

## Frequently Asked Questions on the 2020 Optimal Resources for Cancer Care Standards Chapter 9: Research

### Standard 9.1: Clinical Research Accrual

**ACR Lung Cancer Screening Registry; because this registry is collecting cancer screening and progression of disease information, can we still use this in our calculations?**

Because this database collects information with no guarantee that it will be used in cancer research or lead to clinical scenarios that evaluate one form of care versus another, it does not qualify for accrual for CoC Standard 9.1. However, a clinical research study that utilizes information from these types of databases through an Institutional Review Board (IRB) mechanism can be used for accruals in Standard 9.1 (with signed consent).

**The patient that is enrolled in a prevention or screening program does not have to have been diagnosed with cancer to qualify, correct?**

That is correct.

**If a facility has a biorepository and specimens are waiting to be used for studies, can these patients be counted towards accrual?**

Yes. Patients who have their pathological specimens sent to a biorepository with the intent of using that tissue to do cancer research may be counted towards accrual. The process would require the patient signing a consent for the tissue to be used and an IRB would need to approve the program.

**Is it okay to use the previous year's analytic caseload for this denominator?**

You should be using the current year's caseload with the current year's accruals. If the caseload is incomplete, it is recommended that you use the previous year and add 10% to be safe. You will still need to make sure you meet the required accrual percentage as compared to the correct year's analytic caseload.

**If the patient is referred for consideration of a clinical trial but not eligible for one or none are available at time of visit, do these count in our numbers?**

No, the patient must be enrolled in the clinical research study.

**If a trial is available, but patient refuses because of distance to travel for CT, does this count?**

No, the patient must be enrolled in the clinical research study.

**Which registries do NOT count for accrual for Standard 9.1?**

- Lung Cancer CT Database (ACR)
- National Mammography Database
- Society of Thoracic Surgeons (STS) on lung and esophageal resections
- American College of Surgeons COVID-19 Registry
- American Society of Clinical Oncology (ASCO) COVID-19 Registry
- American Society of Breast Surgeons (ASBrS) COVID-19 Registry
- COVID-19 and Cancer Consortium
- COIDSurg-Cancer
- ASH RC COVID-19 Registry for Hematologic Malignancy

**Please provide an example of a registry study that would be acceptable to count towards clinical trial accrual.**

The intent of the Commission on Cancer's Standard 9.1: Clinical Research Accrual is to increase accruals to and availability of clinical research because of its critical role in advancing knowledge in cancer medicine. Accruals to a clinical research study or clinical trial are eligible for Standard 9.1 if the study/trial:

- Is cancer related
- Is approved by an internal or external Institutional Review Board (IRB)
- Has informed, written patient/subject consent (unless consent is waived by the IRB)

Patient registries, including COVID-19 registries, with an underlying cancer research focus may be appropriate for accrual for CoC Standard 9.1 in some cases.

**Does the report to the committee by the research coordinator also require information on barriers identified and steps to address the barrier?**

Yes, if the required accrual percentage is not met, the report identifies contributing factors and identifies an action plan to address those factors.