

Welcome to this video tutorial on the DARF Header in the PMB Investigational Drug Accountability series.

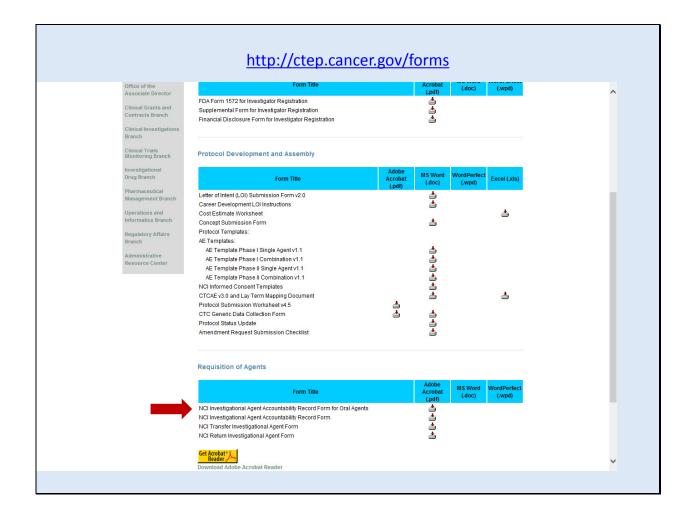
This video will review the process for completing the header of both the original and oral NCI DARF.

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There are two Drug Accountability Record Forms: the original DARF and the Oral DARF.

You see the original DARF at the top of the screen and the Oral DARF underneath it.

DARFs must be maintained to track the disposition of all study-supplied agents for NCI clinical trials.



Both DARFs are available on the CTEP website at http://ctep.cancer.gov/forms.

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The header is the top section of the DARF above the agent transaction area. All fields must be completed on every page.

The headers of the original DARF and Oral DARF contain the same information with 2 exceptions: the Oral DARF contains areas to include the local protocol number and the bottle size.

Unless specifically stated, the information provided applies to both the original DARF and the Oral DARF.

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Line No.	Date	Patient's Initials	Patient's ID No.	Quantity	or	ward	Manufacturer and Lot No.	Recorder's Initials			
				Received	Balance						
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Note that the form has an expiration date located in the upper right corner. Once the expiration date has passed, do not start a new page without verifying it is the current form on the CTEP website.

In the event the current form on the website is expired, continue to use it until an updated form is posted.

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Protoco	l Title:					Dispensing Area:		
Phase	e II Study	of Ziv-Aflil	bercept in Me	tastatic Colo	n Cancer	IDS Pharma	acy - 5th Floor Ro	oom A100
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The header information can be typed before the DARF is printed or handwritten after printing. Please note the font size will automatically adjust based on the number of characters in the field. Anything handwritten must be legible.

Let's begin reviewing the header:

The first area to complete is the page number and record type. The DARF templates do not allow for the inclusion of a page number, it must be written in after printing.

Check the box indicating if this is a control or satellite record.

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Agent N Ziv-Afl		/EGF-Trap	o, AVE 0005, N	SC 724770)	—	Dose Form and St 200 mg / 8 mL	rength: . vial; 25 mg/mL	
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Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed Received	or	and Lot No.	Recorder's Initials
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Under the Name of Institution write out the name, avoiding abbreviations if possible.

For Agent Name include all names on the shipping receipt. While not required, add the NSC number.

Add the Protocol Title. Long titles can be abbreviated, but not to the point the protocol is unidentifiable or could be confused with another trial.

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Line No.	Date	Patient's Initials	Patient's ID No.	Quantity Dispensed Received	nsed or and Lot No. Initials			Recorder's Initials				
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For the Investigator Name include the first and last name. This is especially important with common last names such as Smith.

Add the CTEP Investigator Number. Note that a separate DARF is required for each ordering investigator.

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	of Institution: University H	lospital				NCI Protocol No.: 2468					
Agent N Ziv-Af		/EGF-Trap	o, AVE 0005, N	SC 724770)		Dose Form and St 200 mg / 8 mL	•	mg/mL			
Protoco		of Ziv-Aflil	bercept in Met	tastatic Colo	n Cancer	Dispensing Area: IDS Pharma	acy - 5t	h Floor Roo	om A100		
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Line No.	Date	Patient's Initials	Patient's ID No.	Quantity Dispensed Received		and Lot No.		Recorder's Initials			
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Next is the NCI Protocol Number. The NCI protocol number is required. The local protocol number is optional on both the original and Oral DARF. If a local protocol number is assigned, it can be added to the original or Oral DARF.

Next, identify the Dispensing Area. This is the location where the agent is stored.

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Agent Nam Ziv-Aflibe		/EGF-Trap	, AVE 0005,	NSC 724770)		Dose Form and Si 200 mg / 8 mL	•	mg/mL			
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Investigator						CTEP Investigator	r ID:				
Line No.	Date	Patient's Initials	Patient's ID No.	. Dose	Quantity Dispensed Received	or		Manufacturer and Lot No.	Recorder's Initials		
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Under Dose Form and Strength record the agent strength and formulation in this field. For injectable preparations include the concentration and volume per vial (for example 200 mg/8 mL vial, 25 mg/mL).

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	Name of Institution: State University Hospital NCI Protocol No.: 2468											
Agent Na Ziv-Afli		/EGF-Trap	o, AVE 0005, N	ISC 724770)		Dose Form and St 200 mg / 8 mL	•	5 mg/mL				
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Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed Received	sed or and Lot No. Initials						
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Here is an example of a completed original DARF header.

Next we will review the Oral DARF header.

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Stat		, ,	vital	n advanced renal cell	l carcinoma	John S NCI Protoc 1234	Smith, M.E	Local Protocol SUH-00		Dispensing A		99999	restigator ID: 99 Room A100
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There are two items specific to the Oral DARF. The Local Protocol Number, if there is no local number, leave the space blank or write in N/A and Bottle Size, add the number of tablets, capsules, etc. If this is a liquid preparation indicate the concentration and total volume per container.

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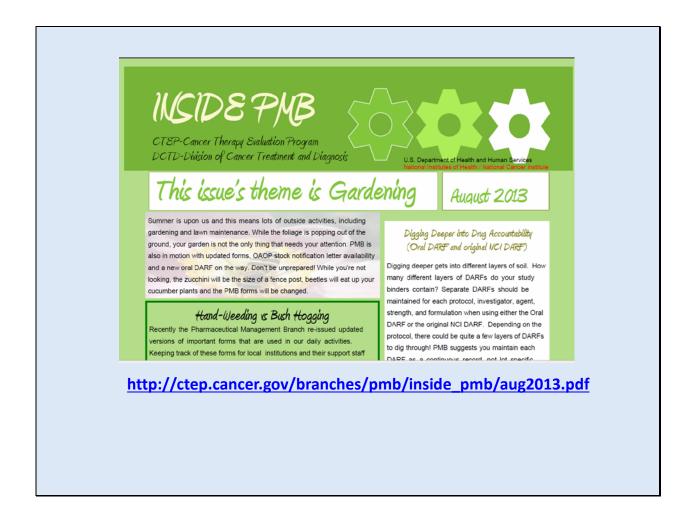
Here is an example of a completed Oral DARF header.

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	of Institution: te Univers	sity Hosp	ital				ator Name: n Smith, M.E).				OTEP Inv	restigator ID:	
	ol Title: 2 trial of pazop	anib for the tre	eatment of patients with	advanced renal cell ca	arcinoma	NCI Protocol No: Local Protocol No:				Dispensing A		h Floor R	doom A100	
	Name: opanib hy	drochlori	ide (NSC 7377	754)			om and Strength: mg Tablets				e.g., # tablets/lolets/bott			
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantit Dispense Receive	d́ or ├─	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials	
1.														
3.														
4.														
5.														
_6.														
7.														
8.														
9.														
10.														
<u>11.</u> 12.														
13.														

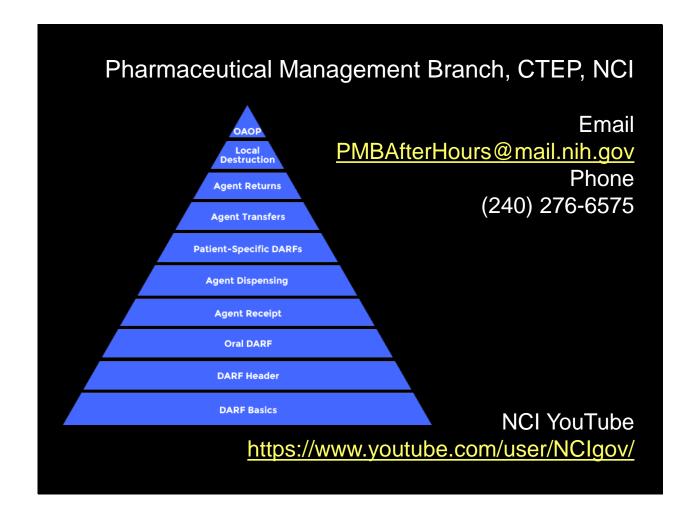
The DARF with a completed header may now be printed. If the appropriate software is available, the form may be saved for future use.



To learn more about the difference between Control and Satellite Dispensing Areas, refer to Section 5.3 of the Audit Guidelines.



Or the August 2013 issue of the PMB newsletter.



Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.

Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.

Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.

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