Policy Name: Authorization of Participants to Register Patients	**Policy Number:** 7.1
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7 Patient registration

All Alliance institutions are allowed to register patients to Alliance and other trials posted on the Cancer Trials Support Unit (CTSU) menu.

7.1 Authorization of participants 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 participants must be registered with the Cancer Therapy Evaluation Program (CTEP) 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).

To perform registrations (including pre-registrations), the site user must be assigned the 'Registrar' role in the CTSU's Regulatory Support System (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:** 7.2
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7.2 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 before patient registration may proceed.

Policy Name: Authorization of Institutions to Register Patients	**Policy Number:** 7.3
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7.3 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 RSS, prior to enrollment of the first patient. Submission instructions are available on the RSS page (https://www.ctsu.org/public/rss2_page.aspx) 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.

Institutions may have their accrual privileges suspended by the Alliance leadership.

7.3.1 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 RSS.

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 in order 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 one week 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.

Policy Name: Procedures to Register Patients to Alliance Studies	**Policy Number:** 7.5
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

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.

A study-specific Registration Worksheet/Eligibility Checklist is available for each study. Information required at registration includes:

- Registering institution and investigator names and CTEP ID numbers
- Patient demographic information
- Pre-study and eligibility information
- Stratification factors
- Companion 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.

Policy Name: Registration on Weekends or After Business Hours	**Policy Number:** 7.6
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7.6 Registration on weekends or after business hours

Patients must be consented and registered to a treatment study before protocol treatment begins, with the following exception.

Treatment prior to registration is allowed if **all** of the following criteria are met:

- Patient is to be registered to an acute leukemia or high-grade Burkitt's-like lymphoma non-randomized study, or to a study in which the induction arm is standard chemotherapy.
- Immediate treatment is necessary (i.e., patient is in medical crisis).
- This treatment policy exception is stated in the protocol.

Patient must be registered on the next business day. The institution must document in writing the reason why treatment was started before registration and submit documentation to the Alliance Statistics and Data Center.

Policy Name: Registration to Companion Studies	**Policy Number:** 7.7
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7.7 Registration to companion studies

Patients may be registered to companion studies at the same time as they are registered to the treatment study. It is important for the registering institution to check protocol requirements for companion studies (e.g., whether patient participation is mandatory or optional) before registering the patient. The majority of companion studies are "embedded" within the treatment study, that is, the description of the companion study, registration and data collection procedures, and consent are included within the treatment protocol and consent form. Some companions are "freestanding", that is, described in a separate protocol document with a separate consent form. Freestanding companion studies may be optional for the institution as well (i.e., they do not need to be offered to the patient).

A patient who has been registered to a treatment study may later be registered to a companion study, if allowed by the protocol. This may happen even though the registering institution for the treatment study is no longer a member of the Alliance, provided the institution has accepted responsibility for the patient via transfer, including patient registration and submission of the patient's data.

Policy Name: Procedure to Register Patients to Intergroup Studies	**Policy Number:** 7.8
Section: Patient Registration – 7	**Date Revised:** March 15, 2013

7.8 Procedure to register patients to intergroup studies

For registration of patients to intergroup studies not coordinated by the Alliance that are available on the CTSU menu, the Alliance institution must use OPEN. The institution must indicate its network group affiliation with the Alliance in order to receive enrollment credit for the Alliance.