

Review of Accountability of Investigational Agents

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Alliance Group Meeting, 11/2014

Pop Quiz – Warm up!

 What is the appropriate way to fix a mistake that is made on a research document?

- When an PMB supplied IND is needed at a satellite location, how does the IND get from the main location, to the satellite location?
- When is a patient specific DARF required?



Ask your Neighbor:

"In your pharmacy",

- •How are your INDs stored?
- •How are your INDs secured?
- •What is the process for temperature monitoring, recording and reviewing?
- •How do you ensure the drug counts between the DARF and shelf supply are consistent? – How is it documented?
- •What do you do for Double-Blinded studies?



Lets Discuss!

 How are NCI supplied investigation products required to be tracked?



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as an IND spon investigational p	sor and that invourposes, spon-	vestigational agents sors of clinical trials	1 CFR 312.57. The information are under the control and accurand their company collaborative however, in order for you to	ounted for by compe ors, the applicable Ir	etent authority. The institutional Review Bo	nformationard, NC	on may be disclosed to CI, FDA, and the Depa	researchers for rtment of Health and Human	OMB Expir
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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

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Name	of Institution:					Investigato	or Name:	CTEP Inv	CTEP Investigator ID:				
Protoc	col Title:				NCI Protocol No: Local Protocol No:			Dispensing Area:					
Agent	Name:					Dose Form	n and Strength:		Bottle size (e.g., # tablets/bottle):				
Line	Date	Patient's	Patient's ID No.	Dose	Quanti	*	ance Forward	Manufacturer	Recorder's	Expiration	Date	Quantity	Recorder's
No.	Date	Initials	Patient's ID No.	Dose	Dispense Receiv		Balance	and Lot No.	Initials	Date (if available)	Patient Returned	Patient Returned	Initials
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DARF – Headers

National Institutes of Health National Cancer Institute	Division of Cancer Treatm Cancer Therapy Evaluation		PAGE NO. I		
Investigational Agent Accountability	Record		CONTROL RECORD		
Name of Institution:		NCI Protocol No.:			
Southeast Cancer Control Consortium		CALGB 40503			
Agent Name:		Dose Form and St	rength;		
Bevacizumab/Placebo NSC 704865	Refrigerate	100 mg vial (2.5m	ng/ml - 4 ml vial)		
Protocol Title:		Dispensing Area:			
Endocrine Therapy in Combination with anti-VEGi		Main Pharmacy			
Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Plus Bevacizumab For Wome					
Advanced Breast Cancer	Will Hollione Neceptor- Positive	supplied by Gene	ntech and provided by NCI		
Investigator Name:		NCI Investigator N	0.)		
James N. Atkins	01234				



Oral DARF General Instructions

- Completing and Using the form
 - Per protocol specifications (by bottle or tablet)
 - Not in protocol? Just be consistent
 - Don't for get the header information

http://ctep.cancer.gov/branches/pmb/faq/docs/accounting_for_oral_agents.pdf



Oral DARF – Documenting Returns

Using the Return Portion

- Document the return on the correct form
- Correct dispensing row
- Date and quantity (number of caps or tabs)
- If dispensing didn't occur on the ORAL DARF do not document it on the ORAL DARF



Exercise: ORAL DARF Completion

How to use the Oral DARF -general



National Institutes of Health PAGE NO. National Cancer Institute Investigational Agent Accountability Record X CONTROL RECORD Division of Cancer Treatment and Diagnosis Oral agents ONLY Cancer Therapy Evaluation Program SATELLITE RECORD CTEP Investigator ID: Investigator Name: Name of Institution: 01234 Southeast Consortium for Cancer Clinical Trials Hether Seifert NCI Protocol No: Local Protocol No: Dispensing Area: Protocol Title: Main Pharmacy HE123456 Study of Oral DARF completion and oral IND returns HE123456

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Agent M&I	Name: VIS					Dose Form and Strength: 1 piece		Bottle size (e.g., # tablets/bottle): 50/packet						
						bottle				Dieces				
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if	Date Patient	Quantity Patient	Recorder's Initials		
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Be the Auditor!

Find as many mistakes as you can.....



collectio	on of information, inclu	ding suggestions	for reducing this burden, to:	NIH, Project Clearance Bra	nch, 6705 Rock	ledge Drive, M	ASC 7974, Bethesda, N	MD 20892-	7974, ATTN: PR	A (0925-0613). Do	not return the com	pleted form to this	address.		
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What did you find??????



collectio	on of information, inclu	ding suggestions	for reducing this burden, to:	NIH, Project Clearance Bra	nch, 6705 Rock	ledge Drive, M	ASC 7974, Bethesda, N	MD 20892-	7974, ATTN: PR	A (0925-0613). Do	not return the com	pleted form to this	address.		
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Most Common Non-compliance – DARF

- If there is a space/box/line for something, it needs to be filled in/checked with the correct study information
 - Protocol titles
 - Agent Name
 - Dispensing location
 - Control or Satellite location (check boxes)
 - Page numbers
 - Dose form/strength
 - Manufacturer lot number (use Julian date if not provided)



It's Pharmacy!

- Security and Storage
 - temperature
- IND Order, Receipt, Transfer, Return and Destroy
- Documents



Guidelines and Regulations

Storage

- ICH guideline 4.6.4, 5.13.2, and 5.14.3
- 21 CFR 312.69

Supply and Handling

- ICH Guideline 5.13.3 and 5.14
- 21 CFR 312.59

Accountability

- ICH Guideline 4.6
- 21 CFR 312.57 (a) and 312.62 (a)

Dispensing

- ICH Guideline 4.6.6
- 21 CFR 312.61
- Guidelines For Auditing of Clinical Trials for Cooperative Groups (1/113)

Resources

- CTMB web site:
 - http://ctep.cancer.gov/branches/ctmb/clinicalTrials/ docs/ctmb_audit_guidelines.pdf
- PMB web site:
 - http://ctep.cancer.gov/branches/pmb/
 - Drug Accountability Record Form (current version):
 - http://ctep.cancer.gov/forms/docs/ agent_accountability.pdf
 - Oral Darf: http://ctep.cancer.gov/forms/docs/ oral_agent_accountability.pdf



Conclusion

THANK YOU!

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