

IND Drug Log Guidelines

1) An NCI DARF (Drug Accountability Record Form) should be kept on each strength of investigational drug. An investigational drug is considered to be any drug (including commercially-available drugs being used in an investigational setting) provided by the NCI/drug company free of charge for patients registered on specific protocols. The DARF should include all the following information in the upper section as requested:

- a) Name of your institution/hospital
- b) NCI protocol number – CALGB protocol number
- c) Drug/Agent name
- d) Dose form and strength
- e) Protocol title (can be abbreviated)
- f) Dispensing area (pharmacy or dispensing location)
- g) Investigator's name (usually use PI's name)
- h) NCI Investigator's number

The sign-in and sign-out of drug applies to the lower section of the DARF and should include the following information on each line (lines are numbered 1 – 24):

- a) Date : drug should be signed out as needed daily
- b) Patient's initials : use all three initials if possible
- c) Patient's ID number : use assigned CALGB pt. ID number – not hospital/chart number
- d) Dose : the drug dosage administered that day or to be administered daily if dispensing oral medication
- e) Quantity dispensed/received : the amount of vials received (e.g., +5) or dispensed (e.g., -5) or number of pills received (e.g., +540 pills) or dispensed (e.g., - 90 pills)
- f) Balance : this number should always match the physical drug inventory located in the storage cabinet/shelf or refrigerator
- g) Manufacturer and lot # : always list lot number(s) noted on drug labels (You may mix lot numbers on drugs unless otherwise specified by NCI). If drug section of protocol discusses Julian dates, then Julian dates should be used in place of lot #s
- h) Recorder's initials : this is the person responsible for dispensing the drug

Do NOT use ditto marks (") on the drug log to continue a lot number, pt ID, pt initials, etc.

Any time you receive drug from NCI/drug company or send drug to another location at your institution to be administered on a specific date, please make notation on that date how much drug was sent/received and if applicable, where it was sent.

Transfer Sent Example:

10/7/09	Transfer to Clinton	-15 vials	30 vials	L00562	st
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Also, a drug log must be maintained at the satellite office/institution.

Transfer Received Example:

10/7/09	Received from Goldsboro	+15 vials	15 vials	L00562	st
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If drug is stored ("spends the night") at satellite offices/clinics, then a DARF must be maintained.

If the study has double blind study drug, then all drug received for the study is patient specific and DARFs should be patient specific. You will know that drug is patient specific when the shipping invoice notes the patient initials on the shipping invoice.

2) Ordering Investigational Drug - You should use the Clinical Drug Request form (NIH 966) and follow procedures to order drug from NCI or other designated distributor as noted in the protocol section for drug information.

3) Use of Investigational Drug - If drug is provided for a specific protocol, you are to use only drug provided. Do NOT use commercial drug or drug from another protocol or source. You must have the NCI staff's approval in writing to use the same drug with identical NSC #s from another protocol (Drug Transfer Form). ***Under NO circumstances do you exchange commercial drug for investigational/ protocol drug or vice versa.*** This is considered a MAJOR deviation and will cause your audit to be *Unacceptable*, requiring a re-audit within 12 months.

4) Storage of Investigational Drugs - Investigational/protocol drugs should always be kept separate from commercial drugs. Investigational drugs should always be kept in a secure location (e.g., locked cabinet/room with limited access by authorized personnel) with proper labeling on box or plastic bag where drug stored. Each protocol drug should be labeled and kept separately in individual containers. NEVER place food in refrigerator with investigational drugs.

5) Shipping Invoices – Verify the accuracy of the amount of drug shipped as listed on the shipping invoice. Initial and date shipping invoice. Any investigational drug you receive should have a shipping invoice. If one does not accompany a drug shipment, please call immediately to NCI/drug company so that they can find out why one was not included and provide one for your records. You must be able to account for all shipments from NCI with shipping invoices at a CALGB audit. In addition, you must have NCI drug return invoices for all investigational drug returned to NCI/drug company.

7) Circumstances for return of drug

- Drug expiration : Each vial of drug should have an expiration date and should be checked periodically and noted on the container. When drug has expired, it will need to be returned to NCI/drug company as directed in the protocol, if applicable. If not addressed in the protocol, inquire with the distributor or provider.
- Protocol closure : If a protocol using investigational drug closes and all patients placed on study have completed treatment, you may return the investigational drug to NCI, **if** you do not have another protocol open that uses the same drug with the exact same NSC#. Once drug is returned to NCI, it is destroyed. It is required that drug be returned to NCI within 3 months/90 days of protocol closure or last treatment given to protocol patient. Oral IND medicines should be destroyed on site unless NCI/drug company requires they be returned. Return only unopened vials. Note return directions in the protocol for any provided oral drug.

If you have a circumstance where a patient returns drug to you, do NOT place this drug back into your stock since you do not know if the drug has been stored in the required manner for the complete time the patient has possessed the drug. (Would you want drug that someone else had taken home with them?) You should utilize a generic destruction log if you need to account for returned drug unless the protocol guidelines specifically direct you to log the returned drug onto the patient specific drug log.

Remember, you must be able to account for all supplies of investigational/ protocol drugs that are provided by NCI or the drug company in analogous fashion to the handling of narcotics.

Please try to be NEAT when recording on DARF

Good Examples of DARFs

Pt TS # 211566

Public reporting burden for this collection of information is estimated to average 6 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 (0925-0240). Do not return the completed form to this address.

OMB No. 0925-0240
Expires: 02/28/2011
NIH-2564

National Institutes of Health National Cancer Institute	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO.
Investigational Agent Accountability Record		CONTROL RECORD <input checked="" type="checkbox"/>
		SATELLITE RECORD <input type="checkbox"/>

Name of Institution: Southeast Cancer Control Consortium	NCI Protocol No.: CALGB 90601
Agent Name: Bevacizumab/Placebo NSC 704865 Refrigerate	Dose Form and Strength: 400mg vial (25mg/ml - 16 ml vial) <i>(Julian dates)</i>
Protocol Title: A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma	Dispensing Area: Main Pharmacy provided by NCI
Investigator Name: James N. Atkins	NCI Investigator No.: 01234

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.	9/1/09	Rec'd	from NCI		+10	10	09199	ST
2.	9/3/09	TS	211566	1290mg	-3	7	09199	ST
3.	9/24/09	TS	211566	1290mg	-3	4	09199	ST
4.	10/15/09	TS	211566	1290mg	-3	1	09199	ST
5.	10/28/09	Rec'd	from NCI		+10	11	09222	ST
6.	11/5/09	TS	211566	1290mg	-1	10	09199	ST
7.	11/5/09	TS	211566	1290mg	-2	8	09222	ST
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9.								
10.								
11.								
12.								
13.								

Good Example

Pt TS # 211566

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National Institutes of Health National Cancer Institute	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>
Investigational Agent Accountability Record		
Name of Institution: Southeast Cancer Control Consortium		NCI Protocol No.: CALGB 90601
Agent Name: Bevacizumab/Placebo NSC 704865 Refrigerate		Dose Form and Strength: 100mg vial (25mg/ml - 4 ml vial) (Julian dates)
Protocol Title: A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma		Dispensing Area: Main Pharmacy provided by NCI
Investigator Name: James N. Atkins		NCI Investigator No.: 01234

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.	9/1/09	Rec'd	from NCI		+10	10	09196	ST
2.	9/3/09	TS	211566	1290 mg	-1	9	09196	ST
3.	9/21/09	TS	211566	1290 mg	-1	8	09196	ST
4.	10/15/09	TS	211566	1290 mg	-1	7	09196	ST
5.	11/5/09	TS	211566	1290 mg	-1	6	09196	ST
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								

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National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO. 1

CONTROL RECORD

SATELLITE RECORD

Investigational Agent Accountability Record

Name of Institution: Southeast Cancer Control Consortium-East Site	NCI Protocol No.: CALGB 40603
Agent Name: Bevacizumab NSC 704865 Refrigerate	Dose Form and Strength: 400 mg vial (25mg/ml - 16 ml vial)
Protocol Title: Randomized Phase II 2x2 Factorial Trial of the Addition of Carboplatin and/or Bevacizumab To Neoadjuvant Weekly Paclitaxel Followed by Dose-Dense AC in Hormone Receptor-Poor/HER2-Negative Resectable Breast Cancer	Dispensing Area: Clinic Pharmacy provided by NCI
Investigator Name: James N. Atkins	NCI Investigator No.: 01234

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.	10/7/09	Rec'd from SCCC		Main	+ 2	2	GT556	RB
2.	10/8/09	ED	198426	650mg	- 2	0	GT556	RB
3.	10/21/09	Rec'd from SCCC		Main	+ 2	2	GT556	RB
4.	10/22/09	ED	198426	650mg	- 2	0	GT556	RB
5.	11/4/09	Rec'd from SCCC		Main	+ 2	2	GT556	RB
6.	11/5/09	ED	198426	650mg	- 2	0	GT556	RB
7.								
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Good Example

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Investigational Agent Accountability Record				CONTROL RECORD <input checked="" type="checkbox"/>	
				SATELLITE RECORD <input type="checkbox"/>	
Name of Institution: Southeast Cancer Control Consortium			NCI Protocol No.: CALGB 50401		
Agent Name: CC-5013/Revlimid/Lenalidomide			Dose Form and Strength: 5 mg capsules (21 capsules/bottle)		
Protocol Title: A Randomized Phase II Trial of Rituximab vs. Lenalidomide (Revlimid™ or CC-5013) vs. Rituximab plus Lenalidomide in Recurrent Follicular Non-Hodgkin's Lymphoma (NHL) After Relapse from a Rituximab-Containing Combination Regimen			Dispensing Area: Main Pharmacy		
			Supplied by Celgene & distributed by Biologics		
Investigator Name: James N. Atkins			NCI Investigator No.: 01234		

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.	9/1/09	Rec'd	from Biologics		+20 bottles	20	B1005	ST
2.	9/10/09	Rec'd	from Biologics		20	40	B1005	ST
3.	9/10/09	G, DE	212229	15mg/d	-3	37	B1005	ST
4.	9/16/09	W, MJ	212253	15mg/d	-3	34	B1005	ST
5.	10/8/09	G, DE	212229	15mg/d	-3	31	B1005	ST
6.	10/14/09	W, MJ	212253	15mg/d	-3	28	B1005	ST
7.	11/5/09	G, DE	212229	15mg/d	-3	25	B1005	ST
8.	11/11/09	W, MJ	212253	15mg/d	-3	22	B1005	ST
9.								
10.								
11.								
12.								
13.								
14.								

Good Example