US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

03/06/2025

OPDIV:

NIH

Name:

CRU Clinical Management System

PIA Unique Identifier:

P-5871175-590386

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.

Agency

Is this a new or existing system?

Existing

Does the system have Security Authorization (SA)?

Yes

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

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

The PIA has been updated to meet the requirements of Executive Order - Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government.

Describe the purpose of the system.

The purpose of the Clinical Research Unit (CRU) System is to document, track, monitor, analyze, and evaluate data and information obtained for research participants through the NIH and the National Institute of Environmental Health Sciences (NIEHS) Institutional Review Board (IRB) approved clinical, basic, and population-based research activities and protocols about participants' health and environmental exposures.

The following are included in the CRU System:

Non-study Specific Inquiries to the CRU - collection of limited personal information to assess

research participant eligibility.
Body Weight and Puberty - investigating impact of obesity on pubertal development in girls.

Bisphenol A (BPA) Pharmacokinetic (PK) Controlled Exposure Study (BPA/PK) - Understanding how BPA (used to make plastics/resins/chemicals) acts in the body, and how the body rids it.

Calorie Restriction, Environment and Fitness: Reproductive Effects Evaluation Study (CaREFREE) - studying healthy female volunteers' reproductive history, family history, and current metabolic status based on appetite, food intake regulation and metabolism.

COVID-19 SeroSurvey - collection of samples and data to identify the presence and rate of development of anti-COVID-19 antibodies in North Carolina.
Role of Functionally Relevant Cyclooxygenase-2 (COX-2) Gene Single Nucleotide Plymorphisms in Lymphocyte Differentiation (COX-2).

Environmental Polymorphisms Registry (EPR) - collection of deoxyribonucleic acid (DNA) to examine various risk factors. First Period - investigating normal reproductive development in girls.

Human Endothelial Function (Fibromuscular Dysplasia (FMD) Blood Vessel Study) - examining certain endothelial (the thin membrane lining the inside of the heart and blood vessels) and FMD.

Role of Glucocorticoid Receptor Single Nucleotide Polymorphisms [SNPs] in Receptor Function and Metabolic Disease - a gene association study.

Gonado Pulsatility - study of rare clinical syndrome of idiopathic hypogonadotropic hypogonadism (IHH) for comprehensive phenotyping.

Drug Interaction Risk of the Grapefruit Juice Component and Dietary Supplement.

Inflammatory Response - examining the role of innate immunity on the inflammatory response of monocytes and macrophages to endotoxin.

The Molecular Basis of Inherited Reproductive Disorders - examining the genetic characteristics of subjects with isolated gonadotropin-releasing hormone (GnRH) deficiency.

Innate Immunity Signal Transduction in Human Leukocytes - collection of human leukocytes through routine blood specimens.

Lung Inflammation - study to provide consistent method for obtaining biological samples and respiratory health-related information to evaluate lung function.

Military Myositis - environmental risk factors for the development of myositis in military personnel.

Myorisk - determining if environmental risk factors are more common in individuals who have myositis with the anti-synthetase syndrome, compared with healthy volunteers.

Myositis - studying adult- and childhood-onset myositis.

Natural History of Asthma with Longitudinal Environmental Sampling (NHALES) - explore interaction between environmental exposures and disease progression in moderate-severe atopic asthmatics with persistent disease.

Sample Collection Registry - collection of biologic and environmental samples.

Smoke Exposure and COVID-19 infection - examining immune system of smokers at the single cell level before and after infection.

Effect of Single Nucleotide Polymorphisms [SNPs] - investigating the role of SNPs in response elements on the inflammatory response to DNA Damage.

Role of Transforming Growth Factor (TGF)-Beta in Asthmatic Epithelial Cell Susceptibility to respiratory syncytial virus (RSV) Infection - Role of Functionally Relevant Single Nucleotide Polymorphisms.

Twins or Siblings - studying development of systemic rheumatic disease when one twin or sibling has developed symptoms and the other has not.

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

The exact data collected for each protocol, and from each individual, will differ based on final approval of the NIEHS IRB. Collectively, the Personally Identifying Information (PII) collected, stored, maintained, and shared includes:

Personal information (name, date of birth, country of citizenship, social security number (SSN), mother's maiden name, mail address, phone number, email address, preferred language, next of kin name, emergency contact information (address and phone number), and relationship to study participant, emergency contact address and phone number, subject identification number),

Demographic information (age, sex, marital status, income level, education level, occupation, religious preference, employment status),

Medical information (medical record number (MRN), medical history, medical records including height, weight, ultrasound images, x-ray images, body scans, human biospecimens, Single Nucleotide Polymorphisms Genotype [SNPs], Genotype data, medical notes, lab values, study visit dates and times, medical assessments, biometrics and biometric identifiers),

Study-specific information (environment data, diet, home and cleaning products used, dust specimens),

Records containing PII (image of study participant and any other PII already noted) that are created from video communications via Microsoft Teams and Zoom, as well as is iMedConsent, a system provided by the NIH medical records department that allows for electronic participant signatures on protocol and admissions consents.

Education records, military service information (periods of service, branch of service, and deployment locations), and foreign travel.

Submission of all data is voluntary. Providing the data is a requirement to be able to participate in the research protocol/activity. Failure to provide any or all required data may exclude the participant from research activity eligibility.

Medical Visit Data and Specimens and Environment Specimens are collected and stored according to the parameters specified in the NIH IRB approved study-specific protocol. Study information is shared with potential participants during the NIH IRB approved enrollment period and study participants may choose to voluntarily end participation at any time.

Users log in to this system using the NIH Identity, Credential, and Access Management Services: Identity Management Services (IMS), which maintains its own unique privacy impact assessment (PIA) on record, including all legal authorities documented. The purpose of the IMS is to authenticate and authorize all users and computers in a Windows domain type network; assigning and enforcing information security policies for all computers and installing or updating software. The IMS collects unique usernames and passwords (user credentials) and stores them in an encrypted format. The IMS is an essential service which 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.

The CRU Systems uses a wide spectrum of technology and applications to conduct NIH IRB approved research protocols and associated activities. CRU collects, maintains, and shares personal, demographic, and medical information, study- specific data, education records, specimens, military service and foreign travel information. Users log in to this system using the NIH Identity, Credential, and Access Management Services: IMS, which maintains its own unique PIA on record with all legal authorities documented.

The following CRU technology and applications may collect, maintain and/or store PII and maintain their own unique PIA:

Public-facing webpages providing study descriptions and eligibility requirements.

NIEHS Join a Study Listserv: an email notification for interested study participants.

Clinical Conductor: maintains Participant Contact Information, Demographics, NIH MRN, Subject Identification Number (SIN), Study Visit Dates and Times, Study Status.

Twilio: collects phone number, study visit date, and appointment information.

Research Electronic Data Capture (REDCap): collects Name, EMail Address, Telephone Number, Mailing Address, DOB, sex, Occupation History, Employment Status, Income, NIH MRN, SIN, Medical and Medication History, human immunodeficiency virus (HIV) Status, medical imaging, Single Nucleotide Polymorphisms (SNPs) Genotype, Wearable Device Data.

TraCs: software provided by the North Carolina Translational & Clinical Sciences Institute (NC TraCS), collects no patient data, but stores principle investigator, associate investigator, and/or trainee information about CRU requests to monitor actions requested and their fulfillment.

NIEHS provided services:
NIEHS government issued cell phones for verbal information sharing.

NIH Outlook Email is used for electronic correspondence and includes Name, Email Address, Study Information, Educational Materials, and Study Visit Dates and Times.

NIEHS Shared Drive is used by NIEHS staff to store electronic study records and may include Name, EMail Address, Telephone Number, Mailing Address, Country of Citizenship, Preferred Language, Date of Birth, demographics, Next of Kin's Address and Phone Number, Emergency Contact Address and Phone Number, Religious Preference, SSN, Education, Occupation History, Employment Status, Income, NIH MRN, SIN, Medical and Medication History, Study Visit Dates, Medical Assessments, HIV Status, Biometrics, medical images, SNPs, Genotype, Wearable Device

Data.

NIEHS Telephone Voicemail System may capture name, phone number, and voluntary recorded information.

Clinical equipment such as ultrasounds, pulmonary function testing, Electrocardiogram (ECG).

BodPod records subject identification number, name, MRN, DOB and assessment data.

Laboratory freezers and refrigerators: to store patient lab samples with participant MRN, DOB, SIN.

Actigraph- records name, DOB, and participant's activity information.

Scanner(s): used to make copies of study participant documentation.

CRU Medical Records Room: used to store paper copies of study participant documentation.

Outside services are used by NIEHS staff and study participants:
U.S. Postal Service to provide recruitment letters, Study Visit Packets, Study Visit Dates and Times, and Appointment Reminders.

Federal Express to submit human samples, NIH admission and study consent forms with Name, EMail Address, Telephone Number, Mailing Address, Country of Citizenship, Preferred Language, DOB, Race, Ethnicity, Gender, Marital Status, Next of Kin's Address and Phone Number, Emergency Contact Address and Phone Number, Education, Occupation History, Employment Status, Income, NIH MRN.

Courier services for pickup of study documents and human specimens. Information may include name and home address.

LabCorp, Quest, NIH Laboratories to provide human specimens, lab assessment results, name, date of birth, and NIH MRN (NIH only).

Wake Radiology - xray images with su

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

Yes

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

Social Security Number
Date of Birth
Name
Biometric Identifiers
Mother's Maiden Name
E-Mail Address
Mailing Address
Phone Numbers
Medical Records Number
Medical Notes
Education Records
Military Status
Employment Status
Foreign Activities

Human Biospecimens, Single Nucleotide Polymorphisms (SNPs) Genotype, Subject Identification Number (SIN)
Demographics (age, sex, education level, income level, marital status, occupation, religion), Next of Kin, Relationship to Kin
Ultrasound Images, X-ray images, Body Scans, Wearable Device Data

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

Employees
Public Citizens
Patients

How many individuals' PII is in the system?

10,000-49,999

For what primary purpose is the PII used?

The purpose is to track, monitor, and evaluate NIH clinical, basic, and population-based research activities and protocols.

Specific Personally Identifiable Information (PII) is used to maintain the integrity of the data and to allow for participants to identify themselves for recontact efforts and cohort maintenance.

PII is also required to admit participants and compensate them for their participation through the NIH.

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

Not Applicable.

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

National Institute of Environmental Health Sciences and other applicable legal authorities (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101).

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

Yes

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.

09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains
- In-Person
- Hardcopy
- Email
- Online

Government Sources
- Within OpDiv

Non-Governmental Sources
- Public
- Private Sector

Identify the OMB information collection approval number and expiration date

Not Applicable.

Is the PII shared with other organizations?

Yes

Identify with whom the PII is shared or disclosed and for what purpose.

Describe any agreements in place that authorizes the information sharing or disclosure.

The Clinical Research Unit (CRU) has Material Transfer Agreements (MTAs) to share data, laboratory samples, and/or human materials with the following: Centers for Disease Control and Prevention, National Institutes of Health, National Cancer Institute, North Carolina State University, University of Colorado, University of Michigan, La Jolla Institute for Allergy and Immunology, St. Jude Children's Research Hospital, the Regents of the University of Michigan, Massachusetts General Hospital, and Social & Scientific Systems, Inc.

The CRU also has contractual agreements for certain services related to research study participation with Wake Radiology for radiology services, with ZRT* Laboratory for urine and blood testing services, and with Myriad RBM for medical-laboratory testing.

*ZRT is not an acornym

Describe the procedures for accounting for disclosures.

Not Applicable.

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

Individuals are notified at the time they are given the study-specific informed consent document that their PII will be stored within a secure database. Study staff verify that the individual understands the information outlined in the consent document and the document is signed by the study participant and witnessed by the study investigator or delegated study staff.

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.

Individuals have the option to refuse/opt-out of the collection or use of their PII through the informed consent process. Opting out of collection or use of their PII may preclude the individual from participating in the research study.

Consent forms are required to be read and signed by all research protocol/activity participants. These forms clearly identify what information will be collected from them, for what purpose, and how it will be shared, if applicable. It also seeks permission to re-contact the individuals in the future if changes are needed. If participants elect not to be re-contacted any changes will result in that person's data being destroyed. If participants elect to be re-contacted, any changes will initiate the re-contact at which time new consent forms will be presented outlining any changes and seeking approval from the participant for those changes. All consent forms (and all research protocol/activity forms and data) must be reviewed, approved, and cleared by the NIEHS Institutional Review Board prior to any data being collected.

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

NIEHS does not anticipate major changes to the system that would affect disclosure and/or changes in data use. However, if this were to occur, individuals would be contacted and presented with a

modified informed consent document that would provide them with details of the system changes that occurred and how that might affect the use of their PII. Individuals would, again, sign the informed consent if they wish to continue in the research project given the changes that were made or would have the option to refuse or opt-out.

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.

At any time, an individual may contact the study staff or investigator (each participant is provided with contact information of key study staff) if he or she feels that their information has been inappropriately obtained, used, disclosed, or inaccurately documented. The study staff and/or investigator will work to understand and mitigate any concerns from the individual and make corrections as appropriate. The individual may at any time choose to withdraw from a research study. The individual may also opt to have his/her study data redacted or allow for use of his/her study data in study analysis if the NIH IRB approved study-specific protocol allows.

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

PII stored in the system is monitored by the study data manager on a routine basis (at least monthly) to verify integrity, availability, and accuracy. If discrepancies are noted in the PII, the study data manager will confirm whether or not the discrepancy warrants a change in the database by either confirming with the study coordinator or investigator and/or by manually verifying against other source systems (e.g. Clinical Research Information System [CRIS], Biomedical Translational Research Information System [BTRIS]). In addition, study investigators may request data that includes PII for purposes of recruitment or re-contact; the results of these data requests undergo a thorough quality control process by the study data management team to ensure the accuracy and verify the relevancy of the results to the original request.

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.

All requests for access are sent to the Medical Director of the Clinical Research Unit who reviews them with the Operations Manager and then are either approved or denied. The decision is based on the functional role and requirements of the study. This is documented and stored as in Portable Document Format (PDF) on a secure shared drive once the privileges have been assigned to the individuals.

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.

The Clinical Research Unit (CRU) has the ability to restrict data access via roles and limited to the functions and information that is essential to their job function. Minimum required access is determined by the operations manager and is approved by the Medical Director of the CRU.

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.

NIEHS has annual and refresher training for security and privacy awareness via Collaborative Institutional Training Initiative (CITI). According to NIH policy, all personnel who use NIH applications must attend security awareness training every year. There are five categories of mandatory IT

training (Information Security, Counterintelligence, Privacy Awareness, Records Management and Emergency Preparedness).

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

NIH Clinical Research Training and CITI Biomedical 101 Training is required every three years.

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.

Records pertaining to the admissions and medical treatment of patients accepted in a research project are retained and disposed of under the authority of the NIH Intramural Records Retention Schedule Items contained in DAA-0443-2012-0007-0010, Patient Medical Records. These records will be filed by the unit system using clinical number and patient name. Each medical record includes the complete record of admissions and medical treatment for a patient accepted in a research project. These records are electronic. Inactive records for patients who have not been seen in the Clinical Research Unit (CRU) for 5 consecutive years will be evaluated annually for their need in relation to scientific reference. These electronic files will be destroyed when the NIEHS Director of Clinical Research determines that the records are no longer needed for scientific reference. All retention and destruction of records will be in accordance to NIH Policy Manuals and SORN 09-25-0200.

This project follows NIH guidelines for records management with regards to records retention and destruction of the database and associated records (NIH Intramural Records Retention Schedule Items, DAA-0443-2012-0007-0003). The NIEHS Clinical Research Unit will maintain all study records for at least 7 years after the end of the study or until advised by the NIH that record retention is no longer necessary. Study records that must be retained include copies of case report forms, signed informed consents, regulatory documentation, source documents, and other study documentation as specified by the applicable regulatory requirement(s).

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

Physical Controls: The Information Technology (IT) hardware used to host PII is located in a secured data center facility. The facility is only open to authorized personnel whose access is monitored by locking doors with badge readers for both ingress and egress. Each discrete ingress and egress event is logged. The facility is under 24 hour surveillance by facilities security for security and environmental hazards.

Technical Controls: The IT hardware and software used to host the PII is segregated from default commodity networks to prevent unauthorized or malicious access. Access controls lists and event logs are kept and monitored to detect unauthorized, suspicious or malicious activity. Access lists are restricted to approved IT technical personnel. Two factor authentication must be used for access. File integrity and auditing software are employed on hardware.

Administrative Controls: All technical personnel who access IT systems which contain PII have met background investigation criteria for public trust positions. All personnel have taken mandatory security training and awareness classes and refreshers. Personnel accessing these systems use a privileged and separate account for administrative access to systems.

Identify the publicly-available URL:

https://joinastudy.niehs.nih.gov/studies/index.htm

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?

Yes