

CTSUSU

Cancer Trials Support Unit

OPEN Person Types and Business Rules

Revision 4

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Document Information

Revision Information for the OPEN Person Types and Business Rules

Revision History

| # | Date | By | Description |
|---|------------|--------------------|---|
| 1 | 2017/07/25 | Mark Stauffer | 2017/07/20: Created the initial version of the document, based on "OPEN_Person_Types_and_Access_Rules.docx". 2017/07/25: Added the OPEN crediting rules. |
| 2 | 2017/08/21 | Mark Stauffer | Added the DTL rules. |
| 3 | 2024/01/03 | Rachel Albershardt | Added NINT person type and removed Drug Shipment Investigator. |
| 4 | 2024/04/15 | Lucille Patrichuk | Added ID.me information. |

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1. OPEN Person Types and Business Rules

The following table outlines the OPEN person types and business rules. It should be noted that the rules apply for patient enrollments as well as transfers through the Transfer and Update Module (T&UM) in OPEN.

Table 1: OPEN Person Types and Business Rules

| N/A | Treating Investigator | Crediting Investigator | Consenting Investigator |
|--|--|--|---|
| Description | <p>The Treating Investigator is the investigator who will have contact with the patient throughout the course of the study.</p> <p>NOTE: Information from Frequently Asked Questions (FAQ) posted on the OPEN website.</p> | <p>The Credit Investigator is the investigator who will receive payment and will have the ultimate responsibility for the patient and audit activities for the study.</p> <p>When the Treating Investigator is not a member of the group the site would like to credit for the enrollment, the site will need to choose an investigator who is affiliated with the site and is a member of the credited group.</p> <p>NOTE: Information from FAQ posted on the OPEN website.</p> | <p>The Consenting Investigator is the person responsible for obtaining patient consent.</p> |
| Required in OPEN? (Applies to all Rules) | Yes | Yes | Yes (Only for Registration and Credentialing Repository (RCR)/Delegation of Task (DTL) rules) |
| Number allowed in OPEN (Applies to all Rules) | Only one Treating Investigator can be selected per enrollment. | Only one Crediting Investigator can be selected per enrollment. | Only one Consenting Investigator can be selected per enrollment. (Only for RCR/DTL rules) |

Table 1: OPEN Person Types and Business Rules (continued)

| N/A | Treating Investigator | Crediting Investigator | Consenting Investigator |
|--|--|--|--|
| <p>RCR Rules</p> | <p>Registration Types Allowed:</p> <ul style="list-style-type: none"> • IVR (default). • NPIVR – if there is a protocol exception to allow this. • NINT – if the protocol is flagged for NINT participation. <p>Rules:</p> <ul style="list-style-type: none"> • Must have an “Active” CTEP-IAM account linked with an ID.me account. • Be Active at the enrolling site on the Lead Protocol Organization (LPO), or any participating group roster for the protocol. • An Institutional Review Board (IRB) in the RCR profile must match the approved site’s IRB, if registration type of the person is either IVR, NINT or NPIVR. | <p>Registration Types Allowed:</p> <ul style="list-style-type: none"> • IVR (default). • NPIVR – if there is a protocol exception to allow this. • NINT – if the protocol is flagged for NINT participation. <p>Rules:</p> <ul style="list-style-type: none"> • Must have an “Active” CTEP-IAM account linked with an ID.me account. • Be Active at the enrolling site on the credited group. The credited group could be LPO, or any participating group for the protocol. • An IRB in the RCR profile must match the approved site’s IRB, if registration type of the person is either IVR, NINT, or NPIVR. | <p>Registration Types Allowed:</p> <ul style="list-style-type: none"> • IVR (default). • NPIVR – if there is a protocol exception to allow this. • AP – if there is a protocol exception to allow this. • NINT – if the protocol is flagged for NINT participation. <p>Rules:</p> <ul style="list-style-type: none"> • Must have an “Active” CTEP-IAM account linked with an ID.me account. • Be Active at the enrolling site on LPO, or any participating group roster for the protocol. • An IRB in the RCR profile must match the approved site’s IRB, if registration type of the person is either IVR, NINT, or NPIVR. |
| <p>DTL Rules (In addition to RCR Rules)</p> | <p>Must be on the enrolling site’s DTL assigned to the “Enrolling Person/Treating Investigator” task.</p> | <p>Must be on the enrolling site’s DTL assigned to the “Enrolling Person/Treating Investigator” task or is the Clinical Investigator on the site DTL.</p> | <p>Must be on the enrolling site’s DTL assigned to the “Consenting Person” task.</p> |

Registration Types: IVR = Investigator, NPIVR = Non-physician Investigator, AP = Associate Plus, NINT = Non-Investigational New Drug/Non-Treatment

2. OPEN Crediting Rules

Below is the list of crediting rules for OPEN enrollments:

- US sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.
- Canadian sites must credit the NCTN Group that holds the CTA.
- International sites must credit the LPO if they are a member of the LPO.
- International sites that are not members of the LPO must receive approval from their credited group and consistently credit the same group for the protocol.

Adolescent and Young Adult (AYA) Trials

- COG-led AYA trials open cross network for participation by all US Adult Network Groups:
- COG investigators must credit COG with enrollments.
- US non-COG sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.
- CCTG sites may participate and credit CCTG only if the COG-led AYA trial is formally endorsed by CCTG.

NCTN AYA trials led by an Adult Network Group

- US sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.
- CCTG sites may participate and credit CCTG only if the trial is formally endorsed by CCTG.

Other Participating Sites or Networks on NCTN Trials

- Occasionally other networks or sites outside of the NCTN are authorized to participate on NCTN trials. Sites participating outside of a network are termed non-member collaborators (NMCs) and must be listed on the protocol cover page along with the enrolling investigator at the site.
- NMCs will credit themselves for any enrollments
- Other participating networks will credit their member network for enrollments.

3. OPEN Access

The following table outlines the access rules for site staff and registrars.

Table 2: Access Rules for Site Staff and Site Registrars

| | Site Staff | Registrar |
|---------------------|---|---|
| Description | Site staff persons at the enrolling site. | User that can enroll patients and submit patient transfers. |
| Access Level | User can view enrollment history at an institution but cannot enroll subjects at that institution. | User can view enrollment history at an institution and has enrollment privileges. |
| RCR Rules | <p>Registration Types Allowed:</p> <ul style="list-style-type: none"> • IVR • NPIVR • NINT • AP • A <p>Rules:</p> <ul style="list-style-type: none"> • Must have an “Active” CTEP Registration. • Must have an Active CTEP-IAM account linked with an ID.me account. • Be Active at the enrolling site on the LPO, or any participating group roster for the protocol. • NINT access is limited to protocols flagged for NINT participation. | <p>Registration Types Allowed:</p> <ul style="list-style-type: none"> • IVR • NPIVR • AP • NINT <p>Person Rules:</p> <ul style="list-style-type: none"> • Must have an “Active” CTEP Registration. • Must have an Active CTEP-IAM account linked with an ID.me account. • Be Active at the enrolling site on the LPO, or any participating group roster for the protocol. • Must have a Registrar role on the LPO or a PO’s roster as defined through the Regulatory Support System (RSS) at the enrolling site irrespective of the network being credited, if the site is an unrestricted participant. |

Table 2: Access Rules for Site Staff and Site Registrars (continued)

| | Site Staff | Registrar |
|--|--------------|---|
| | | <ul style="list-style-type: none"> If a site is restricted to participate on a specific roster owner, the registrar role must be associated with the site roster for the restricted participant organization (e.g. site restricted to Alliance). This rule is true except for Non-Member Collaborators (NMCs). If the site is an NMC, the registrar role should be at the protocol level at the enrolling site on the NMC roster. NINT access is limited to protocols flagged for NINT participation. <p>Site Rules:</p> <ul style="list-style-type: none"> The enrolling institution must be on the roster of the LPO or a Participating Organization (PO) for the protocol. <p>The enrolling site must have a site registration status of 'approved' in RSS to be able to enroll patients.</p> |
| DTL Rules (In addition to RCR Rules) | No DTL rules | <p>If the protocol requires a DTL, then the person must be listed on the enrolling site's DTL as having the Registrar task and have the RSS OPEN registrar role. If a person has the RSS OPEN registrar role but is not assigned the "enrolling person" task on the DTL, then the person will have read-only access to OPEN.</p> <p>NINTs may not be added to a DTL, if an individual changes their registration type to a NINT, all active DTL tasks that they hold will be set to inactive.</p> |

Registration Types: IVR = Investigator, NPIVR = Non-physician Investigator, AP = Associate Plus, A = Associate, NINT = Non-Investigational New Drug/Non-Treatment