

# Optimal Resources for Cancer Care 2020 Standards Webinars

Effective January 1, 2020

Review all information in the manual

- Address changes to Accreditation process
- New terms defined in glossary
- Specifications by category

Access the 2020 Standards and Resources page for more information on the standards and upcoming activities

<https://www.facs.org/quality-programs/cancer/coc/standards/2020>

9

# Research



- **Clinical research**
  - Advances science
  - Assists with ensuring that patient care approaches the highest possible level of quality



# 9.1 – Clinical Research Accrual

## Scope of the Standard

- As prescribed for cancer program category, **the required percentage of subjects is accrued to eligible cancer-related clinical research studies each calendar year**
- Clinical Research Coordinator reports to the cancer committee
  - Clinical research information
  - Annual enrollment in clinical research studies
- **Establish a screening policy and procedure**
  - Identify participant eligibility for clinical research studies
  - How to provide clinical research information to subjects
- Through the Clinical Research Coordinator, the cancer committee evaluates and assesses the eligibility and screening processes **to identify and address barriers** to enrollment and participation



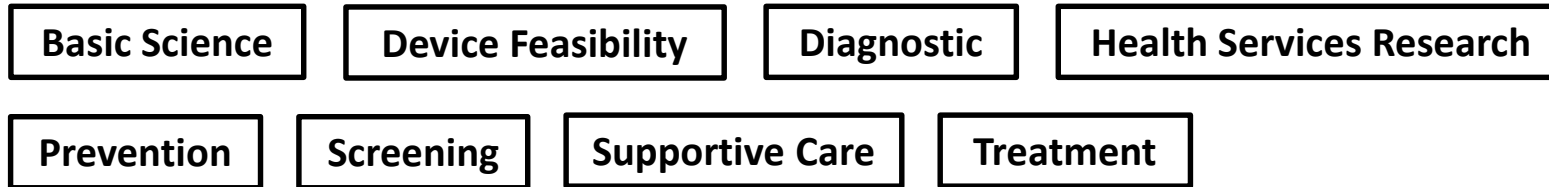
## Scope of the Standard

- Research studies eligible to count as accruals must:
  1. **Be cancer-related**
  2. **Be approved by an internal or external Institutional Review Board (IRB)** that is responsible for the review and oversight of the research study
  3. **Have informed, written patient/subject consent** (unless consent is waived by the IRB)

# 9.1 – Clinical Research Accrual

## Scope of the Standard

- Categories of cancer-related clinical research studies eligible for accrual:





## Scope of the Standard

- Additional categories of cancer-related clinical research studies for accrual are:
  - **Cancer-specific biorepositories or tissue banks**
  - **Economics of care** related to cancer care
  - **Genetic studies**
  - **Patient registries** with an underlying cancer research focus

- **Clinical Research Accrual** exception:
  - Humanitarian Use Devices studies cannot be counted as an accrual under this standard



# 9.1 – Clinical Research Accrual

How is compliance calculated?

- The denominator is the **number of annual analytic cases**
- The numerator is the **number of subjects enrolled in eligible research studies** who were:
  - Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within your program or facility
  - Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within a staff physician's office of your program or facility
  - Diagnosed and/or treated at the program or facility, then referred by your program or facility for enrollment onto a cancer-related clinical research study through another program or facility, or
  - Referred to your program or facility for enrollment onto a cancer-related clinical research study through another program or facility



# 9.1 – Clinical Research Accrual

- Important notes for counting accruals:
  - If a subject is enrolled in two different trials/studies, then **the subject may be counted in the numerator twice**
  - However, it qualifies as one accrual if one subject is enrolled into two arms of one protocol or one subject is enrolled into a sub-study of one protocol



# 9.1 – Clinical Research Accrual

Category	Percentage Requirement
ACAD	6
CCCP	4
CCP	2
FCCP	2
HACP	Exempt
INCP	6
NCIP	20
PCP	30
VACP	2



## Scope of the Standard

- The Clinical Research Coordinator tracks and reports to the cancer committee:
  - The **specific clinical research studies** where subjects were accrued, including the trial/study name and, when applicable, the clinicaltrial.gov trial number
  - **Number of subjects accrued**
  - **Open clinical research studies**
  - **New trials**
  - If the required accrual percentage is not met, **the report identifies contributing factors and identifies an action plan** to address those factors

# 9.1 – Clinical Research Accrual

- On-site documentation reviewed by site visit reviewer
  - **Tracking documents** that detail the number of subjects accrued to specific clinical research studies
- **Pre-Review Questionnaire (PRQ) documentation:**
  - **Cancer committee minutes**
  - **Policy and procedure**



## Compliance

1. The program has a screening **policy and procedure** to identify participant eligibility for clinical research studies and how to provide clinical trial information to subjects. These processes are assessed to identify and address barriers to enrollment and participation
2. The **number of accruals** to cancer-related clinical research studies meets or exceeds the required percentage
3. The Clinical Research Coordinator **reports all required information to the cancer committee** and the report is documented in the cancer committee minutes





## 9.2 – CoC Special Studies

- Hypothesis-based special studies are designed to **evaluate patient care, set benchmarks, and provide feedback** to improve patient care in cancer programs
- The Commission on Cancer (CoC) will periodically **design and conduct special studies**
- Based on study criteria, selected accredited programs will be required to participate in each study for standard compliance
- The cases included in the study and due date will be specified in the study documentation provided by the CoC. To fulfill the standard, **all selected programs must submit all requested information for the cases identified by the specified deadline**

## 9.2 – CoC Special Studies

- The program uploads all required documentation or data as required for the special study

