Policy Name: Authorization of Institutions to Register Patients	Policy Number: 7.1
Section: Patient Registration – 7	Date Revised: December 16, 2024

7   Patient registration

All Alliance institutions are allowed to register patients to Alliance and other trials, unless otherwise indicated (i.e., limited access studies), posted on the Cancer Trials Support Unit (CTSU) menu.

7.1   Authorization of institutions to register patients

Institutions intending to register patients must have IRB approval for the study. IRB approval documentation must be submitted to CTSU for entry into Regulatory Support System (RSS), prior to enrollment of the first patient. Submission instructions are available on the Regulatory page of the CTSU website.

Compassionate (expedited, emergency) approval, in which an institution wants immediate approval to put a patient on a treatment study not yet approved by its IRB, is not allowed. The IRB must give full-board approval before patients may be registered on a treatment study. Select non-treatment studies, such as laboratory or survey studies that present minimal risk to participants, may qualify for expedited review, which is noted at the time of protocol activation.

7.1.1   Limited access studies

Some studies may limit access to a subset of institutions, for quality assurance or other reasons (e.g., phase 1 studies). Participating sites in limited access studies will be identified in CTSU RSS.

Policy Name: Authorization of Site Personnel to Register Patients	**Policy Number:** 7.2
Section: Patient Registration – 7	**Date Revised:** December 16, 2024

7.2   Authorization of site personnel to register patients

All Alliance studies will use the Oncology Patient Enrollment Network (OPEN) online registration system (https://open.ctsu.org) maintained by the CTSU except where otherwise indicated in the protocol. Site personnel who register patients on NCTN trials must be registered with the Cancer Therapy Evaluation Program (CTEP) via the NCI Registration and Credential Repository (RCR) and have a valid and active CTEP Identity and Access Management (IAM) account. This is the same account (username and password) used to access the member portion of the CTSU website (https://www.ctsu.org). Refer to the CTEP website for additional details on registration types and required documentation.

To perform patient registrations (including pre-registrations), site personnel must be assigned the 'Registrar' role in the CTSU RSS, found under the 'Regulatory' tab in the member portion of the CTSU website. The principal investigator (PI) of each main member must approve all personnel authorized to register patients.

Policy Name: Credentialing	Policy Number: 7.3
Section: Patient Registration – 7	Date Revised: December 16, 2024

7.3   Credentialing

If a protocol requires credentialing for the registering physician (e.g., to demonstrate proficiency in performing a particular type of surgery) or the registering institution (e.g., to administer radiation therapy), then the credentialing requirements listed in the protocol must be met.

Policy Name: Confirming Patient Eligibility	Policy Number: 7.4
Section: Patient Registration – 7	Date Revised: December 16, 2024

7.4   Confirming patient eligibility

The institution confirms eligibility before registration or randomization by verifying the eligibility criteria listed in the protocol. Institutions should refer to all relevant protocol sections to ensure that all conditions for appropriate entry of a patient on study are met.

Exceptions to eligibility criteria or other protocol requirements will not be granted.

Treatment should begin no later than two weeks after registration, unless otherwise specified in the protocol.

As a general rule, sites should not register a patient to more than one interventional study when it is expected that one protocol's intervention might impact the other study's endpoints (e.g., registering a patient for two studies, where both protocols' treatments are expected to have an impact upon response, overall survival, etc.), although exceptions may be allowed by the study chair in collaboration with the executive officer. The study team should carefully consider the scientific and practical implications before allowing such exceptions.

7.5 Procedures to register patients to Alliance studies

Registration to Alliance studies is available 24 hours a day via OPEN. All participating sites (Alliance and non-Alliance sites) will use OPEN to enroll patients. OPEN can be accessed from the member portion of the CTSU website.

Study-specific OPEN Enrollment Form(s) are available for each study on the CTSU website. Information required at registration includes:

- Registering institution and investigator names and CTEP ID numbers
- Patient demographic information
- Pre-study and eligibility information
- Stratification and/or grouping factors if applicable
- Sub-study participation information if applicable

The OPEN system will provide the site with a printable confirmation of registration and treatment information.

7.5.1 Pre-registration

For select studies it is necessary to obtain a patient ID for study screening and eligibility using a pre-registration procedure. Patients will be pre-registered using OPEN.

7.5.2 Multiple-Step Registration

For select studies it is necessary to verify eligibility for additional treatment or treatment changes (i.e., safety run-in, cross-over, delayed or re-randomization). Patients will be registered for each step using OPEN.

7.6 Procedure to register patients to studies led by other Lead Protocol Organizations

For registration of patients to studies led by other Lead Protocol Organizations that are available on the CTSU menu, the Alliance institution must use OPEN. The institution must indicate its network group affiliation with the Alliance to receive enrollment credit for the Alliance.