Group Meeting
Chicago, IL
May 8, 2014

Barbara Barrett, MS, CCRP
Alliance Audit Program Director
CRP Committee Meeting

Revised CTMB Guidelines Effective March 1, 2014

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What was revised?

- Introduction to the new NCTN program (NCI National Clinical Trials Network)

- All references to memberships with the new membership types (LAPS/NCORPs, etc)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What was revised?

- More extensive list of site source documents needed at audit time, including documents for *advanced* imaging studies (section 4.4)

- Site source documents needed when the IRB of record is the CIRB (section 5.2.1)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What was revised?

- Clarifications of responsibilities of the Control Dispensing Area for investigational agents (section 5.3.1)

- Clarifications of responsibilities of the Satellite Dispensing Area for investigational agents (section 5.3.2)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What was revised?

- Clarification of pharmacy *non-compliance* of repackaging and reshipping study agents to other locations/patients (section 5.3.4)

- Audit review of agent storage includes checking temp logs, etc. (section 5.3.4)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What's new?

Additional step in the selection of Protocols and Patient Cases

- 10% rule applies to protocols with advanced imaging studies/imaging studies embedded in treatment protocols (section 4.2)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Recap of Patient Selection

Sect. 4.2 – Audit case selection includes:

- 10% -Tx cases from lead audit Group
- 10% -CTSU endorsed credited to lead Group
- 10% -CTSU non-endorsed credited to LG
- 10% -DCP cancer control/prevention studies
- 10% advanced imaging studies/imaging studies embedded

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What's new?

- Oral NCI Investigational Agent Accountability Record – Oral DARF

- ****Use is required as of March 1, 2014 (section 5.3) ****

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

The PMB policy and a copy of the new new Oral DARF may be obtained at: http://ctep.cancer.gov/protocolDevelopment/requisition_agents/docs/oral_agent_accountability_policy.pdf and http://ctep.cancer.gov/forms/docs/oral_agent_accountability.pdf

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

When to use an Oral DARF

- For on-going studies with supplied oral agents - start each new DARF page with an Oral DARF.
- Transition to Oral DARF must be completed by ***by Sept 1, 2014***.
- Create an Oral DARF for any new study using NCI supplied oral agents
- **Compliance will be checked at audit time**

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

Print Form | Save As | Reset Form

Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.

Form Approved:
OMB No. 0925-0613
Expires: 03/31/2016

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

Investigational Agent Accountability Record

Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.

CONTROL RECORD ☐

SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

When to use an Oral DARF

- While in transition between regular and new Oral DARF, patient returns should be documented on the Oral DARF *only* if dispensing was documented on the Oral DARF.
- Complete upper portion in full.
- Upper portion contains new box for local Protocol #, only if needed.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

When to use an Oral DARF

- Not intended for patient compliance
- Use one line per transaction, and complete the line in full.

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

More Do's and Don'ts of Oral DARFs

- Do use for all open-label and blinded trials using oral formulations
- Do use the fields that are right of the dark line for patient returns
- Don't maintain lot-specific DARFs (oral or regular DARFs)

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

More Resources for Oral DARFs

For more info, the May 2014 Inside PMB newsletter link is: http://ctep.cancer.gove/branches/PMB/inside_pmb/many2014.pdf

Questions or comments regarding accountability and storage of investigational agents should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) or email PMBafterhours@mail.nih.gov

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

What's new?

Auditing of eDARFs

- Sites must print an eDARF and eOral DARF for each supplied agent/dose/patient specific form that includes all info found on an NCI DARF

Note: NCI does not endorse any eDARF pharmacy package

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY


QUESTIONS?

Barbara Barrett, MS, CCRP
Alliance Audit Program Director

312-206-8216
bbarrett@uchicago.edu

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY