Clearing the Fog – NCI Site Codes

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Alliance Spring Group Meeting, May 13, 2016

Presentation Objectives

- Provide a brief overview of NCTN/NCORP grants and how they relate to NCI site codes
- Review sections in the NCTN/NCORP guidelines that describes, “What is an Enrolling Site?”
- Discuss examples and different scenarios to better understand NCI site codes
- Discussion and Questions

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NCTN/NCORP Grants & NCI Site Codes (1)

- Within NCI's NCTN and NCORP cooperative research grants, they include research programs that may have multiple participating institutions and practice sites and could be referred to as a "package".
  - They are linked together across NCI, NCTN Group, and NCORP Research Base systems according to their funding mechanism (NCTN Main Members/NCORP/LAPS grants).
  - Relationships between sites under the grant are captured by the assigned institution site code and member role.

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NCTN/NCORP Grants & NCI Site Codes (2)

- A single institution/practice site cannot be in more than one grant (or visualized on next slide's diagram as a "swim lane").
- People (physicians and research staff) must be rostered at a site within a research program or "package" to be able to consent, enroll, and treat patients and to collect, review, and submit patient data.

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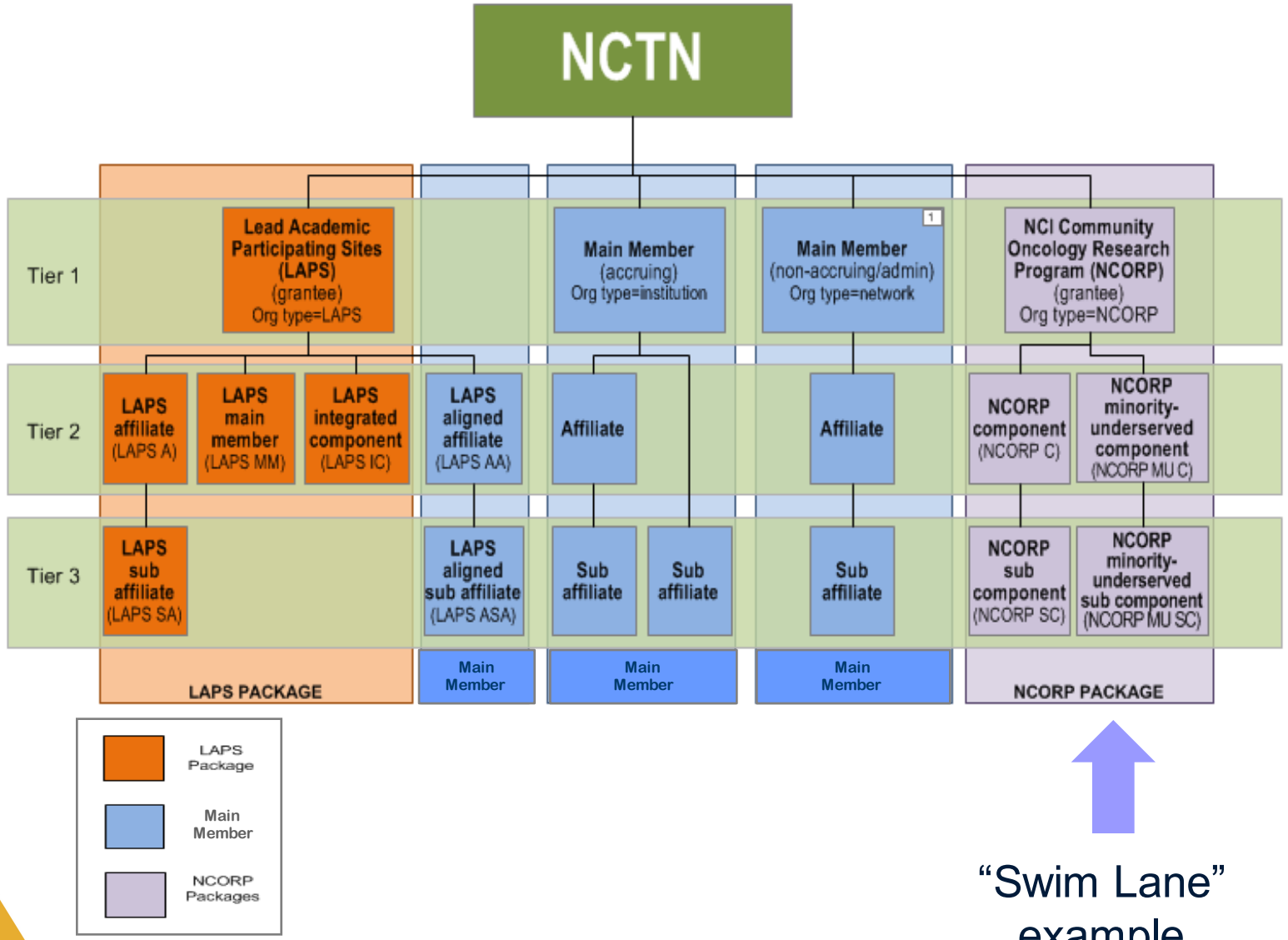
NCTN Organization Chart



"Swim Lane" example

Definition of Engaged in Research

- Required to provide documentation of where research activities are being conducted
  - Engaged in research (consenting, enrolling, and treating)
    - [45 CFR part 46] In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

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NCTN/NCORP Guidelines

- Sites engaged in research:
  - Must have a CTEP Site Code;
  - Must be covered under an FWA (must be able to confirm coverage on the OHRP website);
  - Must be claimed on an NCTN/NCORP roster; and
  - Associated accrual must be credited to the CTEP Site Code, not to a “parent” institution at a geographically distinct location.

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Institutions Requiring a Site Code

- Institutions meeting the federal regulations/guidelines of engaged in research.
- Institutions holding a federal grant.
- Unique geographic location that requires drug shipment even if that site is legally part of another entity and conducts research under the parent entity's FWA

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CTEP Site Codes: General Principles

Example: Two "sites" (e.g., university hospital and cancer center *OR* community hospital and outpatient clinic)

- Same "campus", same legal entity, same FWA >>> one CTEP Site Code.
- Same "campus", different legal entities, different FWAs >>> two CTEP Site Codes.
- Different locations (i.e., not on the same "campus"), same legal entity, same FWA >>> two CTEP Site Codes.
- Different locations (i.e., not on the same "campus"), different legal entities, different FWAs >>> two CTEP Site Codes.

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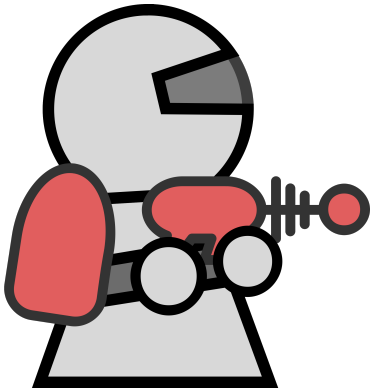
Disclaimer

- The examples in this slide set are meant to provide guidance. Questions pertaining to individual scenarios should be directed to CTEP or DCP as appropriate.

- Please don't shoot the messenger.



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Who needs a site code? (1)

- Big Health System
  - University Hospital **Yes**
    - Meets federal and NCI requirements for holding a site code.
  - Community Hospital 1 – across town or across the river in a different state **Yes**
    - Though legally part of the health system and functioning under its FWA, the separate geographic location requires a site code.
  - Radiation Facility on University Hospital Campus **No**
    - Location is part of the main campus and part of the health system.

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Who needs a site code? (2)

- Affiliate Hospital 1 **Yes**
  - The Cancer Center at the hospital functions in partnership with the University Hospital, but has its own FWA and is legally separate.
- Affiliate Cancer Clinic 1 **No**
  - Located on the hospital campus and the clinic is owned and operated by the hospital.
- Affiliate Cancer Clinic 2 **Yes**
  - Clinic is owned and operated by the hospital; but, is located on the other side of town.
- Dr. Sam's Office **Yes**
  - Located in rented space on hospital property
  - Functions as own legal entity and holds its own FWA.

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Enrolling Site Definition

- **Enrolling site** – Refers to the site where the patient/participant is consented, receives treatment, and will have study-related exams/visits (medical home).
  - ***It is not the location where the web or phone registration to a study is completed, e.g., via a computer or phone at the research office.***

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Enrolling Site Criteria

- Patient's primary care site (their "medical home").
- Where the patient's primary physician is based.
- **Site primarily responsible for the clinical care and monitoring of the patient.**
- Must be covered by an IRB.
- Must be covered by an FWA.

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Drug Shipment and Site Codes

The NCI-registered investigator must indicate:

- The shipping address for their PMB-distributed agents (at this time one drug shipment address allowed per investigator).
- The shipping designee who will be responsible for receiving, properly recording, and storing the agent.
- The ordering designee(s) who may order agent from PMB on behalf of the investigator.

Note: The “investigator” (not the “site”) is ultimately responsible for all investigational agent ordered in their name.

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Enrolling Site Examples

- Example 1:
  - Hospital A is an NCORP component. They consented and will treat the subject; however, the NCORP is responsible for the enrollment and enters data on their behalf.
    - Hospital A should be the enrolling site in OPEN.
- Example 2:
  - Hospital B enrolls a patient and is responsible for the patient's care and monitoring but sends the patient to an outside facility for their routine RT.
    - Hospital B is the enrolling site in OPEN but should ensure the RT facility can submit data to TRIAD on behalf of Hospital B.

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Take Home Message

- The enrolling site code (also called registering site code) used should be the clinical site that is **primarily responsible** for the clinical care and monitoring of the patient for the majority of trial events (e.g. assessment of investigational agent/treatment toxicity, dose modification determinations, assessment of disease and response status to therapy, etc.).

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Types of Scenarios

- Change in Primary Site
- Changing Swim Lanes
- Site Closures
- Multi-Modality Studies

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Scenario 1
Change in Primary Site

- What if a patient has protocol exams/tests and is consented at one site but would like to be treated at a site closer to home?
  - Patient transfer would need to occur if the patient is transitioning to a new medical home; however, no transfer is necessary if a patient is visiting a component site under their medical home for part of their care or receiving routine care at an outside facility.
  - Reference OHRP Guidance, *Engagement of Institutions in Human Subjects Research (2008).*

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Scenario 2
Changing "Swim Lanes"

- What happens if my site switches its grant funding?
  - The change will need to be communicated to CTEP for LAPS changes, to DCP for NCORP changes, the NCTN Groups for main member changes; however, the site code will remain the same for the site.
    - NCORP/LAPS need to also communicate changes with their Grants Specialist
  - Site must ensure ongoing IRB coverage for previously enrolled patients under the new network's IRB or through their existing IRB.
  - Site remains responsible for follow up of previously enrolled patients. If that is not possible, the patient should be transferred or, as a last resort, removed from study.

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Scenario 3
Site Closures

- What should I do when a patient is enrolled to a site that has closed after their enrollment?
  - If the patient has completed treatment and follow-up prior to site closure, no further action is needed. If treatment or follow-up are ongoing, the patient should be transferred to another institution or, as a last resort, removed from study.
    - Remember to notify your LAPS/NCORP grant holder (if applicable) and your NCTN affiliated group of any site closures.
    - Contact the LPO for any studies with enrollments at the site to verify data collection is complete.
    - Notify ECU Help Desk and PMB.
    - Copy CTSU on your correspondence.

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Scenario 4

Multi-Modality Studies

- Patient is enrolled to a combined modality trial (e.g., chemotherapy followed by RT). If the patient receives chemotherapy at one site code and radiation at another site code, to which site code should the patient be enrolled? Special Note: RT facility is required to be credentialed for the radiation portion of trial.
  - The site code used should be the code of the site that is responsible for overall care and follow-up of the patient. The patient does not need to be transferred in between sites.

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Questions?

- Contact information for questions:
  - CTSU: ctsucontact@westat.com or 1-888-823-5923
  - ECU Help Desk: ecuhelpdesk@mail.nih.gov
    - For questions about site codes
  - PMB: pmbafterhours@mail.nih.gov
  - LAPS email box: NCTNProgram@mail.nih.gov
  - NCORP questions:
    - Cynthia Whitman (whitmanc@mail.nih.gov)
    - Marge Good (goodmj@mail.nih.gov)
    - Or your DCP Program Director

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