Glossary

This glossary defines terms used in VA training materials. The definitions are those found in VA and VHA handbooks, directives, and memorandums. Thus, they are specific to research conducted within the VA.

Term	Definition
508 Compliance	Meeting all mandates required by Section 508 of the Americans with Disabilities Act (ADA) to ensure that all web pages are accessible to disabled persons. VA Handbook 6102
Access	Access is the obtaining or using of information, electronically, on paper or other media, for the purpose of performing an official function. VHA Handbook 1605.1.
Adverse Event (AE)	For the purposes of human research, an AE is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research or the research intervention, or the assessment. VHA Handbook 1200.5
Alternative Work Location	For the purposes of information security, an “alternate work location” is any place where VA personnel are performing VA work while outside a VA managed facility, or when remote computing is the only means of access (for example, a small department office with only dial-in access). Examples include residences and hotel rooms. VA Directive 6504
Asset	Property of VA or another government agency such as personnel, hardware, software, data and facilities. VA Directive 6504
Associate Chief of Staff (ACOS) for Research and Development (R&D)	The ACOS for R&D is the individual with delegated authority for management of the research program at facilities with large, active programs. VHA Handbook 1605.1.
Audit	A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor’s standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirements(s). Good Clinical Practice: Consolidated Guidance (ICH-E6)
Authentication	Confirmation of the identity of a party involved in data transmission which is a process that determines a user's identity, as well as determining what a user is authorized to access, e.g. a financial database or a support knowledgebase. The most common form of authentication is user name and password, although this also provides the lowest level of security. VA Handbook 6102

Authorization	A Privacy Rule Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. HIPAA Authorization for Research
Authorization of Trusted Devices	The process of deciding if device X is allowed to have access to service Y. This is where the concept of trusted devices exists. Trusted devices (devices authenticated and indicated as "trusted") are allowed access to services. Untrusted or unknown devices may require authorization based on user interaction before being granted access to the services. This does not principally exclude the automatic authorization given by an application. Authorization always includes authentication. VA Handbook 6102
Availability	Making sure that information and vital services are available to users when required. VA Directive 6504
Business Associate	A business associate is an individual, entity, company, or organization who, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of PHI, or provides certain services to VHA and the provision of those services involves the disclosure of PHI by VHA. VHA Handbook 1605.1.
Case History	A case history is a record of all observations and other data pertinent to the investigation on each research subject. An investigator is required to prepare and maintain adequate and accurate case histories. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study. VHA Handbook 1200.5.
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the Sponsor on each trial subject. Good Clinical Practice: Consolidated Guidance (ICH-E6)
CFR	Code of Federal Regulations VA Handbook 6102
Clinical Investigation	Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the at, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. 21 CFR 50.3
Clinical trial/study	Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. Good Clinical Practice: Consolidated Guidance (ICH-E6)

Common Rule	Federal Policy for the Protection of Human Subjects adopted by 17 federal departments and agencies in 1991. It includes required review of research by an IRB, informed consent of subjects and assurances of compliance by research institutions receiving federal support. VA has adopted the rule in regulatory form at 38 CFR Part 16. OHRP Policy Guidance
Compliance (in relation to trials)	Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory and other requirements. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Condition of Access	The condition of access consists of circumstances under which a VHA employee would require or need access to protected health information contained in VHA records. VHA Handbook 1605.2
Confidentiality	Protecting information from unauthorized disclosure or intelligible interception. VA Directive 6504
Contractor	A contractor is a person who receives compensation for those services provided to VHA, such as: data processing, dosage preparation, laboratory analyses, research, or medical or other professional services. VHA Handbook 1605.1
Controllable Environment	Inside VA office buildings and other VA facilities where the security risks have been recognized and control can be exerted on work guidance. VA Directive 6504
Covered Entity	For purposes of VA policy, a covered entity is a: (1) health plan, (2) Health care provider who transmits any health information in electronic form in connection with a transaction covered by 45 CFR Parts 160 and 162, or (3) Health Care Clearinghouse. VHA Handbook 1605.2
CPRS	Computerized Patient Record System employed at all VA healthcare facilities.
Data Safety Monitoring Board (DSMB)	An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial. Good Clinical Practice: Consolidated Guidance (ICH-E6)
De-identified Information	De-identified information is health information tat does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. VHA Handbook 1605.1
Deletion	To delete is to remove, erase, or expunge information or data in a record. VHA Handbook 1605.1
Department of Health and Human Services (DHHS)	The United States government's principal agency for protecting the health of all Americans and providing essential human services.

Designated Record Set	A Designated Record Set is a group of records maintained by or for VHA that are the medical records and billing records; enrollment, payment, claims, adjudication, and case or medical management records; or used, in whole or part, to make decisions regarding individuals. VHA Handbook 1605.1
Diagnosis	Diagnosis is the identification of a disease, condition, situation, or problem based on the systematic analysis of signs and symptoms. VHA Handbook 1605.1
Disclosure	Disclosure is the release, transfer, provision of access to, or divulging in any other manner information outside VHA. The exception to this definition is when the term is used in the phrase "accounting of disclosures." VHA Handbook 1605.1
Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Duly Authorized Representative	The duly authorized representative is an individual authorized in writing by a competent beneficiary or legally appointed guardian to act for the beneficiary. VHA Handbook 1605.1
Email (e-mail)	Electronic mail; the transmission of messages over communications networks. VA Handbook 6102
Entire Medical Record	The term "entire medical record" refers to all information about an individual in all VHA systems of records listed in Appendix B, excluding research records. VHA Handbook 1605.2
Essential Documents	Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. Good Clinical Practice: Consolidated Guidance (ICH-E6), see Section 8.
Extramural Research	Extramural research as defined in Directive 1200 is research performed by investigators not in the employ of VA, but may be under contract with VA. For the purposes of this specific handbook, the privacy requirements for disclosing information to outside entities under contract with VA is covered under Intramural Research when the disclosure is necessary for the entity to fulfill the terms of the contract. VHA Handbook 1605.1
Federal Information Processing Standards (FIPS)	Specifies the security requirements for a cryptographic module utilized within a security system protecting sensitive information in computer and telecommunications systems. FIPS PUB 140-2
Firewall	A dedicated device (hardware and/or software) placed between internal and external networks to control access and prevent misuse or abuse. VA Handbook 6102
FOIA (Freedom of Information Act)	Title 5 of the United States Code, section 552, provides that, upon request, federal agencies, Congress, and the Courts must provide copies of records in its custody as implemented in the agency's FOIA regulations and policies. FOIA Update

FOIA Officer	Normally, the Chief, Health Information Management Service (HIMS) is designated as the facility FOIA Officer. VHA Privacy Office
Food and Drug Administration (FDA)	Agency within the Department of Health and Human Services that enforces the Food, Drug, and Cosmetic Act and related public health laws.
Functional Categories	The term "functional categories" refers to a grouping (into classes) of individuals based upon VHA employee duties and responsibilities. All VHA employees must be categorized into at least one functional category. Individuals with more than one function may be categorized in multiple-functional categories. VHA Handbook 1605.2
Good Clinical Practice (GCP)	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Health Care Facility	The term "health care facility" encompasses all offices and facilities, including but not limited to Veterans Integrated Service Networks (VISNs), VA medical centers, VA Health Care Systems, Community-based Outpatient Clinics (CBOCs), Readjustment Counseling Centers, and VHA Research Centers of Excellence. VHA Handbook 1605.1
Health Care Operations	Health care operations are any of the following activities: conducting quality assessment and improvement activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management; reviewing competence or qualifications of health care professionals, evaluating practitioner performance, health plan performance, conducting training programs, certification, licensing, or credentialing activities; conducting medical reviews, legal services, and auditing functions; business planning and development; and business management and general administrative activities including management, customer service, and the resolution of internal grievances. VHA Handbook 1605.1
Health Information	Health information is any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, and findings or treatment, including such information as: laboratory examinations, X-rays, microscopic slides, photographs, prescriptions, etc. VHA Handbook 1605.1
Health Record (HR)	The HR consists of both the electronic medical record and the paper record, where applicable. The HR is also known as the legal health record. The HR can be comprised of two divisions, the HR and the Administrative Record. The HR includes documentation of all types of health care service provided to an individual in any aspect of health care delivery. The term includes records of care in any health-related setting used by health care professionals while providing patient care services, reviewing patient data, or documenting their own observations, actions, or instructions. The Administrative Record contains the administrative aspects involved in the care of a patient, including demographics, eligibility, billing, correspondence, and other business-related information. VHA Handbook 1605.1

HIPAA	The Health Insurance Portability and Accountability Act of 1996.
Host Based/Personal Firewall	A system designed to prevent unauthorized access to or from a private network. Firewalls can be implemented in both hardware and software, or a combination of both. Firewalls are used frequently to prevent unauthorized Internet users from accessing private systems or networks connected to the Internet. All messages entering or leaving the remote computer or network pass through the firewall, which examines each message and blocks those that do not meet the specified security criteria. VA Directive 6504
Human Subject	A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)). The definition provided in the Common Rule includes investigators, technicians and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes. VHA Handbook 1200.5 In FDA-regulated research, a human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. 21 CFR 50.3
Individually Identifiable Information	Individually-identifiable information is any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is retrieved by the individual's name or other unique identifier. Individually-identifiable health information is covered regardless of whether or not the information is retrieved by name. VHA Handbook 1605.1
Individually-identifiable Health Information	Individually-identifiable health information is a subset of health information, including demographic information collected from an individual, that is: (1) Created or received by a health care provider, health plan, or health care clearinghouse; (2) Relates to the past, present, or future condition of an individual and provision of or payment for health care; and (3) Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual. VHA Handbook 1605.1
Information Security	Protection of information to ensure its confidentiality, integrity and availability. VA Directive 6504
Information Security Officer (ISO)	Field security staff charged with information protection throughout VA. OI&T Field Security Operations
Information Technology (IT)	In accordance with the definition in the Clinger-Cohen Act, IT is defined as any equipment, software or interconnected system or subsystem that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information. VA Handbook 6502.2

Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Institution	In the context of VA research policy, an institution is a VA medical center or integrated VA health care system and its satellite facilities including community-based outpatient clinics. VHA Handbook 1200.5
Institutional Review Board (IRB)	An independent body composed of medical, scientific and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Integrity	Safeguarding the accuracy and completeness of information and computer software and services. VA Directive 6504
Intramural Research	Intramural research is research performed by VA employees or appointees (including those serving without compensation) at VA facilities and approved off-site locations. VHA Handbook 1605.1
Investigational Device	As defined by the FDA, an investigational device is a device that is the object of a clinical study designed to evaluate the safety or effectiveness of the device (21 CFR 812.3(g)). Investigational devices include transitional devices (21 CFR 812.3(r)) that are objects of investigations. However, for the purposes of the VHA Handbook, an investigational device may be an approved device that is being studied for an unapproved use or efficacy. VHA Handbook 1200.5
Investigational Drug	An investigational drug is a drug or biological product that is used in a clinical investigation. The FDA considers the term “Investigational New Drug (IND)” synonymous with investigational drug (21 CFR 312.3). However, for purposes of VA research policy, an Investigational Drug may be an approved drug that is being studied for an unapproved or approved use in a controlled, randomized or blinded clinical trial. VHA Handbook 1200.5
Investigational Device Exemption (IDE)	An IDE is an FDA-approval of the application for an exemption that permits an un-marketed device to be shipped for the purpose of doing research on the device. VHA Handbook 1200.5
Investigational New Drug (IND)	An IND used to refer to either an investigational new drug application or to a new drug that is used in clinical investigations. IND is synonymous with “Notice of Claimed Investigational Exemption for a New Drug.” VHA Handbook 1200.5
IND Safety Report	Written notification by the sponsor to FDA and all participating investigators of any adverse experience associated with the use of an investigational drug that is both serious and unexpected; or any finding from tests n laboratory animals that suggests a significant risk for human subjects. 21 CFR 312.32

Investigational Product	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Investigator	An investigator is an individual under the direction of the Principal Investigator (PI) who is involved in some or all aspects of the research project, including the: design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator must be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970. The FDA considers an investigator and a PI to be synonymous. VHA Handbook 1200.5
Investigator Agreement	Agreement signed by an investigator with a sponsor that ensures the investigation is conducted in accordance with the investigational plan and applicable FDA regulations involving medical devices. FDA Guidance: Investigator Responsibilities for Significant Risk Device Investigations
Investigator Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Law Enforcement Official	A Law Enforcement Official is an officer or employee of any agency or authority of the United States (U.S.), a State, a territory, a political subdivision of a State, a territory, or an Indian tribe, who is empowered by law to conduct the following law enforcement activities: (1) Investigate or conduct an official inquiry into a violation or potential violation of law; or (2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law. VHA Handbook 1605.1
Legal Guardian	A legal guardian is a person appointed by a court of competent jurisdiction to maintain and care for the property of an individual, and/or an individual who the court has declared incompetent due to physical or mental incapacity or age. A VA Federal fiduciary is not a legal guardian. VHA Handbook 1605.1
Legally Authorized Representative	A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of VA research policy, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older). VHA Handbook 1200.5

Limited Data Set	A Limited Data Set is protected health information from which certain specified direct identifiers of the individuals and their relatives, household members, and employers have been removed. These identifiers include name, address (other than town or city, state, or zip code), phone number, fax number, e-mail address, Social Security Number (SSN), medical record number, health plan number, account number, certificate and/or license numbers, vehicle identification, device identifiers, web universal resource locators (URL), internet protocol (IP) address numbers, biometric identifiers, and full-face photographic images. A limited data set is not de-identified information or data. A limited data set may be used for research, health care operations, and public health purposes. VHA may disclose a limited data set for research, health care operations, and public health purposes pursuant to a data use agreement. VHA Handbook 1605.1
Limited Medical Record	The term limited medical record means a subset of the entire medical record. The functional category determines the subset (see Appendix A). A VHA employee has limited access to protected health information data contained in the VHA systems of records according to the functional category. Access is granted based on specific conditions related to the performance and completion of the VHA personnel's responsibilities. VHA Handbook 1605.2
Maintain	For the purpose of VHA Handbook 1605.1, "maintain" includes: preserve, store, collect, use, and disseminate. VHA Handbook 1605.1
Major Information System	A large and sensitive system or project that requires special management attention because of its importance to the mission of VA; high development, operating and maintenance costs; high risk or return; or significant role in the administration of VA programs, finances, property or other resources. VA Handbook 6502.2
Marketing	Marketing is a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Marketing excludes communications made: to an individual for treatment, for case management; for recommending alternative treatments or therapies; for recommending alternative health care providers or settings of care; for describing health-related products or services provided by a health care provider; or for describing services, including payment for such services provided by, or included in, a plan of benefits. VHA Handbook 1605.1
Medical Emergency	A medical emergency is a condition that poses an immediate threat to the health or life of a person that requires immediate medical intervention. VHA Handbook 1605.1
Minimum Necessary Information	The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request. Unless an exception applies, this standard applies to a covered entity when using or disclosing PHI or when requesting PHI from another covered entity. A covered entity that is using or disclosing PHI for research without Authorization must make reasonable efforts to limit PHI to the minimum necessary. A covered entity may rely, if reasonable under the circumstances, on documentation of IRB or Privacy Board approval or other appropriate representations and documentation under section 164.512(i) as establishing that the request for PHI for the research meets the minimum necessary requirements. Protecting Personal Health Information in Research

Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), GCP, and the applicable regulatory requirement(s). Good Clinical Practice: Consolidated Guidance (ICH-E6)
Next of kin	A person related to an individual (e.g. spouse, son, daughter, or sibling). The next-of-kin is not automatically a personal representative of an individual. VHA Handbook 1605.1
Non official Records	Non-official records are those records that are maintained and used only by the individual who wrote them. Their maintenance must remain separate from official records. They must not be shown to anyone, nor be required by or under the control of VHA so that the individual who maintains the records may destroy them at any time. These records are not subject to the FOIA. *NOTE: Any questions concerning whether particular documents are non-official records need to be referred to legal counsel.* VHA Handbook 1605.1
Non VA Owned Equipment (OE)	Non-VA owned equipment, including employees' personal equipment, commercial equipment (such as hotel and internet cafe equipment), and equipment owned by other agencies. VA Directive 6504
Official Records	Official records are those records that are obtained, created, and maintained by VHA. VHA Handbook 1605.1
Patient	A patient is a recipient of VHA-authorized care under 38 U.S.C.-Veterans' Benefits. This includes, but is not limited to, care in a: VA medical center, nursing home care unit, community nursing home, domiciliary, outpatient clinic or readjustment counseling center. VHA Handbook 1605.1
Payment	A payment is an activity undertaken by a health plan to obtain premiums, to determine its responsibility for coverage, or to provide reimbursement for the provision of health care including eligibility, enrollment, and authorization for services. Activities undertaken by a health care provider to obtain reimbursement for the provision of health care, including pre-certification and utilization review, are payment. VHA is both a health plan and a health care provider. VHA Handbook 1605.1
Personal Digital Assistant (PDA)	Describes a class of handheld computing devices (Palm, Pocket PC, etc.) designed to serve the mobile computing needs of individuals. Applications delivered with PDA hardware include email, calendar events, contacts, and PC synchronization. VA Directive 6504
Personal Representative	A personal representative is a person, who under applicable law, has authority to act on behalf of the individual. This may include power of attorney, legal guardianship of an individual, the executor of the estate of a deceased individual, or someone under Federal, state, local or tribal law with such authority (e.g., parent of a minor). VHA Handbook 1605.1
Personnel	The term VA personnel includes those officers and employees of the Department; consultants and attendings; without compensation (WOC); contractors; others employed on a fee basis; medical students and other trainees; and uncompensated services rendered by volunteer workers, excluding patient volunteers; providing a service at the direction of VA staff. *NOTE: Compensated Work Therapy (CWT) workers are not VHA personnel; they are patients receiving active treatment or therapy.* VHA Handbook 1605.1

Principal Investigator	Within VHA, a PI is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers a PI and investigator to be synonymous. VHA Handbook 1200.5
Privacy Act Information (PAI)	Information covered by and protected under the Privacy Act of 1974. VA Directive 6504
Privacy Board	"Privacy Board" is a term created by the Standards for Privacy of Individually-identifiable Health Information (45 CFR Parts 160 and 164) to describe a board comprised of members with varying backgrounds and appropriate professional competencies, as necessary, to review the effect of a research protocol on an individual's privacy rights when an Internal Review Board (IRB) does not. VHA Handbook 1605.1
Privacy Impact Assessment (PIA)	An analysis, required by the E-Government Act of 2002, of how VA electronic personal information is maintained, used, and collected. VA Handbook 6502.2
Privacy Officer	Normally, the Chief, Health Information management Service (HIMS), is designated as the facility Privacy Officer. VHA Handbook 1605.1
Privacy Protected Information (PPI)	Electronic information in a VA IT system that directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or by which VA intends to identify specific individuals in conjunction with other data elements. VA Handbook 6502.2
Protected Health Information (PHI)	PHI is individually-identifiable health information maintained in any form or medium. *Note: PHI excludes employment records held by a covered entity in its role as an employer.* VHA Handbook 1605.1
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol reference documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Protocol Amendment	A written description of a change(s) to or formal clarification of a protocol. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Protocol Deviation	Any departure from the defined procedures and treatment plans as outlined in the protocol. Good Clinical Practice: Consolidated Guidance (ICH-E6)
Reasonable Reliance	In certain circumstances, a covered entity may rely on the judgment of the party requesting the disclosure as to the minimum amount of information that is needed by the requester. Such reliance must be reasonable under the particular circumstances of the request and VHA may be required to obtain documentation or representations from the specific requester. VHA Handbook 1605.2

Record	A record is any item, collection, or grouping of information about an individual that is VHA maintained, including, but not limited to: education, financial transactions, medical history, treatment, and criminal or employment history that contains the name, or an identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph. "Records" include information that is stored in any medium including paper; film and electronic media; and computers, minicomputers, and personal computers, or word processors. *NOTE: Tissue samples are not considered a record.* VHA Handbook 1605.1
Required by Law	A mandate contained in Federal, state, local or tribal law that compels an entity to collect, create, use, or disclose PHI and is enforceable under the law. This includes, but is not limited to: court orders, court-ordered warrants, and summons issued by a governmental or tribal inspector general. VHA Handbook 1605.1
Research	Research is defined as the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. The Common Rule (38 CFR 16) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. VHA Handbook 1200.5
Research and Development (R&D) Committee	Facility level committee that is responsible, through the Chief of Staff (COS) to the Medical Center Director, for oversight of the research program and for maintaining high standards throughout the R&D Program. VHA Handbook 1200.1
Research Records	Research records consist of IRB records as well as case histories (also referred to as investigator's research records) or any data gathered for research purposes. VHA Handbook 1200.5
Researcher	A researcher is the PI and/or investigator. VHA Handbook 1200.5
Right of Access	An individual has the right to have access to (e.g., look at, view) or obtain a copy of records pertaining to the individual which contain individually-identifiable information. VHA Handbook 1605.1
Routine and Recurring Disclosure	A routine and recurring disclosure is a disclosure of protected health information maintained by VHA to a type of requestor for a purpose consistent with normal health care functions on a frequent or recurrent basis; for example, disclosure of health information to insurance carriers for reimbursement of services. *NOTE: See Appendix C for a list of Routine and Recurring Disclosures.* VHA Handbook 1605.2
Routine Use	A “routine use” is a Privacy Act discretionary authority published in the Federal Register that permits VHA to disclose information or records from a Privacy Act-protected record without the patient's prior signed authorization. A “routine use” permits the: (1) Release of PHI only when disclosure is also authorized by other applicable legal authorities, including 45 CFR Parts 160 and 164; and (2) Release of drug or alcohol abuse, HIV, or sickle cell anemia medical information only when the disclosure is also authorized by 38 U.S.C. 7332. VHA Handbook 1605.1
Security Incident	An event that has, or could have, resulted in loss or damage to VA assets, or an action that breaches VA security procedures. VA Directive 6504

Sensitive Information	VA sensitive information is all Department data, n any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and information that can be withheld under the Freedom of Information Act. VA Directive 6601
Source Data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). Good Clinical Practice: Consolidated Guidance (ICH-E6)
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial). Good Clinical Practice: Consolidated Guidance (ICH-E6)
Sponsor	A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that is has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators. 21 CFR 56.102
Sponsor-investigator	An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator. 21 CFR 56.102
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). Good Clinical Practice: Consolidated Guidance (ICH-E6)
Subpoena	A subpoena is a document issued by, or under the auspices of, a court to cause an individual to appear and give testimony before a court of law. A subpoena cannot require VHA to disclose Privacy Act-protected records, unless the subpoena is signed by a judge. VHA Handbook 1605.1
Subpoena Duces Tecum	A “subpoena duces tecum” is a document issued by, or under, the auspices of a court that requires an individual to produce documents, records, papers, or other evidence to be brought to a judicial court for inspection. A “subpoena duces tecum” is not sufficient authority to authorize the disclosure of Privacy Act-protected records, unless the subpoena is signed by the judge of a court. VHA Handbook 1605.1

System Manager	The System Manager is the VHA official assigned the responsibility for a Privacy Act-covered system of records as identified in the system description that is published in accordance with VA Handbook 6300.5. The health care facility official with the program assignment is responsible for the maintenance of the records at the facility. VHA Handbook 1605.1
System of Records	The System of Records is a group of Privacy Act-covered records that contains personal information about an individual from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to an individual. The System of Records also includes all designated record sets. VHA Handbook 1605.1
Telecommuting or Telework.	Performing VA work at a work location other than one directly maintained by the Department, including work done at home. In the context of security, the term applies equally to work performed while traveling on VA business or when at a customer's or vendor's site. VA Directive 6504
Test Articles	Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or sections 351 or 354-360F of the Public Service Act. 21 CFR 56.102
Treatment	Treatment is the provision, coordination, or management of health care or related services by one or more health care providers. This includes the coordination of health care by a health care provider with a third party, consultation between providers relating to a patient, and the referral of a patient for health care from one health care provider to another. VHA Handbook 1605.1
Use	"Use" is the sharing, employment, application, utilization, examination, or analysis of information within VHA. VHA Handbook 1605.1
VA Data or VA Information	All information that is obtained, developed, or produced by or for VA or its employees as part of its business activities. VA Directive 6504
VA Protected Information (VAPI)	VA sensitive information, Privacy Act Information (PAI), PHI, or other VA information that has not been deliberately classified as public information for public distribution. VA information that VA would have to release under the Freedom of Information Act is not VA Protected Information. All VA Protected Information should be classified as one of the following: VA Proprietary, VA Restricted, or VA Highly Restricted. VA Directive 6504
VA Sensitive Information	VA sensitive information is all Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and information that can be withheld under the Freedom of Information Act. Examples of VA sensitive information include the following: individually-identifiable medical, benefits, and personnel information; financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information; information that is confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and other information which, if released, could result in violation

	of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs. VA Directive 6504
Veterans Healthcare Administration (VHA)	One of the three organizations under the Department of Veterans Affairs. The mission of the Veterans Healthcare System is to serve the needs of America's veterans by providing primary care, specialized care, and related medical and social support services. VHA webpage
Virtual Private Network (VPN)	A network scheme in which portions of the network are connected via the Internet, but the information sent across the Internet is encrypted. VPN can provide remote access to an organization's network via the Internet, sending data over the public Internet through secure "tunnels." VA Handbook 6102
Without Compensation (WOC) Appointment	A WOC appointment is a personnel appointment by which an individual contributes time to VA activities but receives no monetary compensation. VHA Handbook 1605.1

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