US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

06/11/2024

OPDIV:

NIH

Name:

NIAID Electronic Master File (NeTMF) System

PIA Unique Identifier:

P-4583097-198940

The subject of this PIA is which of the following?

Minor Application (stand-alone)

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

No

Does the system include a Website or online application available to and for the use of the general public?

Yes

Identify the operator.

Contractor

Is this a new or existing system?

New

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

The National Institute of Allergy and Infectious Diseases (NIAID) defines an Electronic Trial Master File ((eTMF) as a vendor cloud-hosted, web-based system that is utilized for the oversight, management and operation of a clinical trial. The NIAID Electronic Trial Master File (NeTMF) is a minor SaaS application housed in an Amazon Web Services (AWS) cloud operated by TransPerfect. The NeTMF supports the implementation of the TrialInteractive eTMF for the National Institutes of Health (NIH) and NIAID to ensure compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2) and other applicable and current clinical research regulations and requirements. The system provides for effective clinical trial management by serving as a repository of the essential clinical trial documentation and data records stored in the eTMF. This repository provides for clinical trial protocol compliance evaluation, safe conduct trial oversight, and provides for the evaluation data quality.

The Trial Master File (TMF) Reference Model (RM) is a supported initiative through the Clinical Data

Interchange Standards Consortium (CDISC), a recognized and highly respected professional association. This model consists of standardized taxonomy and metadata and outlines the clear definition and organization of TMF content using standard nomenclature. TransPerfect's eTMF module utilizes a default template based on the Drug Information Association (DIA) TMF Reference Model version 3.2.1 that was released in November, 2020.

Describe the type of information the system will collect, maintain (store), or share.

The NIAID eTMF system supports the creation and storage of new scientific and/or technological knowledge enabling NIAID Clinical Trial research. The personally identifiable information (PII) collected and utilized by the system to process the Curriculum Vitae (CV) and applicants are as follows: clinical investigator's/Principal Investigator (PI)/research practitioners' names, photographic identifiers, addresses, phone number, email addresses, usernames, certifications and certificates of education, and their CVs/resumes.

Users log in to the various supported systems using the NIH Identity, Credential, and Access Management (IAM) Services, which maintains its own unique privacy impact assessment (PIA) on record, including all legal authorities documented. The IAM Services collect unique user credentials and stores them in an encrypted format. The IAM Services are an essential service that facilitates and governs network access to various resources.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

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Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Name
Photographic Identifiers
E-Mail Address
Mailing Address
Phone Numbers
Certificates
Education Records
Resumes\Curriculum Vitae (CV)
Certificates of education
Username

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Employees
Business Partner/Contacts (Federal/state/local agencies)
Vendor/Suppliers/Contractors

How many individuals' PII is in the system?

100-499

For what primary purpose is the PII used?

Principal Investigators working on NIAID Clinical Trials must provide evidence of their credentials. Researchers' certificates of education, background information, and resumes are collected and stored within NIAID eTMF as evidence of their qualifications.

Describe the secondary uses for which the PII will be used.

None

Identify legal authorities governing information use and disclosure specific to the system and program.

42 U.S.C. 241(d), 281

Are records on the system retrieved by one or more PII data elements?

No

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains
In-Person
Online
Government Sources
Within OpDiv
Non-Government Sources
Private Sector

Identify the OMB information collection approval number and expiration date

NIH Public Law 114-255, Section 2035, exempts research conducted by NIH from Paperwork Reduction Act (PRA) requirements.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

Principal Investigators' CV are stored in NeTMF as key documents required for regulatory compliance as part of Good Clinical Practices (GCP). Principal Investigators understand that their PII is submitted into the clinical trial records as required by the regulatory filing process.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.

Principal Investigators are notified that their resumes are required in order to work on NIAID clinical trials at the time of being chosen as a Principal Investigator. Any individuals who do not wish to have their PII utilized understand that they are not candidates for being principal investigators in clinical trials. There is no option to opt-out of submitting their CV as part of being a Principal Investigator.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

Business Owners and System Owners are the owners of the data within eTMF and own the Principal Investigator's contracts. They are responsible for any and all written communications that would notify the Principal Investigators of any changes to the system and the data within.

Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.

Principal Investigators are responsible for what PII is obtained, used, or disclosed. Based on the PII obtained, it is the Principal Investigator's responsibility to resolve any inaccuracies within the system. As eTMF is a repository for the PI's CVs, any post-submission changes to the CVs must follow the clinical trial's administrative process as defined by the Business Owner.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

During the course of each clinical trial's activities, the system maintains the information for the Principal Investigator(s) that are assigned to the trial in question. Annual Reports are created on a periodic basis, which would document any changes to the trials, including any changes to the principal investigator(s) who are assigned to the clinical trials and their information. In the event there are changes to Principal Investigator's information during the course of a clinical trial, it is the Principal Investigator's responsibility to notify the Clinical Trial head and provide updated information. This is standard process under NIAID Clinical Trials and Principal Investigator's must agree to notify of any changes before being chosen to work on a clinical trial.

After the clinical trial is completed, the periodic reviews cease as the last review would document the last accurate state of the information.

Identify who will have access to the PII in the system and the reason why they require access.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Access to information on the system is role based, with minimum required access assigned.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Access to information on the system is role based, with minimum required access assigned.

Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.

According to NIH policy, all personnel who manage or operate NIH applications must successfully complete annual security awareness training. There are five categories of mandatory information technology (IT) training (Information Security, Counterintelligence, Privacy Awareness, Records Management and Emergency Preparedness). Training is completed on the http://irtsectraining.nih.gov site with valid NIH credentials. Administrators and Privileged Users require additional training specific to their roles and responsibilities.

Describe training system users receive (above and beyond general security and privacy awareness training).

Role based training for administrators of the system.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

Information maintained in the NIAID eTMF as part of clinical trial regulatory activities are retained and disposed under the authority of the (NIH Intramural Records Schedule, Item I-0003: Records of All Other Intramural Research Projects. These are temporary records, cut off at termination of project/program or when no longer needed for scientific reference, whichever is longer. Destroy 7 years after cutoff.

[Disposition Authority: DAA-0443-2012-0007-0003]

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

Administrative: Documented processes have been in place to determine and grant the appropriate role-based access to all data, including PII housed within the system. This access will be reviewed periodically as defined in process documentation to validate the continued access to the system and the PII .

Technical: Users who have the appropriate role/group permissions have the ability to view PII data, while those that do not have such access cannot view PII. All data is contained to the eTMF system.

Physical Controls: The eTMF system is vendor-hosted in a FedRAMPed AWS Datacenter that is based within the AWS East region, with a secondary location housed within the AWS West Regions. Amazon's AWS Datacenters have strict physical controls in place in that no-third party entities, such as NIH personnel, may gain access to the Datacenter without requesting access through AWS Physical Access processes. The system is within a dedicated instance so the vendor does not allow any other organizations to be housed within the same instance as the eTMF system.

Identify the publicly-available URL:

https://niaid.trialinteractive.com/

Note: web address is a hyperlink.

Does the website have a posted privacy notice?

Yes

Is the privacy policy available in a machine-readable format?

Yes

Does the website use web measurement and customization technology?

Yes

Select the type of website measurement and customization technologies is in use and if it is used to collect PII.

Does the website have any information or pages directed at children uner the age of thirteen?

No

Does the website contain links to non- federal government websites external to HHS?

Yes

Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?

No