Before beginning the field review, please take time to review this document. It includes definitions, functional category descriptions, knowledge requirements, competency statements and resources. You will be asked in the survey to evaluate all of these.

NOTE: You do not have to complete this survey in one sitting. You can exit the survey and return later to complete it.

Survey instructions:
A team of ONS members who work in clinical trials are reviewing and updating the Clinical Trials Nursing Competencies. Based upon an updated review of the literature and personal experience, the team has revamped the competencies. The main changes include:

- Inclusion of new functional areas which subsume some previous categorizations
- Separation of required knowledge from skills and behaviors
- Addition of recommended resources to aid in knowledge and competency development
- Addition of a more advanced level of competencies for those with more experience or who are functioning at a higher level than the novice CTN

Definitions:

- Oncology clinical trials nurse core competencies include the fundamental knowledge, skills and expertise required to proficiently: a) care for participants in clinical trials with a past, current, or potential diagnosis of cancer, b) manage oncology clinical trials in diverse settings, c) ensure protection of subjects enrolled in clinical trials, and d) assure that scientific integrity is maintained through data reliability.
- Level 1 competencies: The knowledge, skill and behaviors that reflect what someone with less than 2 years of experience as an oncology CTN should be able to achieve. These competencies should apply across most settings where clinical trials occur.
- Level 2 competencies: The knowledge, skill and behaviors that reflect what someone with more than 2 years of experience as an oncology CTN should be able to achieve. This assumes competence at level 1 has been reached. Achievement of this level may take more than 2 years to achieve depending upon the CTN's opportunities provided in the work environment and commitment to professional development.
## Protocol Compliance
The oncology clinical trials nurse facilitates compliance with the requirements of the research protocol and good clinical research practice while remaining cognizant of the needs of diverse patient populations.

<table>
<thead>
<tr>
<th>Knowledge Required</th>
<th>Level 1 Skills and Behaviors</th>
<th>Level 2 Skills and Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical trial study designs</td>
<td>• Identifies patient care needs in the context of study design.</td>
<td>• Assists in developing institutional clinical research SOPs.</td>
</tr>
<tr>
<td>• Federal and state clinical research regulations</td>
<td>• Adheres to applicable federal, state, and institutional regulations, policies, and procedures related to clinical research.</td>
<td>• Develops, implements, and assesses process improvement strategies for compliance with applicable regulations and SOPs.</td>
</tr>
<tr>
<td>• Good Clinical Practice (GCP)</td>
<td>• Complies with processes and procedures required by different types of sponsors (e.g., private industry, federally-sponsored research including National Cancer Institute, investigator-sponsor).</td>
<td>• Develops and implements nursing feasibility review process to assist in determination of protocol implementation.</td>
</tr>
<tr>
<td>• International Air Transport Association requirements for shipping and receiving biological specimens</td>
<td>• Participates in discussions regarding feasibility of protocol implementation.</td>
<td></td>
</tr>
<tr>
<td>• Institutional Policies and procedures for human subject protection and clinical research</td>
<td>• Identifies and develops methods to overcome institutional and external barriers to protocol compliance</td>
<td></td>
</tr>
<tr>
<td>• Confidentiality</td>
<td>• Identifies the institutional review board (IRB) of record for each protocol and adheres to IRB policies including preferred method of contact.</td>
<td></td>
</tr>
<tr>
<td>• Institutional policies for shipping and receiving experimental agents</td>
<td>• Participates in providing</td>
<td></td>
</tr>
<tr>
<td>• Institutional policies related to protocol feasibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• FDA and NIH requirements related to registration and results reporting for clinical trials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Unanticipated problem reporting requirements to sponsor and IRB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Developing a Corrective and Preventative Action (CAPA Plan)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Drug development process</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Resources
- **FDA Regulations**: 21 CFR Parts 11, 50, 54, 56, 312, 812
- **FDA Guidances**
- **ICH GCP Guidelines**
- **OHRP Regulations**:
  - 45 CFR Part 46
- **OHRP Guidances**
- **OHRP YouTube videos**:
  - *Research Use of Human Biological Specimens and Other Private Information*
  - *Reviewing and Reporting Unanticipated Problems and Adverse Event*
  - *Institutional Review Board (IRB) Membership*
  - *IRB Records*
  - *IRB Records II*
- **ONS Manual for Clinical Trial Nursing** - 3rd edition, Chapter 2, 8, 9, 10, 11, 16, 40, and 41

**timely, informative, and accurate communication to the IRB.**
- Facilitates and participates in the preparation for and conduct of meetings with sponsors, monitors, and auditors.
- Provides timely, accurate, and complete reporting of adverse events, unanticipated problems, deviations, violations, and non-compliance to the IRB and sponsor.
- Assists in developing CAPA plans for UPs, deviations, violations and issues of non-compliance.
- Recognizes the role and responsibilities of research team members in different settings including the role of the patient
- Collaborates with principal investigator, pharmacy, and other appropriate personnel to ensure proper use of and accountability for experimental drugs or devices.

**Informed Consent**
The oncology clinical trials nurse demonstrates leadership in ensuring patient comprehension and safety during initial and ongoing clinical trial informed consent discussions.

<table>
<thead>
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<tbody>
<tr>
<td>Historical perspective of ethical research and informed consent</td>
<td>Assesses for psycho-social (e.g. literacy, capacity, language, distress) barriers to effective informed consent discussions.</td>
<td>Develops, implements, and evaluates plans to overcome psycho-social barriers to effective informed consent discussions.</td>
</tr>
<tr>
<td>IC Regulations &amp; Guidance documents including IC for non-English speaking subjects and vulnerable populations</td>
<td>Ensures the initial and ongoing consent process is performed and documented.</td>
<td>Develops and enacts comprehensive process to assure compliance with re-consenting needs.</td>
</tr>
<tr>
<td>Elements of an IC document</td>
<td>Assesses ongoing consent through discussions with patients and</td>
<td></td>
</tr>
<tr>
<td>IC Regulations and Guidance documents for assent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- Elements of an assent document

reinforcement of education.
- Describes and abides by institutional policy and process for informed consent.
- Recognizes need for re-consenting and ensures completion.
- Demonstrates understanding of tiered consent process when optional correlative studies (e.g. bio specimen, QoL, PRO collections) are involved.

- Recognizes and collaborates with PI to utilize appropriate consent format.
- Assures compliance with consent for correlative studies by tracking patient’s wishes related to collection of associated specimens/data.

**Resources**

- FDA Regulations:
  - 21 CFR Part 50
- FDA Guidances and other documents
  - Information Sheet
  - Use of Electronic Consent
- ICH GCP Guidelines - Section 4.8
- OHRP Regulations:
  - 45 CFR Part 46
- OHRP Guidance and other documents
- OHRP YouTube video: General Informed Consent Requirements
- ONS Manual for Clinical Trial Nursing – 3rd edition, Chapter 14
- The Belmont Report

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**Management of Clinical Trial Patients**

The oncology clinical trials nurse uses a variety of resources and strategies to manage the care of patients participating in clinical trials, ensuring compliance with protocol procedures, assessments, and reporting requirements as well as management of symptoms.

**Knowledge Required**

- Oncology disease process including; biology, staging, treatment & symptom management.
- The Research Protocol: Organization & Contents
- Common Terminology Criteria for Adverse Events (CTCAE )
- Response Evaluation Criteria in Solid Tumors (RECIST)
- Resources available to the oncology patient (e.g. psychosocial & financial)

**Level 1 Skills and Behaviors**

- Collaborates with the investigator to ascertain study patient eligibility for a clinical trial, including documentation of criteria specified in the protocol.
- Coordinates & schedules protocol required events and other requirements (e.g pharmacokinetic/dynamics, scans, study visits, quality of life, and patient reported outcomes).

**Level 2 Skills and Behaviors**

- Assesses for and addresses factors that affect patient adherence to protocol specific activities.
- Addresses factors that affect the assessment of adverse events and disease response to protocol treatment, (e.g. patient financial constraints, child or elder care needs, transportation,
- Common Toxicity Criteria for Adverse Events
- CTEP-AERs
- NCCN Guidelines
- NCI
- ONS CTN SIG toolkit – Patient Management
- ONS PEP: Evidence based symptom management
- ONS Manual for Clinical Trial Nursing – 3rd edition, Chapters 10, 15, and 28
- RECIST Criteria
  - Article 1
  - Article 2
- Slides: Clinical Trial Protocol Development
- Tip sheet: Processing & shipping of specimens
- Liz check accuralnet
- Workload assessments: AccrualNet™ – search workload

- Educates the patient and family regarding protocol participation, clinical condition and/or disease process.
- Evaluates patient’s adherence to and documentation of self-administered protocol agents and the return of such agents.
- Utilizes appropriate interventions and communication techniques to promote patients adherence with protocol compliance.
- Assess adverse events & ensures evidenced-based symptom management within the context of the protocol.
- Utilizes clinical judgment in collaboration with investigator to determine disease response, if a dose-limiting toxicity has occurred, and/or if any treatment schedule or drug dose modifications are necessary and communicates findings to the study team and other care providers.
- Assesses patients for physical, psychosocial and financial factors that could interfere with adherence with study requirements & implement interventions as necessary.
- Identifies patients who require increased nursing assessment and management in addition to the clinical trial requirements and employment.
- Ensures for protocol clarity in treatment modification guidelines.
- Develops study specific materials for patient education.
- Develops, implements, and assesses necessary interventions to address issues related to the patient population on a clinical trial.
- Facilitates accurate communication between research sites.
- Provides guidance to participating sites related to patient management per protocol requirements.
- Assesses for and addresses changes that increase the acuity of assigned protocols and that adversely affect protocol management abilities.
- Collaborates with the interdisciplinary team to develop novel nursing practices that have the potential to improve patient outcomes.
- Implement workload assessment processes to ensure patient safety and data integrity.
collaborate with other members of the health care team to ensure patient safety.
- Identifies workload assessment tools and how they can be used to ensure patient safety and data integrity

**Documentation and Document Management**
The oncology clinical trials nurse provides leadership to the research team in ensuring accurate source documentation and maintaining essential documents that validate the integrity of the conduct of the clinical trial.

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<tr>
<td>• State practice act</td>
<td>• Documents all patient encounters in the legal medical record per licensure &amp; institutional requirements.</td>
<td>• Implement a plan to address identified trends related to non-compliance or deficiencies with source documents.</td>
</tr>
<tr>
<td>• ANA Standards of Practice</td>
<td>• Educates other research team members and clinical staff regarding appropriate and accurate source documentation for participants in clinical trials.</td>
<td>• Participates in the development of approved source documents templates or forms.</td>
</tr>
</tbody>
</table>
| • Definitions:  
  o Source document  
  o Essential documents | • Assesses documentation for discrepancies and ensures inaccurate or discrepant documentation is addressed in the medical record or other source documents. | • Participates in the preparation of reports for appropriate regulatory and monitoring bodies or boards. |
| • Contents of a regulatory file/binder | • Maintains patient’s source documents privacy and confidentiality. | • As coordinating center for multi-site clinical trial, ensures effective coordination of essential documents for participating sites. |
| • Basic understanding of electronic data capture & EMR | • Maintains essential documents in a regulatory file or binder per GCP guidelines. |

**Resources**
- ANA Standards of Practice
- ICH GCP guidelines, specifically glossary and Section 8
- ONS CTN SIG Documentation toolkit
- ONS Manual for Clinical Trials Nursing – 3rd edition, Chapter 37 and 39

**Data Management and Information Technology**
The oncology clinical trials nurse provides leadership in the collection of data and demonstrates basic information technology and computer skills to ensure data quality and patient confidentiality.

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• Understand definitions:
  o Data Management Plan (DMP)
  o Clinical Data Management System (CDMS)
  o Clinical Trial Management System (CTMS)
  o Remote Data Capture (RDC)
  o Quality control (QC)
  o Quality assurance (QA)
  o Quality improvement (QI)
• Basic computer skills:
  o Word processing applications
  o Spreadsheet applications
  o Use of local Electronic Medical Record (EMR)
• Sponsor specific remote data capture systems
• Case report form (CRF) development

• Understands the components of and adheres to the data management plan developed for each clinical trial.
• Understands the purpose of case report forms and their relationship to the protocol.
• Understands how case report forms are developed both paper and electronic.
• Assists in troubleshooting with data entry issues whether CRF is paper or electronic.
• Ensures that relevant data from source documents are abstracted and recorded on the protocol specific case report forms.
• Ensures that all data recorded on case report forms can be verified within the source documents.
• Follows appropriate guidelines in making corrections to data entry on case report forms.
• Participates in quality control activities to ensure data integrity including timely responses to database or sponsor queries.
• Understands basic information management and computer technology skills.
• Demonstrates proficiency in the use of local electronic medical record (EMR).

Resources

• FDA Regulations:
  o 21 CFR Part 11
• FDA Guidance:
  o Part 11 Electronic Signatures and Documents
• Data Management course
• ICH GCP Guidelines
• Nursing Informatics Competencies User self-assessment
• ONS Manual for Clinical Trials Nursing – 3rd edition, Chapter 38

• Assists PI in developing data management plans for each clinical trial.
• Develops quality improvement plans to ensure data integrity.
• Uses information management and computer technology to support clinical data management activities.
• Assists in developing case report forms for multi-site trials if coordinating center.
- Demonstrates proficiency with basic computer skills including word processing and spreadsheets.
- Demonstrates proficiency with electronic data management systems.
- Protects patient, protocol, and scientific confidentiality by ensuring security of research data and personal health information.

**Ethical Issues**
The oncology clinical trials nurse demonstrates leadership in ensuring adherence to ethical practices during the conduct of clinical trials in order to protect the rights and well-being of patients and the collection of quality data.

<table>
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<tbody>
<tr>
<td>• ANA Scope and Standards&lt;br&gt;• ANA Code of Ethics&lt;br&gt;• Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice&lt;br&gt;• The Belmont Report&lt;br&gt;• Research integrity definition&lt;br&gt;• Research misconduct definition</td>
<td>• Performs clinical trials duties in accordance with standards of nursing practice and the Code of Ethics.&lt;br&gt;• Promotes ongoing compliance with the key ethical concepts of respect for persons, beneficence, and justice.&lt;br&gt;• Ensures that members of vulnerable and other special needs populations enrolled in clinical trials are identified and that their rights are addressed.&lt;br&gt;• Identifies and follows federal and institutional requirements for research misconduct reporting.&lt;br&gt;• Maintains awareness of what constitutes falsification of data or other research misconduct.</td>
<td>• Continuously assesses and reports situations that can lead to research misconduct.&lt;br&gt;• Work with PI and/or research program to develop and implement interventions to provide education about misconduct in order to mitigate risk.&lt;br&gt;• Work with PI and/or research program to develop and reinforce a Just Culture to facilitate compliance with reporting misconduct.</td>
</tr>
</tbody>
</table>

**Resources**
- ANA Professional Practice Standards
- ANA Code of Ethics
- FDA Regulations:  
  - Financial Disclosure of Clinical Investigators
- FDA Guidance:  
  - Financial Disclosure of Clinical Investigators
- HHS Office of Research Integrity
- OHRP YouTube video: Research Involving Vulnerable Subjects
- ONS Manual for Clinical Trials Nursing – 3rd edition, Chapter 12
- Statement on the Scope and
Standards of Oncology Nursing Practice: Generalist and Advanced Practice
- The Belmont Report

- Understands conflict of interest (COI) regulations and institution-specific policies.

Patient Recruitment and Retention
The oncology clinical trials nurse utilizes a variety of strategies to enhance recruitment and retention while being mindful of the needs of diverse patient populations.

<table>
<thead>
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</thead>
</table>
| • Barriers effecting recruitment and retention to clinical trials such as:  
  o demographic factors  
  o underserved populations  
  o institutional and healthcare and insurance system influences  
• Components of a recruitment and retention plan  
• Clinical trials registries  
• Targeted therapy impact on screening/recruitment  
• Cultural impact on recruitment and retention  
• CTN responsibilities in recruitment and retention | • Identifies barriers to recruitment and retention  
• Work with individual patients to address barriers to recruitment and retention  
• Applies recruitment strategies to ensure timely accrual.  
• Follows protocol-specific recruitment and retention plan, if available  
• Identifies institutional or community-based resources or groups that can assist in achieving recruitment goals. | • Identify trends and challenges in recruitment and retention  
• Develops, implements, and assesses interventions to overcome identified recruitment and retention trends and challenges.  
• Develops a recruitment and retention plan  
• Assists the Principal Investigator in the effective coordination of recruitment and retention efforts. |

Resources
- **Center for Information and Study on Clinical Research Participation (CISCRP)**
- **AccrualNet™**
- **Five Steps to Enhance Patient Participation in Clinical Trials – Guide and Workbook**
- **ONS Manual for Clinical Trial Nursing – Section IV**

- Develops relationships with referring physicians, clinical staff, and ancillary departments to facilitate compliance with recruitment and retention to clinical trials
- Evaluates and determines resources required to implement recruitment & retention plan
- Consistently recognizes physician investigators and research staff for recruitment and retention efforts.

### Financial Implications
The oncology clinical trials nurse identifies the financial variables that affect research and supports good financial stewardship in clinical trials.

#### Knowledge Required

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>- Identifies their organization’s key players for clinical trial billing compliance and what the CTN’s role is within the institution.</td>
<td>- Assist the Principal Investigator and/or finance personnel in determining when protocol requirements or revisions will affect the cost of protocol management.</td>
</tr>
<tr>
<td>- Describes the key components included in study budgets and institutional resources for budget details</td>
<td>- Assists in the assessment and/or development of the coverage analysis and has the ability to determine “qualified” clinical trial status.</td>
</tr>
<tr>
<td>- Analyzes a protocol to identify routine care versus research-related costs and how each is being covered.</td>
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</tr>
<tr>
<td>- Evaluates the financial impact of study requirements on individual patients and their ability to meet these financial obligations.</td>
<td></td>
</tr>
<tr>
<td>- Reports protocol-specific insurance coverage issues to lead study organization for possible consideration of protocol amendment.</td>
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</tr>
<tr>
<td>- Verifies routine care</td>
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</tr>
</tbody>
</table>

#### Resources

- Medicare Benefit Policy Manual, Ch. 14
- National Coverage Determination (NCD) for Routine Costs in Clinical Trials 310.1 Clinical Trial Policy (CTP)
- Patient Protection and Affordable Care Act
- Health Care Reform and Education Act
- **Training Manual for Clinical Trials Billing Compliance**
- **ONS Manual for Clinical Trial Nursing – Section III**
- **ONS CTN SIG Financial Implications Toolkit**
versus research-related costs descriptions in protocol document match the consent document and vice versa.

- Assists with appeal process when payer declines coverage for patients on clinical trial.
- Works with institutional financial resources and/or pharmaceutical company to identify methods for helping patients who are not able to meet financial obligations when on a study.
- Ensures and tracks submission of specified items (e.g., completed case report forms, specimens) to facilitate timely recovery of protocol-related activity costs.
- Ensures that the informed consent document identifies that stipends to patients for protocol-related activities are disclosed.

Leadership and Professional Development

The oncology clinical trials nurse utilizes leadership skills to inspire and motivate the clinical research team towards the common goal of conducting quality clinical research to enhance cancer care across the continuum and takes responsibility for his or her ongoing professional development.

<table>
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</thead>
<tbody>
<tr>
<td>• ANA Professional Practice Standards</td>
<td>• Demonstrates the ability to develop, evaluate, and revise own professional goals.</td>
<td>• Pursues opportunities to participate in local/national research-related activities (e.g., professional nursing and/or research organizations, institutional committees).</td>
</tr>
<tr>
<td>• Understanding of an organizations culture, vision and mission.</td>
<td>• Participates in educational opportunities to increase knowledge</td>
<td></td>
</tr>
<tr>
<td>• Team leadership</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Qualities of an effective leader</td>
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</tr>
</tbody>
</table>

Resources
• ANA Professional Practice Standards
• Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice
• ONS Leadership competencies
• ONS Manual for Clinical Trials Nursing – Section X
• Professional Journals (e.g., Journal of Nursing Management, The Monitor, SoCRA Source, Oncology Nursing Forum, CJON)
• ANA Leadership Institute
• Nursing Times Leadership Skills for Nurses

about clinical trials, best practices, regulations and guidance, the role of the CTN and leadership skills. Document and track as per institution requirements.
• Seeks resources on an ongoing basis that provide oncology treatment and nursing practice updates.
• Demonstrates the ability to skillfully and accurately communicate and collaborate with research team members and others involved in clinical research.
• Disseminates information about the impact of new treatments on cancer care and nursing practice.
• Participates in development of publications related to clinical trials with focus on patient management and impact on current or future nursing practice.
• Provides mentorship to new clinical trials nurses, research team members and other healthcare providers.
• Defines the role of the CTN at an institute by developing tools (e.g., job descriptions, competency assessment which delineates CTN responsibilities).
• Demonstrates the ability to inspire and motivate CTNs and others involved in clinical research.
• Advocates for clinical trials by participating in community outreach efforts to provide general clinical trials education when opportunities arise.