# **06.1** HHS Privacy Impact Assessment (Form) / NIH NINDS Clinical Information Management System (CIMS) (Item)

Form Report, printed by: Wright, Verle, Nov 27, 2012

should be No and only the PIA Summary must be completed.

PIA SUMMARY				
1				
The following required questions with an asterisk (*) represent the information necessary to complete the PIA Summary for transmission to the Office of Management and Budget (OMB) and public posting in accordance with OMB Memorandum (M) 03-22.				
Note: If a question or its response is not applicable, please answer "N/A" to that question where possible. If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of personally identifiable information (PII). If no PII is contained in the system, please answer questions in the PIA Summary Tab and then promote the PIA to the Senior Official for Privacy who will authorize the PIA. If this system contains PII, all remaining questions on the PIA Form Tabs must be completed prior to signature and promotion.				
2 Summary of PIA Required Questions				
*Is this a new PIA?				
No				
If this is an existing PIA, please provide a reason for revision:				
PIA Validation				
*1. Date of this Submission:				
Aug 24, 2012				
*2. OPDIV Name:				
NIH				
*4. Privacy Act System of Records Notice (SORN) Number (If response to Q.:	21 is Yes, a SORN number is required for Q.4):			
09-25-200				
*5. OMB Information Collection Approval Number:				
N/A				
*6. Other Identifying Number(s):				
N/A				
*7. System Name (Align with system item name):				
Clinical Information Management System (CIMS)				
*9. System Point of Contact (POC). The System POC is the person to whom	questions about the system and the responses to this PIA may be addressed:			
Point of Contact Information				
POC Name	Quang Hoang			
*10. Provide an overview of the system:				
CIMS supports the Clinical Research program of NINDS. It consists the Protocol Tracking and Management System (PTMS), that store i patients involved in those research studies.	of two subsystems, the Clinical Study Information System (CSIS) and information relevant to the Clinical Research studies of NINDS and			
*13. Indicate if the system is new or an existing one being modified:				
Existing				
*17. Does/Will the system collect, maintain (store), disseminate and/or pass the system?	nrough PII within any database(s), record(s), file(s) or website(s) hosted by this			
TIP: If the answer to Question 17 is "No" (indicating the system does not contain PII), only the remaining PIA Summary tab questions need to be completed and submitted. (Although note that "Employee systems," – i.e., systems that collect PII "permitting the physical or online contacting of a specific individual employed [by] the Federal Government – only need to complete the PIA Summary tab.)				
Yes				

17a. Is this a GSS PIA included for C&A purposes only, with no ownership of underlying application data? If the response to Q.17a is Yes, the response to Q.17

\*19. Are records on the system retrieved by 1 or more PII data elements?

Yes

\*21. Is the system subject to the Privacy Act? (If the response to Q.19 is Yes, the response to Q.21 must be Yes and a SORN number is required for Q.4)

Yes

\*23. If the system shares or discloses PII, please specify with whom and for what purpose(s):

Does not share or disclose PII.

\*30. Please describe in detail: (1) The information the agency will collect, maintain, or disseminate (clearly state if the information contained in the system ONLY represents federal contact data); (2) Why and for what purpose the agency will use the information; (3) Explicitly indicate whether the information contains PII; and (4) Whether submission of personal information is voluntary or mandatory:

CIMS supports the Clinical Research program of NINDS. It consists of two subsystems, the Clinical Study Information System (CSIS) and the Protocol Tracking and Management System (PTMS), that store information relevant to the Clinical Research studies of NINDS and patients involved in those research studies. Some PII information may be maintained by the CSIS subsystem, but not by PTMS. Submission of a minimal amount of personal information is required for patients who have volunteered to participate in the clinical studies.

\*31. Please describe in detail any processes in place to: (1) Notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) Notify and obtain consent from individuals regarding what PII is being collected from them; and (3) How the information will be used or shared. (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]):

Participants in clinical studies volunteer to participate in the studies and give their written consent to provide PII and medical information. They are notified of such study requirements when they volunteer for the studies, and they are given information on how the study information may be used. It is not feasible to obtain further consent for any later changes in the CIMS system.

\*32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII)

Yes

\*37. Does the website have any information or pages directed at children under the age of thirteen?

No

\*50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN)

Yes

\*54. Briefly describe in detail how the PII will be secured on the system using administrative, technical, and physical controls:

Role based security, using authorized user name and password for network access to CIMS. System resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

#### PIA REQUIRED INFORMATION

# 1 HHS Privacy Impact Assessment (PIA)

The PIA determines if Personally Identifiable Information (PII) is contained within a system, what kind of PII, what is done with that information, and how that information is protected. Systems with PII are subject to an extensive list of requirements based on privacy laws, regulations, and guidance. The HHS Privacy Act Officer may be contacted for issues related to Freedom of Information Act (FOIA) and the Privacy Act. Respective Operating Division (OPDIV) Privacy Contacts may be contacted for issues related to the Privacy Act. The Office of the Chief Information Officer (OCIO) can be used as a resource for questions related to the administrative, technical, and physical controls of the system. Please note that answers to questions with an asterisk (\*) will be submitted to the Office of Management and Budget (OMB) and made publicly available in accordance with OMB Memorandum (M) 03-22.

Note: If a question or its response is not applicable, please answer "N/A" to that question where possible.

2	General Information			
*Is this a	new PIA?			
No				
If this is a	an existing PIA, please provide a reason for revision:			
PIA Vali	dation			
*1. Date	of this Submission:			
Aug 24,	2012			
*2. OPDI	V Name:			
NIH				
3. Unique	e Project Identifier (UPI) Number for current fiscal year (Data is auto-pop	oulated from the System Inventory form, UPI table):		
*4. Privad	cy Act System of Records Notice (SORN) Number (If response to Q.21	is Yes, a SORN number is required for Q.4):		
09-25-2	00			
*5. OMB	Information Collection Approval Number:			
N/A				
5a. OMB	Collection Approval Number Expiration Date:			
*6. Other	Identifying Number(s):			
N/A				
*7. Syste	m Name: (Align with system item name)			
Clinical	Information Management System (CIMS)			
8. Syster	n Location: (OPDIV or contractor office building, room, city, and state)			
Syst	em Location:			
OPD	IV or contractor office building	NIH Building CRC		
Roo	m	CRC/B25750		
City		Bethesda		
Stat		MD		
	State Pip			
*9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:				
Point of Contact Information				
POC Name Quang Hoang				
The following information will not be made publicly available:				
The fellowing information will not be made publicly divinable.				
	POC Title C&A Manager			
POC	Title	C&A Manager		

POC Organization	NINDS/DIR/ITP
POC Phone	301-443-2902
POC Email	hoangq@ninds.nih.gov

<sup>\*10.</sup> Provide an overview of the system: (Note: The System Inventory form can provide additional information for child dependencies if the system is a GSS)

CIMS supports the Clinical Research program of NINDS. It consists of two subsystems, the Clinical Study Information System (CSIS) and the Protocol Tracking and Management System (PTMS), that store information relevant to the Clinical Research studies of NINDS and patients involved in those research studies.

#### SYSTEM CHARACTERIZATION AND DATA CATEGORIZATION

### 1 System Characterization and Data Configuration

11. Does HHS own the system?

Yes

11a. If no, identify the system owner:

Name: Donna Stephenson

Component: National Institutes of Health

Address: Phone:

Email: Stephedo@nih.ninds.gov

FAX:

12. Does HHS operate the system? (If the system is operated at a contractor site, the answer should be No)

Yes

12a. If no, identify the system operator:

\*13. Indicate if the system is new or an existing one being modified:

Existing

14. Identify the life-cycle phase of this system:

Operations/Maintenance

15. Have any of the following major changes occurred to the system since the PIA was last submitted?

No

Please indicate "Yes" or "No" for each category below:	Yes/No
Conversions	No
Anonymous to Non-Anonymous	No
Significant System Management Changes	No
Significant Merging	No
New Public Access	No
Commercial Sources	No
New Interagency Uses	No
Internal Flow or Collection	No
Alteration in Character of Data	No

16. Is the system a General Support System (GSS), Major Application (MA), Minor Application (child) or Minor Application (stand-alone)?

Minor Application (child)

\*17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?

Yes

TIP: If the answer to Question 17 is "No" (indicating the system does not contain PII), only the remaining PIA Summary tab questions need to be completed and submitted. (Although note that "Employee systems," – i.e., systems that collect PII "permitting the physical or online contacting of a specific individual ... employed [by] the Federal Government – only need to complete the PIA Summary tab.)

Please indicate "Yes" or "No" for each PII category. If the applicable PII category is not listed, please use the Other field to identify the appropriate category of PII.

Categories:	Yes/No
Name (for purposes other than contacting federal employees)	Yes

Date of Birth	Yes
Social Security Number (SSN)	No
Photographic Identifiers	No
Driver's License	No
Biometric Identifiers	No
Mother's Maiden Name	No
Vehicle Identifiers	No
Personal Mailing Address	Yes
Personal Phone Numbers	Yes
Medical Records Numbers	Yes
Medical Notes	Yes
Financial Account Information	No
Certificates	No
Legal Documents	No
Device Identifiers	No
Web Uniform Resource Locator(s) (URL)	No
Personal Email Address	Yes
Education Records	No
Military Status	No
Employment Status	No
Foreign Activities	No
Other	None

17a. Is this a GSS PIA included for C&A purposes only, with no ownership of underlying application data? If the response to Q.17a is Yes, the response to Q.17 should be No and only the PIA Summary must be completed.

18. Please indicate the categories of individuals about whom PII is collected, maintained, disseminated and/or passed through. Note: If the applicable PII category is not listed, please use the Other field to identify the appropriate category of PII. Please answer "Yes" or "No" to each of these choices (NA in other is not applicable).

Categories:	Yes/No
Employees	No
Public Citizen	No
Patients	Yes
Business partners/contacts (Federal, state, local agencies)	No
Vendors/Suppliers/Contractors	No
Other	None

\*19. Are records on the system retrieved by 1 or more PII data elements?

Yes

Please indicate "Yes" or "No" for each PII category. If the applicable PII category is not listed, please use the Other field to identify the appropriate category of PII.

Categories:	Yes/No

Name (for purposes other than contacting federal employees)	Yes
Date of Birth	Yes
SSN	No
Photographic Identifiers	No
Driver's License	No
Biometric Identifiers	No
Mother's Maiden Name	No
Vehicle Identifiers	No
Personal Mailing Address	Yes
Personal Phone Numbers	Yes
Medical Records Numbers	Yes
Medical Notes	No
Financial Account Information	No
Certificates	No
Legal Documents	No
Device Identifiers	No
Web URLs	No
Personal Email Address	Yes
Education Records	No
Military Status	No
Employment Status	No
Foreign Activities	No
Other	None

20. Are 10 or more records containing PII maintained, stored or transmitted/passed through this system?

Yes

\*21. Is the system subject to the Privacy Act? (If the response to Q.19 is Yes, the response to Q.21 must be Yes and a SORN number is required for Q.4)

Yes

21a. If yes but a SORN has not been created, please provide an explanation.

#### **INFORMATION SHARING PRACTICES**

#### 1 Information Sharing Practices

22. Does the system share or disclose PII with other divisions within this agency, external agencies, or other people or organizations outside the agency?

No

Please indicate "Yes" or "No" for each category below:	Yes/No
Name (for purposes other than contacting federal employees)	No
Date of Birth	No
SSN	No
Photographic Identifiers	No
Driver's License	No
Biometric Identifiers	No
Mother's Maiden Name	No
Vehicle Identifiers	No
Personal Mailing Address	No
Personal Phone Numbers	No
Medical Records Numbers	No
Medical Notes	No
Financial Account Information	No
Certificates	No
Legal Documents	No
Device Identifiers	No
Web URLs	No
Personal Email Address	No
Education Records	No
Military Status	No
Employment Status	No
Foreign Activities	No
Other	None

\*23. If the system shares or discloses PII please specify with whom and for what purpose(s):

Does not share or disclose PII.

24. If the PII in the system is matched against PII in one or more other computer systems, are computer data matching agreement(s) in place?

Not Applicable

25. Is there a process in place to notify organizations or systems that are dependent upon the PII contained in this system when major changes occur (i.e., revisions to PII, or when the system is replaced)?

Yes

26. Are individuals notified how their PII is going to be used?

Yes

26a. If yes, please describe the process for allowing individuals to have a choice. If no, please provide an explanation.

Patients for clinical studies are all volunteers

27. Is there a complaint process in place for individuals who believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate?

Yes

27a. If yes, please describe briefly the notification process. If no, please provide an explanation.

Individuals can contact the coordinator for their study to request changes or file complaints.

28. Are there processes in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy?

Yes

28a. If yes, please describe briefly the review process. If no, please provide an explanation.

The users of CIMS periodically reveiw their information for correctness

29. Are there rules of conduct in place for access to PII on the system?

Yes

Please indicate "Yes," "No," or "N/A" for each category. If yes, briefly state the purpose for each user to have access:

Users with access to PII	Yes/No/N/A	Purpose
User	Yes	To support their clinical studies
Administrators	Yes	Only as necessary to support the system
Developers	Yes	Only as necessary to support system development
Contractors	No	
Other	No	

<sup>\*30.</sup> Please describe in detail: (1) The information the agency will collect, maintain, or disseminate (clearly state if the information contained in the system ONLY represents federal contact data); (2) Why and for what purpose the agency will use the information; (3) Explicitly indicate whether the information contains PII; and (4) Whether submission of personal information is voluntary or mandatory:

CIMS supports the Clinical Research program of NINDS. It consists of two subsystems, the Clinical Study Information System (CSIS) and the Protocol Tracking and Management System (PTMS), that store information relevant to the Clinical Research studies of NINDS and patients involved in those research studies. Some PII information may be maintained by the CSIS subsystem, but not by PTMS. Submission of a minimal amount of personal information is required for patients who have volunteered to participate in the clinical studies.

\*31. Please describe in detail any processes in place to: (1) Notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) Notify and obtain consent from individuals regarding what PII is being collected from them, and (3) How the information will be used or shared. (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.])

Participants in clinical studies volunteer to participate in the studies and give their written consent to provide PII and medical information. They are notified of such study requirements when they volunteer for the studies, and they are given information on how the study information may be used. It is not feasible to obtain further consent for any later changes in the CIMS system.

	WEBSITE HOSTING PRACTICES			
:	1 Website Hosting Practices			
	*32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII)			
Yes	3			
	Please indicate "Yes" or "No" for each type of site below. If the system hosts both Internet and Intranet sites, indicate "Yes" for "Both" only.			If the system hosts an Internet site, please enter the site URL. Do not enter any URL(s) for Intranet sites.
	Internet	No		
	Intranet	Yes		
	Both	No		
Not pro web	Does the system host a website that is accessible e: OMB M-03-22 Attachment A, Section III, Subsectivides three exceptions: (1) Websites containing infosites that are accessible only by authorized governined at 40 U.S.C. 11103 as exempt from the definite	ction C requires agencies ormation other than "gove nment users (employees,	to post a privacy policy for emment information" as de- contractors, consultants, fo	websites that are accessible to the public, but fined in OMB Circular A-130; (2) Agency intranet ellows, grantees); and (3) National security systems
No 34.	If the website does not meet one or more of the ex nsistent with OMB M-03-22 and Title II and III of the	rceptions described in Q.	33 (i.e., response to Q. 33	is "Yes"), a website privacy policy statement
Yes	5			
	If a website privacy policy is required (i.e., respons ferences (P3P)?	se to Q. 34 is "Yes"), is the	e privacy policy in machine	-readable format, such as Platform for Privacy
Yes	5			
35a	n. If no, please indicate when the website will be P3	P compliant:		
36. No	Does the website employ tracking technologies?			
INO				
	Please indicate "Yes", "No", or "N/A" for each type of cookie below:		Yes/No/N/A	
	Web Bugs		No	
	Web Beacons		No	
	Session Cookies		No	
	Persistent Cookies		No	
	Other			
+^-	Describes a definite and a first of	discrete district difference	W	
	. Does the website have any information or pages	directed at children under	the age of thirteen?	
	n. If yes, is there a unique privacy policy for the site offected?	, and does the unique priv	racy policy address the pro	ocess for obtaining parental consent if any information
20	Does the website collect PII from individuals?			
Yes				
163	,			
ſ	Please indicate "Yes" or "No" for each	category below:	Yes/No	

Name (for purposes other than contacting federal employees)	Yes
Date of Birth	Yes
SSN	No
Photographic Identifiers	No
Driver's License	No
Biometric Identifiers	No
Mother's Maiden Name	No
Vehicle Identifiers	No
Personal Mailing Address	Yes
Personal Phone Numbers	Yes
Medical Records Numbers	Yes
Medical Notes	Yes
Financial Account Information	No
Certificates	No
Legal Documents	No
Device Identifiers	No
Web URLs	No
Personal Email Address	Yes
Education Records	No
Military Status	No
Employment Status	No
Foreign Activities	No
Other	None

39. Are rules of conduct in place for access to PII on the website?

Yes

40. Does the website contain links to sites external to HHS that owns and/or operates the system?

No

40a. If yes, note whether the system provides a disclaimer notice for users that follow external links to websites not owned or operated by HHS.

#### **ADMINISTRATIVE CONTROLS**

#### 1 **Administrative Controls**

Note: This PIA uses the terms "Administrative," "Technical" and "Physical" to refer to security control questions—terms that are used in several Federal laws when referencing security requirements.

41. Has the system been certified and accredited (C&A)?

Yes

41a. If yes, please indicate when the C&A was completed:

Jun 5, 2009

41b. If a system requires a C&A and no C&A was completed, is a C&A in progress?

Not Applicable

42. Is there a system security plan for this system?

Yes

43. Is there a contingency (or backup) plan for the system?

Yes

44. Are files backed up regularly?

Yes

45. Are backup files stored offsite?

Yes

46. Are there user manuals for the system?

47. Have personnel (system owners, managers, operators, contractors and/or program managers) using the system been trained and made aware of their responsibilities for protecting the information being collected and maintained?

Yes

48. If contractors operate or use the system, do the contracts include clauses ensuring adherence to privacy provisions and practices?

49. Are methods in place to ensure least privilege (i.e., "need to know" and accountability)?

Yes

49a. If yes, please specify method(s):

Audit trails

\*50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

50a. If yes, please provide some detail about these policies/practices:

NINDS follows the HHS and NIH policies found in:

NIH POLICY MANUAL

2805 - NIH Web Page Privacy Policy

# **TECHNICAL CONTROLS**

# 1 Technical Controls

51. Are technical controls in place to minimize the possibility of unauthorized access, use, or dissemination of the data in the system?

Yes

Please indicate "Yes" or "No" for each category below:	Yes/No
User Identification	Yes
Passwords	Yes
Firewall	Yes
Virtual Private Network (VPN)	Yes
Encryption	Yes
Intrusion Detection System (IDS)	Yes
Common Access Cards (CAC)	No
Smart Cards	No
Biometrics	No
Public Key Infrastructure (PKI)	No

52. Is there a process in place to monitor and respond to privacy and/or security incidents?

Yes

52a. If yes, please briefly describe the process:

The NINDS SOC monitors and responds to privacy and security incidents, and NINDS follows the NIH IRT's policies and guidelines.

#### **PHYSICAL ACCESS**

# 1 Physical Access

53. Are physical access controls in place?

Yes

Please indicate "Yes" or "No" for each category below:	Yes/No
Guards	Yes
Identification Badges	Yes
Key Cards	Yes
Cipher Locks	No
Biometrics	No
Closed Circuit TV (CCTV)	No

<sup>\*54.</sup> Briefly describe in detail how the PII will be secured on the system using administrative, technical, and physical controls:

Role based security, using authorized user name and password for network access to CIMS. System resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

APPROVAL/DEMOTION				
1	System Informatio	ormation		
Syster	n Name:	Clinical Information Management Sy	stem (CIMS)	
_				
	2 PIA Reviewer Approval/Promotion or Demotion			
Promo	romotion/Demotion: Promote			
Comm	Comments:			
	proval/Demotion Point Joellen Harper Austin, Executive Officer, NINDS 301-496-4697 Contact:			
Date:		Aug 24, 2012		
3 Senior Official for Privacy Approval/Promotion or Demotion				
Promo	otion/Demotion: Promote			
Comm	ents:			
4	1	cial for Privacy or Designee Ap	-	
	Please print the PIA and obtain the endorsement of the reviewing official below. Once the signature has been collected, retain a hard copy for the OPDIV's records. Submitting the PIA will indicate the reviewing official has endorsed it			
This PIA has been reviewed and endorsed by the OPDIV Senior Official for Privacy or Designee (Name and Date):				
Name:	Name: Date:			
Nar	ne:		Karen Plá	
Date:			Sep 28, 2012	
5	5 Department Approval to Publish to the Web			
Appro	ved for web publishing		No	
Date P	ublished:		Sep 1, 2009	
Public	Publicly posted PIA URL or no PIA URL explanation:			

	PIA % COMPLETE		
1	1 PIA Completion		
PIA Percentage Complete:		100.00	
PIA Missing Fields:			