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ABRC Changes to the Common Rule: Effects on Health Research and Community Partnerships

CHANGES IN HEALTH INFORMATION RULES AND REGULATIONS

HIPAA Research Rules

HIPAA/OHRP Intersections

Substance Use Disorder Research

NIH Policies



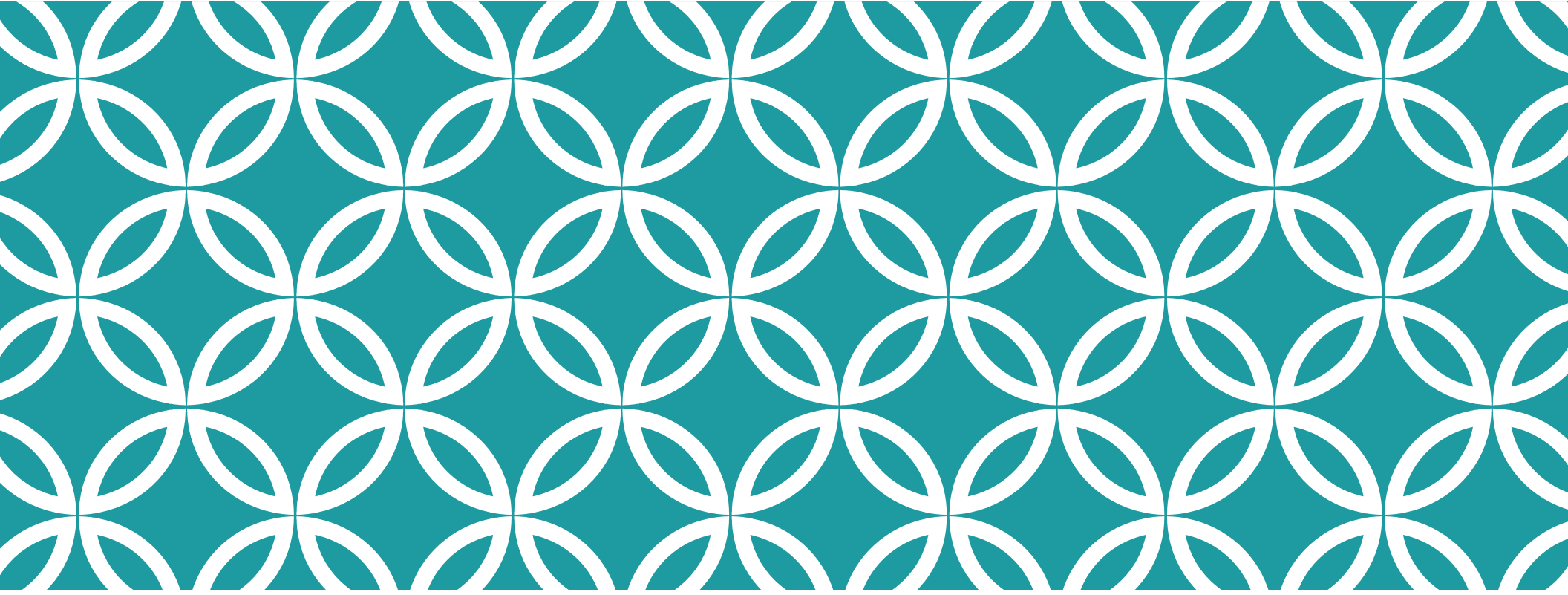
AGENDA

The HIPAA Research Rules

Intersection between the HIPAA and the Current Common Rule/Amended Common Rule

The Federal Substance Use Disorder Confidentiality of Patient Records Regulations (42 C.F.R. Part 2) and Research

NIH Policies



THE HIPAA RESEARCH RULES

Applicability
Requirements
What's New?

WHEN DOES HIPAA APPLY?

HIPAA applies to Covered Entities (CEs) and their Business Associates (BAs)

- Health care providers that bill insurance (or do other HIPAA “standard transactions”)
- Health plans
- Health care clearinghouses
- Individuals/organizations that provide services to, or perform functions on behalf of, a CE (or another BA) and receive or create PHI to perform the services or functions

HIPAA protects Protected Health Information (PHI)

- Health information (including demographics) created or received by a health care provider, health plan or health care clearinghouse;
- That relates to an individual’s health; and
- Identifies the individual directly or indirectly

HIPAA applies to Research conducted by (or on behalf) of a CE

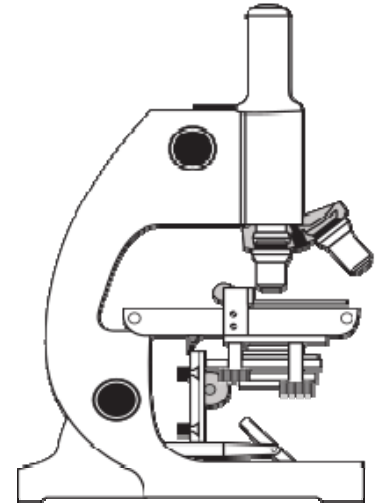
- HIPAA defines “Research” as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”
- Quality improvement and public health surveillance activities are not “Research”

A CE may use and disclose PHI for Research only if one of the HIPAA Research Rules are met.

HIPAA RESEARCH RULES

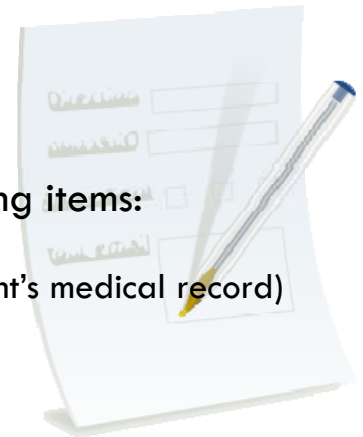
FOR USE OR DISCLOSURE OF PHI FOR RESEARCH

1. HIPAA Authorization (can be combined with the informed consent document)
2. IRB/Privacy Board Waiver of HIPAA Authorization
3. De-identified Data
4. Limited Data Sets/Data Use Agreement
5. Preparatory Research Activities
6. Participant Recruitment
7. Decedents
8. Required by Law
9. Grandfathered Research



What's New?: The Office for Civil Rights (OCR) issued clarifying guidance on authorization for future research and revocation of authorization. The National Committee on Vital and Health Statistics (NCVHS) also recommends OCR adopt new guidance on de-identification and protection of de-identified data. OCR has not acted yet.

HIPAA AUTHORIZATION



The HIPAA Authorization (or informed consent document) must include the following items:

- Specific and meaningful description of the PHI to be used/disclosed (for example: the patient's medical record)
- Who can disclose (for example: the hospital)
- Who can receive/access the PHI (for example: the investigators)
- Description of the research
- Expiration date or event (for example: when the study ends) or a statement that the authorization will not expire
- Patient's right to revoke the authorization in writing and explanation of how to do so (CE may refer to NPP)
- Statement that the patient may not revoke the authorization as to information already disclosed for the research where the information is necessary to maintain the integrity of the research, or a description of other exceptions where the patient may not revoke the authorization
- Statement that the CE disclosing the PHI may not condition treatment, payment, enrollment or eligibility for benefits on the patient signing the authorization
- If the patient will not be allowed to participate in the research without signing the authorization, the authorization must say that
- Statement that the information disclosed may be subject to redisclosure by the recipient and no longer be protected by the federal privacy rule
- If the patient will not be given access to medical records during the study, a statement that there will be no right to access until the study is completed
- Patient signature and date; if signed by the patient's healthcare decision maker, a description of that person's authority to act for the patient

HIPAA AUTHORIZATION & FUTURE RESEARCH

NEW OCR Guidance: <https://www.hhs.gov/sites/default/files/research-and-authorizations-12132017.pdf>

What's required for future research?

- The Authorization “must adequately describe future purposes such that it would be reasonable for the individual to expect that his or her PHI could be used or disclosed for such future research. For example, the description could include specific statements with respect to whether sensitive research, such as genetic or mental health research, or [sic] is contemplated. However, the Privacy Rule does not prescribe a fixed level of detail about the future research or identify particular types of PHI as ‘sensitive.’ In short, the Privacy Rule gives covered entities and researchers (who may or may not be covered by HIPAA) the flexibility to describe the future research and the health information to be used or disclosed for the future research, so long as such description reasonably puts the individual on notice that his or her protected health information could be used or disclosed for the future research.”
- Participants must “opt in” to the future research (if combined with an authorization for another study)

What's **NOT** required?

- “Right to Revoke” reminders
- Specific revocation forms/revocation through a patient portal – if used it must not create barriers/unreasonably delay a participant's revocation right
- Waiving the requirement that a participant revoke the Authorization in writing

When is a Participant's Revocation Effective?

- If a participant submits a written revocation to a non-CE researcher, and the non-CE researcher orally informs the CE of the written revocation, that revocation is effective against the CE upon the CE's receipt of the oral notification
- BUT a CE may continue to use/disclose PHI previously obtained before revocation to maintain the integrity of the research (for example: to account for participant's withdrawal, investigate scientific misconduct or report adverse events) or for other activities permitted by HIPAA (such as Treatment, Payment and Health Care Operations activities)
- Non-CE recipients may also continue to use/disclose PHI previously received because they are not subject to HIPAA

IRB/PRIVACY BOARD WAIVER OF AUTHORIZATION

An IRB or Privacy Board may waive the HIPAA Authorization if it finds that:

- Use/disclosure of PHI involves no more than minimal risk to privacy based on (1) a plan to protect identifying information; (2) a plan to destroy identifying information at the earliest opportunity (unless there is a health/research justification or retention required by law); and (3) written assurances that identifying information will not be reused/disclosed except as permitted or required by law
- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to and use of identifying information

What's the difference between an IRB and a Privacy Board?

- An IRB reviews and oversees research (required by the Common Rule/FDA)
- A Privacy Board is a review board established under the HIPAA Privacy Rule to act upon requests for waiver/alteration of the HIPAA Authorization requirement for a research study
- Their board composition requirements and review/approval procedures are different
- However, Privacy Boards and IRBs can coexist!
 - EXAMPLE 1: An IRB can act as a Privacy Board. An IRB acting as a Privacy Board can waive/alter the HIPAA Authorization requirements and/or receive and consider reports of HIPAA-related problems, such as unauthorized use of PHI
 - EXAMPLE 2: A multisite study might use an informed consent document and separate HIPAA authorization approved by a central IRB. However, a specific site's Privacy Board may approve a waiver or alteration of the HIPAA Authorization at that site

DE-IDENTIFIED DATA

How do you de-identify data?

- Remove (or code) all 18 HIPAA identifiers from the data (including dates of treatment)
- A qualified statistical expert determines that the risk is very small that the information could be used to identify the participant

NCVHS Recommendation (not adopted by OCR yet)

- Impose responsibilities on the recipients of de-identified data sets
- Require CEs/BAs to track disclosures of de-identified data sets and Limited Data Sets and include in an accounting upon a participant's request
- NCVHS (Feb. 2017), <https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2017-Ltr-Privacy-Deidentification-Feb-23-Final-w-sig.pdf>

LIMITED DATA SETS & DATA USE AGREEMENTS

A Limited Data Set (LDS) excludes all 18 HIPAA identifiers except for:

- Geographic designations above the street level or PO Box
- Dates directly related to a participant, such as dates of service, birth date, admission date, discharge date, or date of death
- Any other unique identifying number, characteristic, or code that is not expressly listed as an “identifier”

Research personnel who receive a LDS must sign a Data Use Agreement (DUA) to protect confidentiality

PREPARATORY RESEARCH ACTIVITIES

What are preparatory research activities?

- Preparing a research protocol or developing a research hypothesis
- Identifying prospective research participations (but NOT recruiting)
- Screening patient records to identify whether there are a sufficient number of patients at a facility to function as a site for a clinical trial

What is required?

The researcher must make the following representations in writing to the CE:

- PHI is sought solely to prepare for research
- The PHI is necessary to prepare for research
- No identifying information will be removed from the premises in the course of the review

What about remote access?

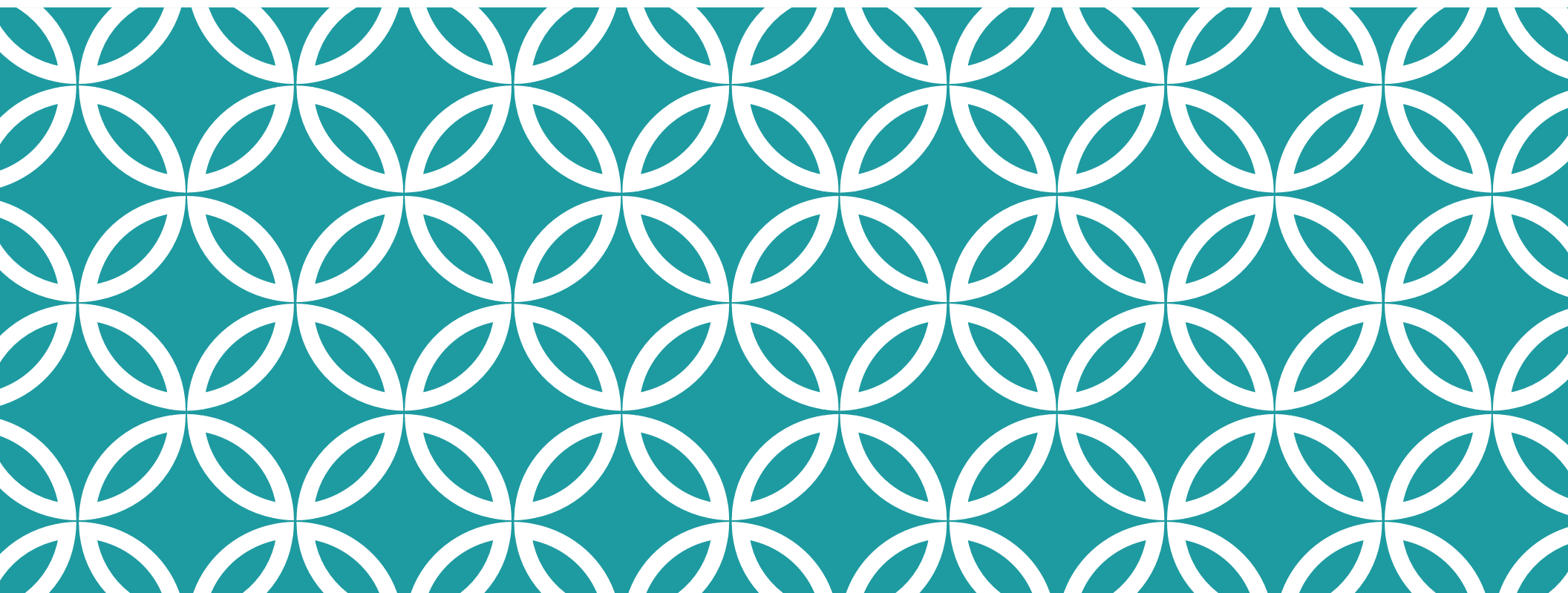
- It's permissible if the CE reasonably determines that the risk of removal of PHI through remote access is low
- Granting remote access to non-CE researchers might not be reasonable
- Remote access must also comply with the HIPAA Security Rule's requirements (such as integrity controls and encryption)

PARTICIPANT RECRUITMENT

A health care provider (a CE) can contact his or her own patients to ask if they are interested in participating in a research study

A CE can also use a BA (including a researcher) to contact his or her patients for this purpose so long as either:

- A HIPAA Business Associate Agreement is in place; or
- An IRB or Privacy Board waives the HIPAA Authorization requirement for the initial contact to recruit the patient (even if a HIPAA Authorization will be sought for the patient's actual participation in the study)



INTERSECTION BETWEEN HIPAA AND THE COMMON RULE

How do they work together?

- The Current Common Rule
- The Amended Common Rule

INTERSECTION WITH THE CURRENT COMMON RULE

If the study involves the use of “identifiable” information from CEs/BAs for research purposes, you must comply with both



However, neither law applies if the information is “de-identified” under the HIPAA standard

INTERSECTION WITH THE AMENDED COMMON RULE: IDENTIFIABILITY

The Amended Common Rule requires a reassessment of what is “identifiable” private information and biospecimens within 1 year of its effective date (every 4 years thereafter)

Potential Consequences?

- Information “de-identified” under HIPAA may become “identifiable” under the Amended Common Rule
 - Example: whole genome sequencing
- Confusion! Different standards of “identifiability” under HIPAA, the amended Common Rule and NIH’s Certificates of Confidentiality Policy

INTERSECTION WITH THE AMENDED COMMON RULE: THE HIPAA EXEMPTION

Amended Common Rule HIPAA Exemption for Secondary Research:

Secondary research is exempted from the requirements of the Amended Common Rule if “[t]he research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under [HIPAA], for the purposes of ‘health care operations’ or ‘research’ as those terms are defined at 45 CFR 164.501 or for ‘public health activities and purposes’ as described under 45 CFR 164.512(b).”

Goal: reduce regulatory burdens and confusion by exempting research that is already protected and regulated by HIPAA

HOW DOES THE HIPAA EXEMPTION WORK?

What is secondary research?

- Research using data/biospecimens collected for purposes other than the research being conducted
- Examples: existing clinical records and data warehouses; tissue banks/repositories

Does it apply to biospecimens?

- SACHRP recommends that OHRP limit this exemption to identifiable information only
- It may apply to secondary research using genetic sequencing information derived from biospecimens
- Rationale: applying the exemption to biospecimens would undermine the new informed consent protections (such as informing participants if the specimens will be used for commercial profit)

Is IRB review still required?

- IRB (or Privacy Board) review is required to approve the HIPAA Authorization or waive the requirement (unless one of the other HIPAA Research Rules applies)

How does it apply to Universities?

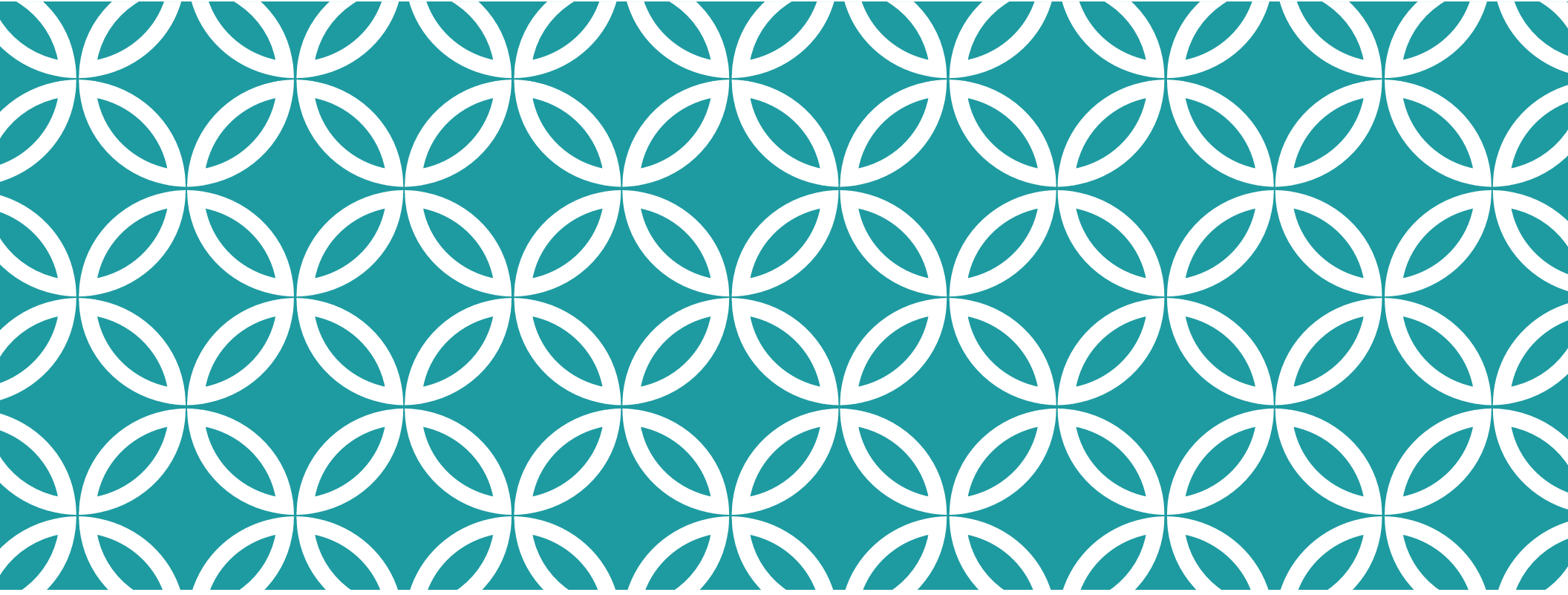
- Applies to internal uses within the University's CE component
- SACHRP recommends that OHRP not permit providers in the CE component to disclose PHI to the University's non-provider researchers
- SACHRP Example: University hospital provider cannot share PHI with an economics professor for purposes of collaborating on a research project under this exemption – HIPAA & the Amended Common Rule apply

What about disclosures to third parties?

- SACHRP recommends that OHRP permit disclosures between and among CEs/BAs for research (example: collaborative research projects)
- SACHRP recommends that OHRP **NOT** permit disclosures to non-CEs/BAs – HIPAA & the Amended Common Rule apply

The Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations:

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-december-12-2017/index.html>



SUBSTANCE USE DISORDER RESEARCH

The new research exception
under 42 C.F.R. Part 2

42 C.F.R. PART 2 (PART 2) IN A NUT SHELL



- Heightened privacy protections apply to PHI originating from federally assisted substance use disorder treatment programs (called Part 2 Programs) that identifies a patient as having (or having had) a substance use disorder (SUD) – called “Part 2 data”
 - “Federally assisted” includes individuals/entities federally licensed or certified (e.g., Medicaid/Medicare) and 501(c)(3) nonprofits
 - A “program” is:
 - An entity (other than a general medical facility), individual or unit within a general medical facility that holds itself out as providing and provides SUD treatment
 - Medical personnel/staff in a general medical facility whose primary function is SUD treatment and who identify as such providers
- Part 2 Programs and other lawful holders of Part 2 data (including researchers) must comply with Part 2’s use and disclosure requirements
- Part 2 data can be disclosed for research purposes with either:
 - The patient’s written consent; or
 - Under the research exception
- The Part 2 consent requirements are complex, difficult to implement and not consistent with the HIPAA Authorization or Common Rule/FDA informed consent requirements
- The 2017 amendments to the research exception have made it easier for researchers to use Part 2 data so that patients suffering from SUDs have the same opportunity to benefit from research as patients suffering from physical disorders
- The Department of Justice (DOJ) enforces Part 2 through criminal fines

THE PART 2 RESEARCH EXCEPTION

A Part 2 Program or other lawful holder of Part 2 Data can disclose Part 2 data for research purposes without participant consent if the recipient:

- Is a CE or BA and has HIPAA Authorization from the participant or waiver/alteration of the HIPAA Authorization requirement from an IRB/Privacy Board
- Is subject to the Common Rule and has informed consent from the participant; waiver/alteration of the informed consent requirement from an IRB/Privacy Board; or documentation that the research is exempt from the Common Rule
- Is a CE/BA subject to the Common Rule, the recipient must meet all of the requirements above

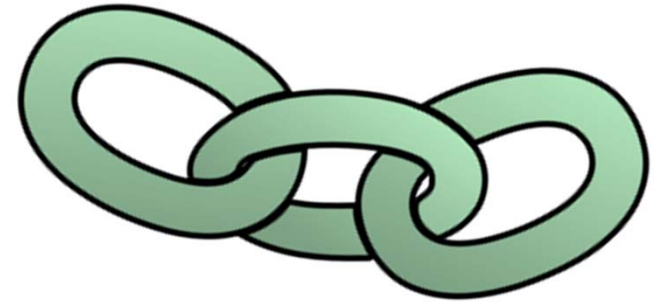
If the recipient is not a CE/BA or subject to the Common Rule, this exception does not apply. Participant consent is required.

RESEARCH OBLIGATIONS UNDER PART 2

On receipt of the Part 2 data, researchers (and their institutions):

- Are fully bound by Part 2 and must resist in judicial proceedings any efforts to obtain access to patient records except as permitted by Part 2;
- Must not re-disclose Part 2 data except back to the individual or entity from whom that Part 2 data was obtained or for data linkages as permitted by Part 2;
- May include Part 2 data in research reports only in aggregate form in which Part 2 data has been rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder;
- Must maintain and destroy Part 2 data in accordance with the security policies and procedures established under Part 2 (these requirements are aligned with HIPAA); and
- Must retain records in compliance with applicable federal, state, and local record retention laws

PART 2 DATA LINKAGES

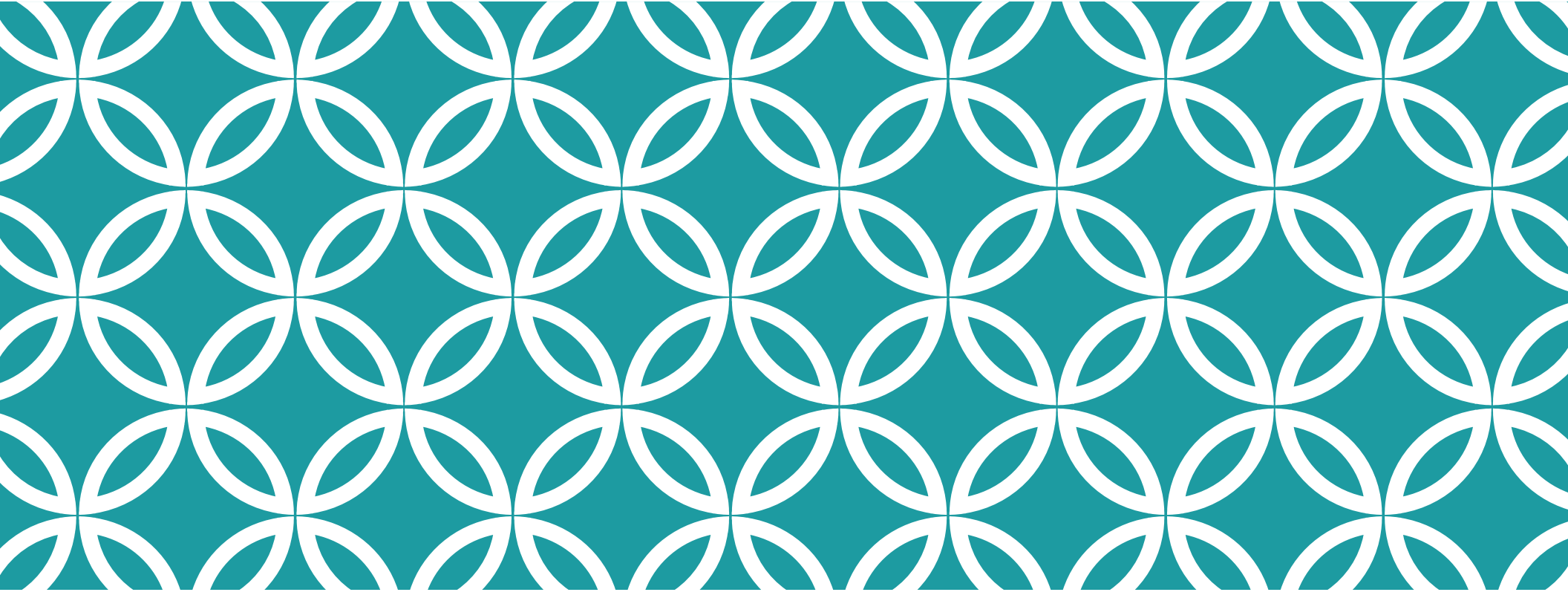


Researchers can use and re-disclose Part 2 data to link Part 2 data to other data sets from federal and non-federal data repositories so long as:

- The request for linkages is reviewed and approved by an OHRP-registered IRB to ensure that participant privacy is considered and the need for identifiable data is justified;
- Upon request, the researcher can provide evidence of the IRB approval of the research project that contains the data linkage component; and
- The researcher ensures that Part 2 data is not provided to law enforcement

Data repositories that receive Part 2 data for data linkages purposes:

- Are fully bound by Part 2 upon receipt of the Part 2 data;
- After providing the researcher with the linked data, are required to destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the Part 2 data non-retrievable; and
- Must ensure that the Part 2 data is not provided to law enforcement



NIH POLICIES

Certificates of Confidentiality
Single IRB Policy
Genomic Data Sharing Policy
Definition of Clinical Trial

NIH CERTIFICATES OF CONFIDENTIALITY (CoC): APPLICABILITY

- Applies to any NIH research starting or ongoing after December 13, 2016
- CoCs issued automatically as part of the NIH funding terms and conditions
- CoC protects “Covered Information”: information collected during the NIH research where:
 - An individual is identified; or
 - For which there is **at least a very small risk**, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual
- Examples of “Covered Information”:
 - Individual level, human genomic data even if it is de-identified
 - BUT summary research results, including genomic summary results, are **NOT** protected
 - **CAUTION:** CoC Policy may apply even if the research is not subject to HIPAA or the Common Rule/Amended Common Rule
- NIH CoC: <https://humansubjects.nih.gov/coc/index>

NIH CoC: DATA SHARING RESTRICTIONS

Researchers cannot disclose this Covered Information without participant consent:

- In any federal, state or local civil, criminal, administrative, legislative or other proceeding
- To any person not connected with the research

Disclosure is permitted only when

- Required by certain laws (such as FDA reporting or state required communicable disease reporting)
- Necessary for medical treatment and made with the participant's consent
- Participant consent
- Disclosure for other research that is compliant with federal laws

Research Institutions must have internal controls (such as policies and procedures) that provide “reasonable assurance” of compliance with the NIH CoC Policy

These restrictions apply to all research issued a Certificate, including research issued a Certificate under the old policy (even if the Certificate has expired or NIH funding ends)

NIH CoC: INFORMED CONSENT REQUIREMENTS

The informed consent document (if sought) must inform participants of the protections and limitations provided by the Certificate

Model language: <https://humansubjects.nih.gov/coc/suggested-consent-language>

Researchers do NOT need to re-consent or otherwise notify existing research participants of the new protections (unless required to do so by the IRB)

OTHER NIH POLICIES

NIH Single IRB Policy (sIRB) (<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>)

- Effective Jan. 25, 2018: requires use of a single IRB for multisite NIH funded research in the U.S. (but not career development, research training or fellowship NIH awards)
- Plans for sIRB must be included in the grant application

NIH Genomic Data Sharing Policy (GDS) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>)

- Informed consent required for use of de-identified biospecimens for certain genetic research proposed in applications/contracts/research to NIH starting on Jan. 25, 2015 even if the biospecimens were initially collected for non-research purposes (such as clinical treatment)
- Applies to: “NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data”

NIH Case Studies Expand Meaning of a “Clinical Trial” (<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>)

- Clinical Trial: “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” (<https://grants.nih.gov/policy/clinical-trials/definition.htm>)
- NIH Clinical Trial Policies: registration/reporting in ClinicalTrials.gov; GCP training; limitations on grants/training awards; review criteria
- Universities express concern that case studies expand definition to include research that is not designed to alter participant health/behavior but involves manipulation that results in temporary physiological and/or behavioral change during the research (<http://www.cogr.edu/sites/default/files/Joint%20Association%20Letter%20on%20NIH%20Clinical%20Trial%20Case%20Studies%2009-18-2017.pdf>)



QUESTIONS AND DISCUSSION

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