THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

The James
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Policy Name: Medical Center Research HIPAA Policy

Applies to:		
☒ OSU Wexner Medical Center [University Hospital, East Hospital, Brain and Spine Hospital, Richard M. Ross Heart Hospital, Harding Hospital, Dodd Rehabilitation Hospital, Ambulatory Clinics and Services]	☒ Ambulatory Surgical Centers [New Albany]	☒ Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and Outreach Sites

Policy Objective

The Ohio State University Wexner Medical Center (OSUWMC) and Arthur G. James Cancer Hospital and Richard J. Solove Research Institute's (The James) strategic plan includes a research goal to "pioneer life-altering biomedical discoveries and their translation into breakthroughs." OSUWMC/The James recognizes the importance of allowing researchers to access valuable data while maintaining a commitment to patient privacy. This policy describes how researchers are allowed to access and use protected health information (PHI) generated or maintained by the OSUWMC/The James. This policy applies to any individuals who access, use, or disclose PHI under the control of the OSUWMC/The James, when doing so for research purposes and should be used in conjunction with University Policy, Protected Health Information and HIPAA

Definitions

Term	Definition
Access	The ability or the means necessary to read, write, modify or communicate data/information or otherwise use any system resource.
Accounting of Disclosures	A patient has a right to receive an Accounting of Disclosures of PHI made by OSUWMC in the six years prior to the date on which the Accounting of Disclosures is requested. 45 CFR 164.512(i)
Alteration of HIPAA authorization (Alteration)	Allows a change in certain authorization requirements, while still requiring authorization for the use of PHI. Examples include making an exception to the required language in an authorization form or eliminating the requirement to obtain a signed authorization (e.g., authorization provided over the phone).
Authorization	Written permission from a patient or patient's Personal Representative for Use and/or Disclosure of PHI that meets the requirements of the HIPAA Privacy Rule.
Breach	The acquisition, access, Use or Disclosure of PHI in a manner that is not permitted under the Privacy Rule which compromises the security or privacy of the PHI.
Data Use Agreement	An agreement into which the Medical Center enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.
De-identified	Health information that 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 is not individually identifiable health information. The safe harbor method or statistical method of de-identification as described in 45 C.F.R Section 164.514 (b) can be used.
Direct Identifiers	Data elements that could be used to identify an individual. These include: 1.Names, 2.Geographic subdivisions smaller than a state (except the first three digits of zip code), 3.All elements of dates (except year) for dates that are directly related to an individual, including dates of admission, discharge, birth, death, and all ages over 89; 4.Telephone numbers, 5.Fax numbers, 6.Electronic mail address, 7.Social security numbers, 8.Medical record numbers,

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	9.Health plan beneficiary numbers, 10.Account numbers, 11.Certificate/license numbers, 12.Vehicle identification and serial numbers, including license plate numbers, 13.Device identifiers and serial numbers, 14.Web URLs, 15.Internet protocol (IP) addresses, 16.Biometric identifiers, including fingerprints and voice recordings, 17.Full-face photos and comparable images, and18.Any other unique number, characteristic, code that could reasonably be used to identify an individual.
Disclosure	Releasing, transferring, giving access to or divulging PHI outside of the Medical Center.
Expert De-Identification Determination	(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable: (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and (ii) Documents the methods and results of the analysis that justify such determination consistent with 42 CFR 164.514(b)(1)
Full waiver of HIPAA authorization (Full Waiver)	Waives the requirement to obtain an individual's authorization for the use and disclosure of PHI for a particular research project (such as a retrospective chart review), or for a specific portion/population of the research (such as a waiver that applies only to review of health records of patients previously treated that are used as controls).
Health Insurance Portability and Accountability Act of 1996 (HIPAA)	Federal regulations that establish the minimum level of protection for patient information and the administrative steps for compliance.
Individually identifiable health information (IIHI)	A subset of health information, created or received, that identifies an individual or can reasonably be used to identify an individual because it includes Direct Identifiers.
Institutional Data	Institutional data includes, but is not limited to, information in paper, electronic, audio, and visual formats and is information created, collected, maintained, transmitted, or recorded by or for the university to conduct university business
Institutional Data Policy (IDP)	The Institutional Data policy specifies requirements for the protection of The Ohio State University's institutional data. All institutional data must be assigned one of four data classification levels based on compliance, privacy, sensitivity, operational usage, and risk.
Institutional Review Board (IRB)	A formally designated committee whose primary responsibility is to protect the rights and welfare of human research subjects. IRBs review, approve the initiation of, and conduct periodic review of research involving human subjects.
IRB approved	Human subjects research that has been reviewed and approved by the IRB to be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
IRB exempt	Human subjects research that OSU's ORRP has determined is not subject to IRB review and approval, as defined by federal regulations and university policy. IRB-Exempt research studies must still follow OSU's Human Research Protection Program.
Limited Data Set	IIHI that excludes certain, listed direct identifiers but that may include city; state; first 5 digits of zip code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. In addition, the recipient must not be able to re-identify the individual.

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Minimum Necessary	The amount of PHI that is necessary to accomplish the particular purpose(s) for which the PHI is being Used, Disclosed, or requested.
Office of Responsible Research Practices (ORRP)	The office at OSU that provides administrative support to the university research community and the committees responsible for research review and oversight, such as the IRB and Privacy Board.
Partial waiver of HIPAA authorization (Partial Waiver)	Permits use and disclosure of PHI for recruitment purposes, prior to obtaining authorization. Specifically, it allows for the identification and, as appropriate, contact of potential participants to determine their interest in study participation.
Principal Investigator	An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical and safe or should it be OSUWMC conduct of a study involving human subjects, providing technical and administrative oversight of the research and making important study-related decisions. Note: Only one individual is designated as the principal investigator of an IRB-approved/-exempted study.
Privacy Board	A Privacy Board is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. A covered entity may use and disclose PHI, without an Authorization, or with an altered Authorization, if it receives the proper documentation of approval of such alteration or waiver from a Privacy Board.
Protected Health Information (PHI)	IIHI (oral, written, or electronic) about a patient's past, present, or future physical or mental health, the receipt of health care, or Payment for that care. This includes the PHI of deceased individuals unless the individual has been deceased for more than 50 years.
Research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
Research Health Information (RHI)	Information collected about research subjects that may pertain to their health or healthcare which has been "unlocked" from HIPAA requirements due to a disclosure from a health care component to a university unit not required to follow HIPAA pursuant to a valid HIPAA research disclosure such as a valid authorization or full or partial waiver of HIPAA authorization. RHI also includes identifiable health information collected only for research purposes by a component of the university not covered under HIPAA.
Treatment	The provision, coordination, or management of health care and related services by one or more health care providers. Treatment may include coordination or management of health care with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.
Use	The sharing, employment, application, utilization, examination or analysis of PHI within the Medical Center.
Workforce	Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the Medical Center or Business Associate, is under the

	direct control of the Medical Center or Business Associate, whether or not they are paid by the Medical Center or Business Associate.

Policy Details

PHI from approved OSUWMC/The James sources may be accessed and used for research purposes, including for subject recruitment and the creation of research databases or data repositories, pursuant to the procedures described in this Policy. All uses of PHI for research purposes must comply with the requirements of HIPAA and the federal Common Rule for the Protection of Human Research Subjects.

A. Data Security, Confidentiality and Ownership
   1. Confidentiality: All PHI maintained by the OSUWMC/The James is confidential.
   2. Ownership of data:
      a. PHI: All PHI (including files, databases, microform, printouts, etc.) is the property of the OSUWMC/The James.
      b. RHI: Once PHI has been properly disclosed from OSUWMC/The James with a patient authorization of pursuant to an IRB waiver, the data becomes Research Health Information (RHI) which is no longer subject to HIPAA. RHI is the property of OSU.
   3. Ownership of breach determination:
      a. PHI: The OSUWMC Compliance and Integrity Potential Breach Committee is responsible for analysis and determination of potential breaches of PHI.
      b. RHI: OSU's Digital Security and Trust (DST), Data Incident Response Team (DIRT) is responsible for analysis and determination of incidents involving RHI.
   4. Regulation of data within OSUWMC/The James: Data is safeguarded in accordance with the Information Security Policy. Unless otherwise noted in the policy, workforce must follow OSU Information Security Control Requirements (ISCR) as defined in the Information Risk Management Framework which addresses storage, access, release, transmission, and disposal of all PHI and other sensitive data for both internal and external use and has established the minimum-security standards.
   5. De-identification of PHI data sets may be performed by HBOC's honest brokers, internal or external statisticians, and others as approved by the Compliance Office.

B. Use of PHI for Research Purposes
   1. PHI may be used for IRB approved or IRB exempt studies, or research that is considered not human subjects research (i.e., deceased individuals).
   2. Information Systems is the data steward for systems which contain PHI.
   3. All restricted data must be protected according to the University Institutional Data policy and deploy data loss prevention protections.
   4. De-identified information through an IRB-approved process and released pursuant to formal agreement can be provided to internal university recipients per Honest Broker Operations Committee (HBOC) approval.
   5. De-identified or coded information provided to external parties is not permitted unless there is a patient authorization, or the data is released pursuant to a valid agreement consistent with university policies E.g. Data Use Agreement (DUA).

C. Access and Storage to PHI for Research Purposes
   1. Electronic:
      a. Electronic access to PHI via IHIS for research purposes for those who do not have a treatment relationship with the patient must submit a request to Health Information System Access Review Committee (HISARC) for review and approval. See College of Medicine website for further instruction.
      b. Data requests for research purposes must be reviewed and approved by Honest Broker Operations Committee (HBOC). Researchers requesting access to datasets for retrospective

secondary research must submit the Honest Broker Data Request Form and must have IRB approval if PHI is requested.
c. Authorized workforce may view PHI directly in pursuant to an IRB approved study.
d. Data should be safeguarded in accordance with the University Institutional Data Policy.

2. Paper:
   a. Investigators must complete a patient authorization form (either in hard copy or in electronic form). See Medical Information Management website for further instruction.
   b. No data is permitted to be recorded. PHI is also not permitted to be removed from OSUWMC/The James, meaning that the investigator cannot make any printouts or records of IIHI. See Medical Information Management website for further instruction.
   c. Paper information must be safeguarded and always secured in accordance with policy.
      i. Documents should not be left unattended and should be kept out of sight in a secure location.
      ii. Documents should be discarded in a secure shredder and should not be placed in the regular trash.

Procedures

A. Use of PHI for Study Feasibility or Activities Preparatory to Research
   1. Representations from the researcher, must state either in writing or orally, that the access, use, or disclosure is necessary for the research purpose, that the use of PHI is only to prepare a research protocol, estimate potential study population or for similar purposes preparatory to research and that no PHI will be removed from the covered entity. Since this use may be prior to IRB approval the IIHI cannot be printed, copied, or used for potential subject contact.
   2. Investigators may request de-identified information or a Limited Data Set using IRB-approved data transfer protocols, such as the Honest Broker Protocol and other approved methods. In this case, no IHIS access approval is required.
   3. Data is obtained through IHIS approved mechanisms.

B. Use of PHI for Research Subject Recruitment
   1. Research Consent Provided: Investigators are permitted to access PHI in approved OSUWMC/The James sources of potential subjects who have already provided consent to be contacted for study(-is) recruitment pursuant to an existing IRB approved or exempted protocol.
   2. Existing Patient Care Relationship: If the investigator is a medical staff member and has an existing patient care relationship with a potential subject, the investigators and members of the clinical treatment team may access PHI for identifying and contacting potential subjects if the IRB approved protocol is related to the patient's care.
   3. No Existing Patient Care Relationship: If an investigator does not have an existing patient care relationship with a potential subject, or if the patient care relationship is unrelated to the subject of the research protocol, the investigator or research staff members are permitted to access PHI of the potential subjects for recruitment purposes by
      a. The research team must not "cold call" potential subjects; investigators must coordinate with a treating clinician before contacting the potential subject. Recruitment scripts (e.g., phone, email, and letter scripts) must contain a link between treating clinician and investigator;
      b. Obtaining a Partial Waiver for recruitment purposes from the Privacy Board or IRB;
      c. Through an IRB-approved recruitment protocol that describes how research staff will access the PHI of potential subjects for screening and recruitment purposes.
   4. To minimize the number of charts reviewed and to select appropriate study volunteers from IHIS records, it is recommended that investigators with IRB approval use a filtering application to screen for study eligible patients.
      a. Investigators without IHIS access should either have a list of patients whose records they want to review or ask for a list of potential subjects meeting eligibility criteria from the Information

Warehouse or other source. IHIS charts from these potential study participants can be sent to the study recruitment staff.

5. Data is obtained through IHIS approved mechanisms.

C. Therapeutic or treatment in context of clinical care
   1. The researcher follows the privacy principals in Use of Patient Information by Hospital and Medical Staff.
   2. If the potential subject declines to provide research consent or HIPAA authorization, no PHI may be retained on that individual.
      a. If the study or study sponsor requires the maintenance of a record of individuals who were not enrolled, the record should not include any IIHI. If IIHI is required, a Full Waiver must be approved by the IRB or Privacy Board and the information must be destroyed at study termination.
      b. If an investigator wants to include information about the individual in a do not contact registry, the investigator must seek a waiver of research consent and a Full Waiver.
      c. An individual has the right to revoke an authorization for uses and disclosures of PHI for research, in writing, at any time, except to the extent that the covered entity has acted in reliance on the authorization. Investigators may continue to use and disclose PHI that was obtained before the individual revoked authorization to the extent that the entity has acted in reliance on the authorization.

D. PHI outside of the context of Clinical Care
   1. De-Identified data: Investigators may obtain a de-identified data set from the IRB-approved data sources, such as HBOC Analytics Center of Excellence (ACE).
   2. Use of Limited Data Set: Investigators may obtain Limited Data sets from the IRB-approved data sources without specific IRB approval. Investigators must complete a Data Use Agreement prior to review by HBOC.

E. General Requirements for Research Databases and Repositories:
   1. Approval: Research-only Databases or Repositories that contain PHI must be approved by the IRB or Privacy Board before they are used in research. If there is a reasonable likelihood that OSUWMC/The James clinical database will also be used for research purposes, IRB or Privacy Board approval must be obtained (for example, if a clinical or departmental operations database is also being used for research).
   2. All databases must have processes in place to ensure that only authorized information is entered and distributed.
   3. Only specifically approved repositories or databases can provide data that would allow for re-identification.
   4. Security: All databases must meet the privacy and security requirements described within the Information Security Policy. To obtain a security review, contact the OSUWMC's Help Desk. It is best practice that researchers work with OSUWMC to maintain electronic research records and databases on OSUWMC managed servers or OSUWMC approved systems.

F. De-Identification methods
   1. Removal of all 18 identifiers (safe harbor) is the most common method of deidentification. Third parties, such as honest brokers should be used.
   2. Expert Opinion: Individuals relying on de-identification by statistical analysis need to work with OSUWMC Compliance Office/privacy officer to evaluate the request. Additional guidance is available on the OSUWMC Privacy/HIPAA Compliance website.
   3. Data Use Agreement may be required as a condition placed by the Compliance office to further safeguard the information.

G. Use of Deceased Patient Information
   1. IRB review: If all subjects in a study are deceased, the research may not require Human Subjects Protection (i.e., IRB review). Review ORRP's policy regarding Human Subject Protections involving deceased individuals.

2. Privacy Board Review: HIPAA regulations still apply to deceased individuals unless the individual has been deceased for more than 50 years. The investigator must complete and patient authorization form or obtain a waiver and submit it to the Privacy Board for review.

H. Use of PHI in Case Reports
   1. Permission is required see policy, Use of Patient Information by the Hospital and Medical Staff for further instruction.

I. Use of Quality Data
   1. See policy, Use of Patient Information by the Hospital and Medical Staff for further instruction.
   2. If quality data is expected or planned to be published or presented outside of OSUWMC/The James to contribute to general knowledge, then it may be considered human subjects review and is subject to IRB review. Consult with ORRP to determine applicable requirements.

J. Disclosure Tracking
   1. Accounting of disclosures for research purposes meets an exemption if:
      a. The individual signed an authorization.
      b. The IRB-approved study protocol's principal investigator is credentialed OSUWMC Medical Staff.
      c. The data is being disclosed as a limited data set with a data use agreement.
   2. Accounting of disclosures for research purposes is required if the disclosure does not meet an exemption.
      i. Simplified accounting may be used for a disclosure for 50 or more individuals.
         (A) The name of the protocol or other research activity; (B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;(C) A brief description of the type of protected health information that was disclosed;(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity. See MIM website for more information.

K. Potential Breach Evaluation:
   1. Investigators must report any potential Breaches of PHI or RHI to the investigator's business unit's Privacy Officer as soon as possible and without unreasonable delay. Potential Breaches include but are not limited to:
      a. giving PHI or RHI to the incorrect individual
      b. loss of PHI or RHI
      c. loss of electronic devices that may contain PHI or RHI.
   2. Potential Breaches of PHI: OSUMWC Office of Compliance and Integrity is responsible for maintaining procedures to properly report actual Breaches of PHI as required under the Privacy Rule. Investigators must also report any potential Breach to the IRB office as soon as possible and without unreasonable delay.
   3. Potential Breach of RHI: OSU's Digital Security and Trust (DST), Data Incident Response Team (DIRT) is responsible for security incidents, unauthorized acquisitions, access, use, or disclosure of RHI.

L. Failure to Adhere to This Policy
   1. Failure to adhere to this policy and procedure may result in corrective action, up to and including termination.

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References

College of Medicine Research Compliance
Medical Information Management
Protected Health Information and HIPAA
Security Policy
University Institutional Data Policy
Use of Patient Information by Hospital and Medical Staff
National Institutes of Health, Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule

Contacts

Office	Telephone	E-mail/URL
Compliance and Integrity	614-293-4477	**privacyoffice@osumc.edu**

History

The Ohio State University Wexner Medical Center		
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