Attachment E01 – NCI/DCTD/CTEP Modified FDA Form 1572

OMB# 0925-0753 Expiration Date: 07/31/2021

Public reporting burden for this collection of information is estimated to be 15 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 (OMB #0925-0753). Do not return the completed form to this address.

Screenshots

NIH NATIONAL CAN	NCER INSTITUT	ΓE						
Registration and Credential Reposite	tory (RCR)			L Kathleen Yost (IVR - 18	Ø 3715) Active	A Notifications	C. Logout	9 Help
Welcome Practice Sites Labs* IRBs* Final Jump To +	you are the Site-Protocol PI.		pate on NCI-sponsored clinical research trials. Click on Populate Sites button to add sites to your 15' cord then search and add sites from the Search for Practice Sites Screen or you can remove existing		-			ch
	+ Add New Record	Site Name*	Site Address*	Updated Action	Undated Date		Populate Si	
		Im Health at Butterworth Campus	100 Michigan Street Northeast, MC001, Grand Rapids, MI 49503, US	NO CHANGE	04/12/2017 10:06:52 AM	RCRUSER	, compare	* •
	Click Previous to return to the	previous screen, Save and Continue to advan	Ince to the next screen or Back to Home to continue later.					

Figure 1: Form FDA 1572 - Electronic Capture of Practice Sites – Before Populating Sites

Registration and Credential Welcome Repository								
And the second se	Form FDA	1572						
Practice Sites	Practice							
	Confirm t	he institutio	ns, clinical centers or cancer centers where you participate on NC	I-sponsored clinical research trials. Click on Populate Sites button to add sites to your 1!	72 form based on the site	es at which you a	re rostered a	nd sites at
IRBs*			e-Protocol PL	a sponsored chines research chais, check on repulse area sociente and sites to your t	172 TOTTT DBSED ON the site	is at winch you a	re rostereu a	itu sites at
Final				search and add sites from the Search for Practice Sites screen or you can remove existir	o sites using the Delete b	utton located in	the Actions of	olumn
Jump To	Too come	oo procince.	and manually at any time by tacking the rate needs to then.		g mes using the believe o	inter rocarco in	Cherectoria c	
	+ Add N	lew Record						Populate Sites
	Actions	CTEP ID*	Site Name*	Site Address*	Updated Action	Updated Date		
	Delete	MI132	Spectrum Health at Butterworth Campus	100 Michigan Street Northeast, MC001, Grand Rapids, MI 49503, US	NO CHANGE	04/12/2017 10:06:52 AM	RCRUSER	^
	Delete	M1059	Munson Medical Center	1105 Sixth Street Traverse City 49684 MI US				
	Delete	MI117	Metro Health Hospital	5900 Byron Center Avenue Southwest Wyoming 49519 MI US				
	Delete	MI309	Spectrum Health Reed City Hospital	300 North Patterson Road Reed City 49677 MI US				
	Delete	M1276	Helen DeVos Children's Hospital at Spectrum Health	100 Michigan Northeast Mail Code 85 Grand Rapids 49503 MI US				
	Delete	M1047	Mercy Health Saint Mary's	200 Jefferson Street Southeast Grand Rapids 49503 MI US				
	Delete	M1081	McLaren Cancer Institute-Northern Michigan	416 Connable Avenue Petoskey 49770 MI US				
	Delete	M1045	Bronson Battle Creek	300 North Avenue Battle Creek 49017 MI US				
	Delete	MI269	Mercy Health Mercy Campus	1500 East Sherman Boulevard Muskegon 49444 MI US				
	Delete	MI108	Lakeland Hospital	1234 Napier Avenue Saint Joseph 49085 MI US				
	Delete	M1044	Bronson Methodist Hospital	Pharmacy Department 601 John Street Kalamazoo 49007 MI US				
	Delete	M1076	Holland Community Hospital	602 Michigan Avenue Holland 49423 MI US				
	Delete	MI324	Lakeland Community Hospital	31 North Saint Joseph Avenue Niles 49120 MI US				
	Delete	MI041	Borgess Medical Center	1521 Gull Road Kalamazoo 49001 MLUS				
	Delete	M1080	West Michigan Cancer Center	200 North Park Street Kalamazoo 49007 MI US				
	Delete	M1246	Marie Yeager Cancer Center	3900 Hollywood Avenue Saint Joseph 49085 MI US				
	Delete	MI133	Spectrum Health-Blodgett Campus	1840 Weathy Southeast Grand Rapids 49506 MI US				
	Delete	MI116	Spectrum Health Big Rapids Hospital	605 Oak Street Big Rapids 49307 MI US				
	Delete	M1075	Mercy Health Partners-Hackley Campus	1700 Clinton Street Muskegon 49442 MI US				*

Figure 2: Form FDA 1572 - Electronic Capture of Practice Sites - After Populating Sites

NIH NATIONAL CAN	ICER INSTITUTE						
Registration and Credential Reposito	ry (RCR)		L Kathleen Yost (IVR - 187	⊖ 15) Active	A Notifications	C+ Logout	• Help
Welcome Practice Sites* Labs IRBs* Final Jump To +	Form FDA 1572 Labs® Enter the clinical lab facilities that provide medical testing and services to the NI Click Add New Record then conduct a search from the Query for Labs screen to	ICI-sponsored clinical research trials on which you participate. to add labs to your profile or click the Delete button from the Actions column to remove a lab as n	eeded.				
	Add New Record Actions CLIA/CLP Number* Lab Name* Lick Previous to return to the previous screen, Save and Continue to advance	to the next screen or Back to Home to continue later.	Updated Action	Updated Date	Updated By	Compare	

Figure 3: Form FDA 1572 - Electronic Capture of Labs - Before Adding New Record

Registration and Credential Reposito	y (RCR)	Kathleen Yost (IVR - 18715)	(O) Active	Notifications	C.	• Help
Registration and Credential Practice Sites* Labs* IRBs Final jump To +	Form TDA 1572 IRBS* Enter the IRBs that oversee the NCI-sponsored clinical trials on which you participate. Click the Populate IRBs button to add IRBs that are associated to your selected Practice S (CIRB), all NCI CIRBs will be pre-populated. Click Add New Record then conduct a search from the Query for IRBs screen to add an IRB to your profile or click the Delete button from the Actions column to remove an IRI separately, cleating one will automatically delete all IRBs remaining on the CIRB. Note: NCI CIRBs are composed of four IRBs, and are added or removed as a package.	tte(s). If any of your Practice Site	s are covere	ed by the NCI (Central IRE	
	+ Add New Record Actions IRB Number* IRB Number* IRB Name* IRB Previous to return to the previous screen, Save and Continue to advance to the next screen or Back to Home to continue later. Click Previous to return to the previous screen, Save and Continue to advance to the next screen or Back to Home to continue later.	Updated Action Up	lated Date		Populate II	
						0

Figure 4: Form FDA 1572 - Electronic Capture of Labs - After Adding New Record

Registration and Credential Reposito	ory (RCR)			L Kathleen Yost (IVR - 1871)	Active Notificat	C.	• Help
Registration and Credential Welcome Practice Sites* Labe* Inia Jump To +	(CIRB), all NCI CIRBs will be pre-p Click Add New Record then cond separately; deleting one will auto	opulated.	Click the Populate IRBs button to add IRBs that are associated to your an IRB to your profile or click the Delete button from the Actions colur				
	+ Add New Record Actions IRB Number* Click Previous to return to the pr	IRB Name* revious screen, Save and Continue to advance to the	IRB Address* next screen or Back to Home to continue later, Previous Stree and Continue (* Back to Home)	Updated Action L	pdated Date Updat	Populate IR d By Compare	
						d	0

Figure 5: Form FDA 1572 - Electronic Capture of IRBs - Before Populating IRBs

stration and Credential Repo	sitory (RCR)				L (athleen Yost (IVR - 18	⊘ (715) Active	A Notifications	C Logout
me ce Sites* To	(CIRB), all Click Add separately	IRBs that oversee NCI CIRBs will be New Record the y; deleting one wi	e pre-populated.	Populate IRBs button to add IRBs that are associated to your selected Practice Site(s your profile or click the Delete button from the Actions column to remove an IRB as				
		ords added succe	essfully.					
	IRB reco	ords added succe						Populate IF
	IRB reco	IRB Number*	IRB Name*	IRB Address*	Updated Action	Updated Date		
	IRB reco + Add N Actions Delete	IRB Number*	1RB Name* National Cancer Inst Central IRB #1 (Adult)	401 N. Washington Street, 7th Floor, Rockville, MARYLAND 20850	Updated Action	Updated Date		
	+ Add N Actions Delete Delete	IRB Number* IRB00000781 IRB00000971	188 Name* National Cancer Inst Central I® #1 (Adul) Schulman Associates Institutional Review Baard, Inc. 188 #1	401 N. Washington Street, 7th Floor, Rockville,MARYLAND 20850 4445 Lake Forest Drive, Suite 300, Cincinnati,OHIO 45242	Updated Action	Updated Date		
	IRB reco + Add N Actions Delete Delete Delete	IRB Number* IRB00000781 IRB00000971 IRB00000883	IBB Name* National Cancer Inst Central IBB #1 (Adut) Schulman Associates Instituctional Review Board, Inc. IBB #1 Spectrum Hith IBB #1	401 N. Washington Street, 7th Floor, Rockville,MARYLAND 20850 4445 Lake Forest Drive, Suite 300, Cincinnati,OHID 45242 25 Michigan Street, Suite 4300, Grand Rapids,MICHIGAN 49503	Updated Action	Updated Date		
	+ Add N Actions Delete Delete Delete Delete	ew Record IRB Number* IRB00000781 IRB00000971 IRB00000883 IRB00000833	IRB Name* National Cancer Inst Central IBI #1 (Andr) Schulman Associates Institutional Review Board, Inc. IBB #1 Goodwyn Institutional Review Board, Ltd, IBB #1	401 N. Washington Street, 7th Floor, Rockville, MARYLAND 20850 4445 Lake Forest Drver, Suite 200, Cincinnati, OHD 45242 25 Michigan Street, Suite 200, Grind Rupist, MICHIGAN 49503 9380 Main Street, Cincinnati, OHD 45242	Updated Action	Updated Date		
	IRB recc + Add N Actions Delete Delete Delete	IRB Number* IRB 00000781 IRB00000971 IRB0000083 IRB0000833 IRB00002605	IBB Name* National Cancer Inst Central IBB #1 (Adut) Schulman Associates Instituctional Review Board, Inc. IBB #1 Spectrum Hith IBB #1	401 N. Washington Street, 7th Floor, Rockville,MARYLAND 20850 4445 Lake Forest Drive, Suite 300, Cincinnati,OHID 45242 25 Michigan Street, Suite 4300, Grand Rapids,MICHIGAN 49503	Updated Action	Updated Date		
	IRB recc + Add N Actions Delete Delete Delete Delete	IRB Number* IRB Number* IRB00000781 IRB0000083 IRB00000833 IRB00002605 IRB00009430	188 Name* National Cancer Inst Central III # 1 (Aulul) Schulman Associates Institutional Review Board, Inc. IBB #1 Spectrum Hith IIB #1 West Michigan Cancer Ctr IBB #1	401 N. Washington Street, 7th Floor, Rockviller,MARTLAND 20850 4445 Lake Forest Drive, Suite 200, Cincinnatt,OHI0 45242 25 Michings Street,Suite 200, Gind Rapids,MCHIGAN 49503 9380 Main Street, Cincinnatt,OHI0 45242 200 North Park St, Salamanoa MICHORA 40007 9609 Media Center Drive, C/O Jacquelyn Goldberg, Rm 5-W432 MSC 9742,	Updated Action	Updated Date		

Figure 6: Form FDA 1572 - Electronic Capture of IRBs - After Populating IRBs

Breakdown of Elements

There are three different sections of Form FDA 1572 that are electronically captured, with the following information displayed for each section:

- 1. Practice Sites
 - a. Add New Record: Allows the investigator to manually search for and add a practice site to their Form FDA 1572.
 - b. Populate Sites: Allows the investigator to automatically add sites to their Form FDA 1572 based on the sites at which they are rostered and the sites at which they are the Site-Protocol PI.
 - c. Delete: Allows the investigator to delete a practice site from their Form FDA 1572.
 - d. CTEP ID: Displays the CTEP ID of the practice site.
 - e. Site Name: Displays the Name of the practice site
 - f. Site Address: Displays the practice site's Address.
- 2. Labs
 - a. Add New Record: Allows the investigator to manually search for and add a lab to their Form FDA 1572.
 - b. Actions: Allows the investigator to delete a lab from their Form FDA 1572.
 - c. Delete: Allows the investigator to delete a lab from their Form FDA 1572.
 - d. Provider Number: Displays the Provider Number of the lab.
 - e. Lab Name: Displays the name of the lab.
 - f. Lab Address: Displays the address of the lab.
 - g. Updated Action: Displays the latest status of the lab.
- 3. IRBs

- a. Add New Record: Allows the investigator to manually search for and add an IRB to their Form FDA 1572.
- b. Populate IRBs: Allows the investigator to automatically add IRBs that are associated to their selected practice site(s). If the practice site(s) are covered by the NCI Central IRB (CIRB), all NCI CIRBs will be prepopulated.
- c. Delete: Allows the investigator to delete an IRB from their Form FDA 1572.
- d. IRB Number: Displays the IRB number.
- e. IRB Name: Displays the name of the IRB.
- f. IRB Address: Displays the IRB's address.