in the PI toolkit.
- Proactively monitors monthly study accrual
- Reviews all adverse event and safety data
- Performs protocol-specific quality assurance modality reviews
- Assists in the analysis and write up of abstracts, manuscripts, and other forms of data presentation in a timely fashion

*Protocol development department will send Study Chair NRG Roles & Responsibilities Form outlining all protocol responsibilities; form to be signed prior to protocol submission to NCI.

See next pages for review process flow charts.

Protocol Development Overview: NRG→NCI



Overview of NCI /CTEP Timelines

Phase 1 and Early Phase 2 **LOIs**	• Absolute deadline of **400 days;**
Late Phase 2 **Concepts**	• Target of 210 days • Absolute deadline of **450 days**
Phase 3 **Concepts**	• **Target of 300 days** • Absolute deadline of **540 days**

Overview of NCI /DCP (NCORP) Timelines

Studies with concepts	• Target of 475 days • Absolute deadline of **525 days;**
Studies without concepts	• Target of 265 days • Absolute deadline of **315 days**

Meet the Protocol Development Department

Disease	Protocol Administrator (PA)
Brain, GI-Non-Colorectal, GU, H&N, Lung	Kathryn Okrent, Carol Lam, Nu Do, Jen Petrask, **Nancy Soto**
Breast, GI-Colorectal	Hope Alcorn, **Francy Fonzi**
GYN: Cervix, Uterine Corpus, Ovary, Developmental Therapeutics, Rare Tumor	Meg Colahan, Leah Madden, Kathryn Miller, Nicole Copeland, **Kia Neff**
NCORP trials are developed within the respective disease site	NCORP Administrator **Erica Field**