



Clinical Trial Review Guide

Developed by the SWOG ORP Liaison Committee

*Comprehensive
Feasibility, Learning and Implementation
Tool*

**SWOG Spring Conference 2017
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Objectives

Overview of the Development and Purpose of the Clinical Trial Guide (Guide)

Overview and Use of the Guide

Proposed Project Assessing Utility and Effectiveness of the Guide at SWOG Research Sites

Oncology Research Professionals Liaison Committee

- RN and CRA Members of each Disease Committee
- Review new protocols during development and provide feedback from a research site perspective.
 - Addressing feasibility and concerns regarding potential logistical challenges with implementation.
- Participate in the development of tools to assist research sites with study selection, implementation and compliance.
- Maintain active lines of communication with SWOG Protocol Coordinators
- Ongoing review and revisions to the CRA disease chapters.
- Mentor and support the development of new disease liaisons.



Review Guide Development

SWOG
Oncology Research Professional
Liaison Committee

SWOG Protocol Coordinators

Pharmacy Liaison

Coverage Analysis Developer

Clinical Trial Review Guide Purpose



Diagram featured by <http://slidemodel.com>



How to use the Review “Guide”

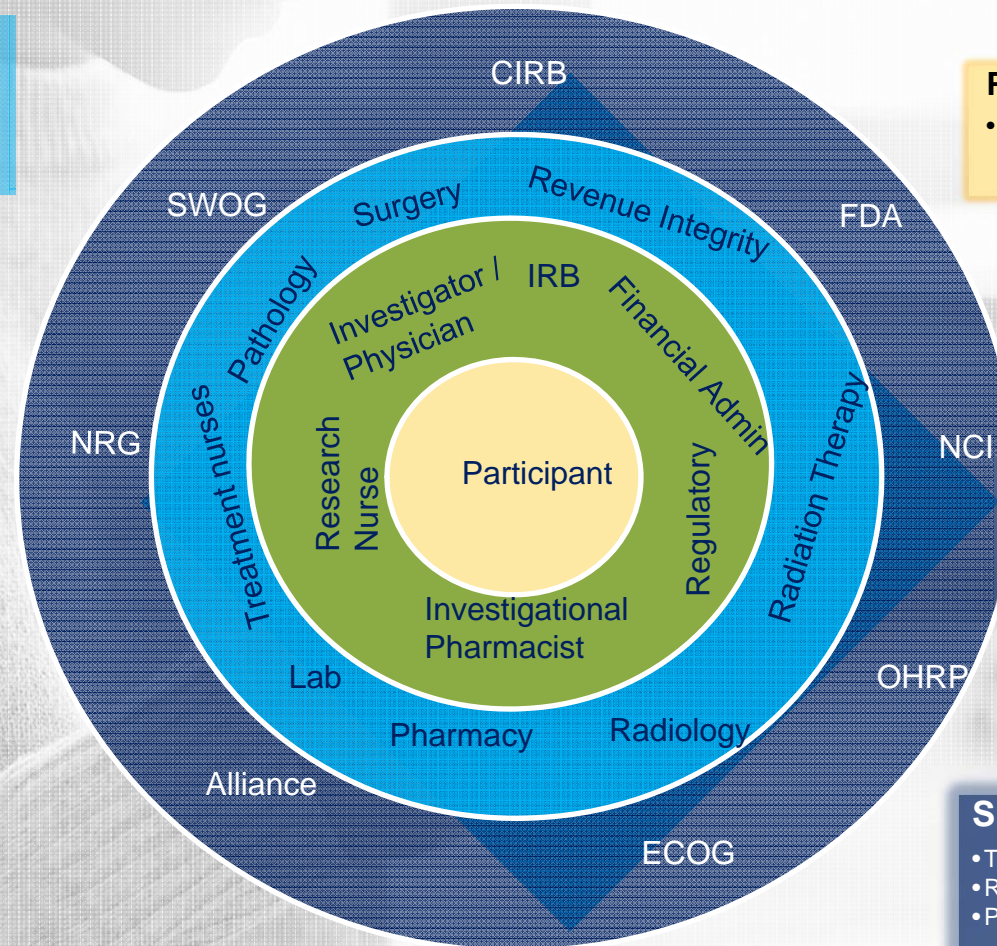
Clinical Trial Protocol
Consent
Training Materials
Funding Memo
Local and National Coverage Analysis

Who Should Use the Review Guide?



[Guide](#)

Integrative Approach



Participant

- Human Subjects Protection Safeguards

Study Team

- Right Study – Right Research Site
- Improved Knowledge of the Trial
- Facilitate Interdisciplinary Collaboration
- Facilitate Implementation plan
- Improved Compliance

Clinical Team

- Improved Research Integration
- Patient Care Outcomes
- Improved Site Operational Outcomes
- Research Billing Compliance

Sponsor

- Timely Study Activation
- Research Compliance & Quality
- Potential Increased Accruals



**More Thorough Review + Experienced Research Staff =
Efficient Implementation + Improved Compliance + Potential Increased
Accruals**



SWOG ORP Liaison Committee Project

Clinical Trial Review Guide: IMPACT on research site

The purpose of this study is to assess the utility and effectiveness of the “Guide” which was developed for cancer research sites to facilitate self-learning, problem solving, and assimilating knowledge into practice.



Objectives

Primary

- To determine the effectiveness of the Guide in assisting cancer research sites with clinical trial selection.
- To determine the effectiveness of the Guide in facilitating self-learning of the clinical trial.
- To determine the effectiveness of the Guide in developing a plan to implement a clinical trial.

Secondary

- To determine the likelihood participants will use the Guide for future studies.
- To determine if a correlation exists between the user and site characteristics and the user's review of the Guide.

Study Participants:

Study Coordinators and Site Managers with varying levels of education, experience, roles and responsibilities from NCI NCTN Group Cancer Research Sites

Self – Reported Demographics: Site Role, Level Education, Certification, Research Experience and Type of Research Site

Pre- Guide Usage Survey

Complete a survey to determine participants level of knowledge and level of preparedness with implementing a **study they reviewed in the past 2 months but not yet implemented**

Note: Refrain from re-reviewing the clinical trial until the Guide is used.

1 week after
1st Survey

Post - Guide Usage Survey

After completion of using the “Guide” on the same study, complete a survey to determine the participants level of knowledge and preparedness with implementing the clinical trial at their site.

Additional Survey Questions

Impact on Study Selection
Future Use of Guide
Interest in Participating in future related studies

The background of the slide is a grayscale photograph of a desk. In the center is a spiral-bound notebook with a pen resting on it. To the right, there is a pill tray containing several white, round pills. In the bottom left corner, a white computer mouse is visible. Overlaid on this background are two semi-transparent blue rectangular boxes containing text.

Potential Future Related Projects

Follow up with sites in 6- 12 months to evaluate

- **Impact**
- **Usage**
- **Benefits**

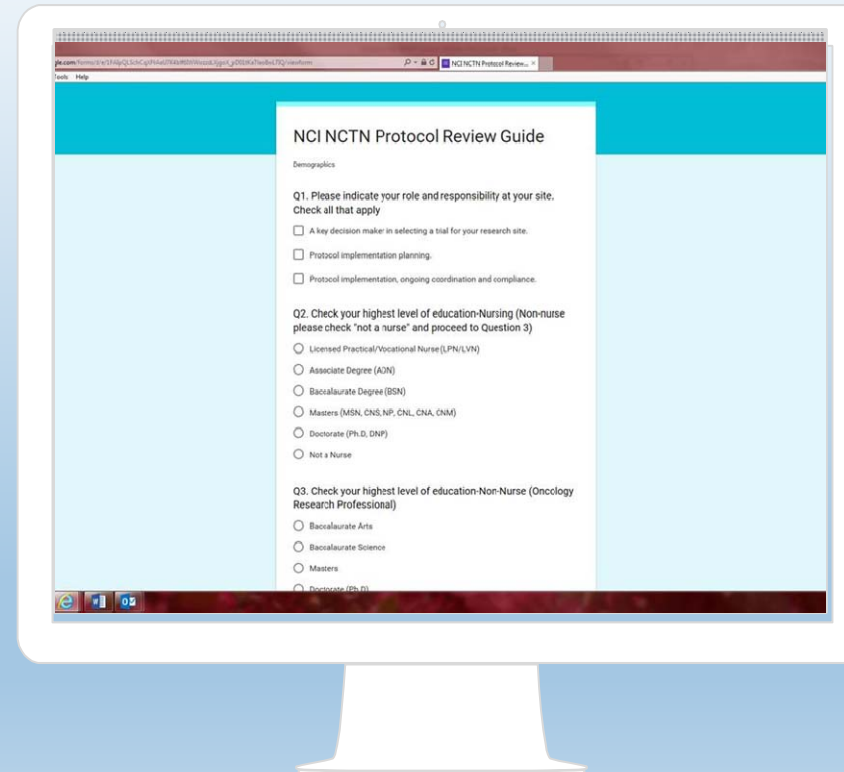
Next Steps

**Questions????
Interested in Participating
in this Study?**



**Stop By the “Clinical Trial
Review Guide” Open
Forum Table**

***Site Recruitment Plans
are in progress !!
Look for more
information from SWOG***



Thank You!!

ORP Liaison Committee

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Any questions?

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