

EMORY UNIVERSITY HIPAA RESEARCH POLICY

THE NEW STRUCTURE OF THE EMORY UNIVERSITY HYBRID
COVERED ENTITY AND HOW IT AFFECTS RESEARCH

The Current Emory University Covered Entity

- Emory University is a Hybrid Covered Entity with Covered Components that are subject to HIPAA, and Non-Covered Components that don't follow HIPAA.
- Covered Components are those that perform Covered Functions: Treatment, Payment, Health Care Operations.
- Current Covered Components = SOM, SON, SOPH, Student Health Services, Student Counseling, . . .
- “ALL IN” APPROACH -
 - If you provide Treatment, you are a Covered Component, whether or not you bill for the Treatment.
 - If you work for a Covered Component, then no matter what work you are doing with identifiable health information, that information is consider PHI and subject to HIPAA.

THE NEW COVERED ENTITY

- Emory University is still a Hybrid Covered Entity.
- BUT to be a Covered Component, the unit must:
 - Provide Treatment AND bill insurance or a government benefits program (e.g., Medicare) for the Treatment; or
 - Process Payment; or
 - Perform Healthcare operations.

THE NEW COVERED ENTITY

- NO MORE ALL-IN APPROACH; FUNCTIONAL APPROACH INSTEAD
- Whether you are working in a covered component depends on whether you are performing a covered function, i.e., Treatment + Billing; Payment or Health Care Operations.
- Ask:
 - Do I work for a unit that has a Covered Component? AND, if so
 - Am I using identifiable health information for a task? AND, if so
 - Is that task:
 - Providing Treatment for which I am billing insurance or a government benefits program; OR
 - Processing payment for insurance or government benefits program; OR
 - Performing other healthcare operations (e.g., quality assurance, training providers, legal audit, etc.)

AND, if so, then you are in the Covered Component and subject to HIPAA.

The New Covered Components

As a “Hybrid Covered Entity”, Emory University has designated certain units within the University to be “Covered Components” and other units to be “non-Covered Components”.

- ❖ “Covered Components” are units, like the School of Medicine, within which health care providers perform “Covered Functions”.
 - ✓ “Covered Functions” means the provision of treatment plus electronic billing of an insurance company or government benefits plan (HIPAA-covered billing).
 - ✓ A person is working in a Covered Component to the extent that he or she is performing a Covered Function.
 - ✓ HIPAA applies only to Covered Components performing Covered Functions.
- ❖ “Non-Covered Components” are units, like the Goizueta Business School, that do not perform Covered Functions and HIPAA does not apply to them.

The New Covered Components

The following is a list of the Covered Components of the Emory University Hybrid Covered Entity:

- ❖ Emory University School of Medicine
- ❖ Emory University of Nursing
- ❖ Emory School of Public
- ❖ Emory College and Emory University Graduate School Departments of Psychology
- ❖ Emory University Student Health Service (for services provided to non-students)
- ❖ Oxford College of Emory University Student Health Service (for services provided to non-students)
- ❖ Emory University Autism Center
- ❖ Emory Psychoanalytic Institute
- ❖ Emory Clinical and Translational Research Lab (ECTRL)
- ❖ Emory University Health Plan (governed by separate privacy and security policies)

Who's No Longer a Covered Component?: Treatment without billing or HIPAA-covered billing

In some Emory University units, Treatment (or Research that includes Treatment) is provided at no charge or without using HIPAA-Covered billing. Those units are NOT considered to be a Covered Component. These units include the following:

- ❖ Emory University Faculty Staff Assistance Program
- ❖ Emory University Counseling and Psychological Service
- ❖ Emory University Psychological Center
- ❖ Emory University Child Study Center
- ❖ Emory University First Responders

How does this affect Research at Emory University?

Possibly the most significant change is that many Research protocols that would have been governed by HIPAA in the past will now NOT be governed by HIPAA. Instead, they will be governed by other laws and regulations, and Emory policies.

So what Research IS governed by HIPAA?

Going forward, the IRB will make a determination as to whether a Research protocol is taking place within a Covered Component by considering the following factors:

- ✓ Are any of the researchers included as Research personnel on the protocol workforce members of a Covered Component?
- ✓ Does the research use identifiable health information?
- ✓ If so, does the Research include treatment for which the Covered Component is collecting payment using HIPAA-covered billing?
- ✓ If the answer to all of these questions is yes, then the Research protocol is considered to be taking place within a Covered Component and is subject to HIPAA.

Revised eIRB Form (Part I)

The eIRB form will be revised to reflect the new structure. The IRB will provide more detailed information, but basically the new form will ask the following questions:

Part I: Are you in a Covered Component for the purposes of this study?

- (1) Is this study conducted or partially conducted at the Atlanta VA Medical Center, or another non-Emory institution that has defined itself as a covered entity?
 - If yes, HIPAA applies.
- (2) Is anyone on the study team a Workforce member of Emory SOM, SPH, SON, or Student Health Services, Oxford Student Health Services, Autism Center, ECTRL, Psychoanalytic Institute or the Department of Psychology?
- (3) Is medical treatment provided as part of your current study?
- (4) Is any treatment described in the protocol being billed, electronically, to an insurance company or a benefits program (such as Medicare/Medicaid)?
 - If the answer to (2), (3) AND (4) is yes, then HIPAA applies.

Revised eIRB Form (Part II)

The second part of the new form addresses the need (or not) for a HIPAA waiver or authorization:

Part II: Are you getting protected health information from a covered entity (e.g., retrospective records study)?

- If yes, regardless of your response to any other questions, HIPAA applies and you need either a waiver or authorization.

Note:

The HIPAA status of studies that are already approved will not change.

The HIPAA status of new studies will be determined as of the date of submission.

So I'm only doing medical records review ...am I off the hook?

- Almost . . .
- You still need to get authorization or waiver of authorization from the IRB to access the records held by the medical facility.
- BUT, the research will not be considered to take place in a Covered Component and thus, will not be subject to HIPAA.
- HOWEVER, look for a new Emory University Sensitive Information Policy.

IRB Process for Research activities that include Treatment

Research activities that include Treatment and for which payment is collected using HIPAA-Covered billing will be considered to take place within a Covered Component and any “Individually Identifiable Health Information” (IIHI) collected as part of that Research will be considered “Protected Health Information” (PHI) and must be protected in accordance with HIPAA. (IIHI is essentially PHI without HIPAA protection.)

- Data from such Research may be included, as appropriate, in a medical record or other portion of a “Designated Record Set” maintained by a Covered Component. Once it is in a Designated Record Set, it will require authorization or a waiver of authorization to access it for research.
- Or it may be maintained in a separate Research record for a Research Participant. If it stays in a separate Research record, it will not be subject to HIPAA.

IRB Process for Research activities that include Treatment

Research activities that include Treatment that does not involve HIPAA-Covered billing will not be considered to take place in a Covered Component, and any IIHI will not be considered PHI while it is in the Research record.

- However, if data from this Research is placed in a medical record at a health care facility that is a covered entity (e.g., Emory Hospital, Emory Clinic) the information will be the PHI of the health care facility and be subject to HIPAA.

Research activities that do NOT include Treatment

Research activities that do not include Treatment will be considered to take place in a non-Covered Component. Individually Identifiable Health Information collected as part of that Research will NOT be considered Protected Health Information.

Data from such Research must be kept in a Research record that is separate from any medical record or any other portion of a Designated Record Set maintained by a Covered Component.

Designated Record Set = medical records, billing records, claims adjudication.

How is IIHI protected if HIPAA doesn't apply?

In order to protect IIHI that is not PHI, Emory University has developed a sensitive health information policy, the “Identifiable Sensitive Health Information Policy”. This policy is expected to be effective in September 2016. It will be located with Emory’s HIPAA Information Security Policies at https://hipaa.emory.edu/home/Policies/emory_security_policies.html. Essentially, it states that all of the requirements for the protection of PHI or ePHI in the HIPAA Information Security Policies will also apply to Identifiable Sensitive Health Information. These policies specifically address the information security regulations in HIPAA, not the privacy regulations, which do not apply to IIHI.

While we're on the subject of information security...

- ❖ The Office of Civil Rights in the United States Department of Health and Human Services has become increasingly more aggressive in pursuing breach investigations against universities and health care institutions.
- ❖ In the past year, the settlement agreements have involved fines ranging from \$375,000 to \$5.5 million. And a very tight compliance schedule.
- ❖ In almost every case, the breaches occurred because the institutions were not complying with their own programs and enforcing their own rules.
- ❖ EVERY CASE involved a workforce member leaving a laptop or actual paper in his/her car.
- ❖ So PLEASE REMEMBER - do not leave anything in your car!

RESOURCES

Please do not hesitate to contact us in the Office of Compliance if you have any questions:


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HIPAA@Emory: Policy Changes and Emory IRB Implementation

EMORY IRB WEBINAR

AUGUST 10, 2016

What studies are no longer covered ?

- ▶ Studies that do not involve treatment and electronic billing, regardless of location at Emory, or researcher affiliation

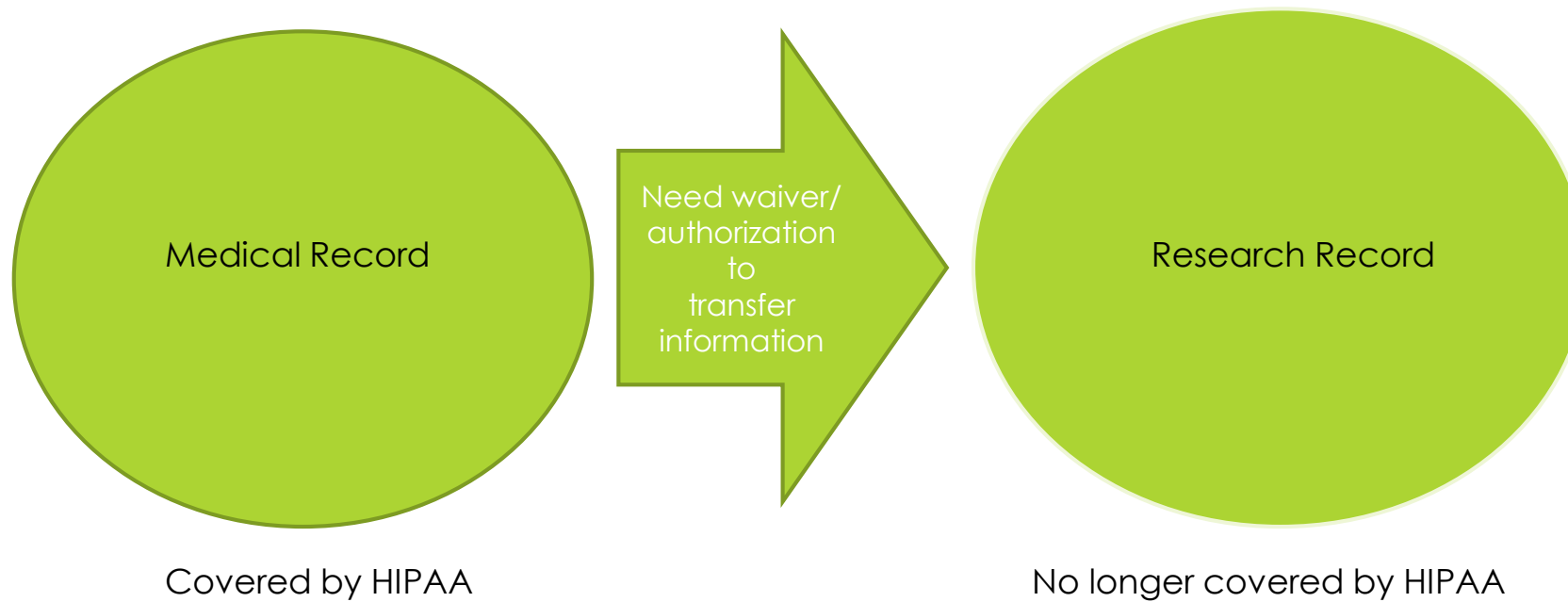
Research data for these studies will not be covered by HIPAA at Emory - *that does not mean a HIPAA waiver or authorization will not be needed to access the data*

- ▶ For example, chart reviews will need a HIPAA waiver
- ▶ Prospective, observational studies will require an authorization or (less likely) a waiver to obtain data from the clinical records
 - ▶ If results of any research tests/procedures are placed in medical record, then HIPAA will apply
- ▶ Once data is in research records, no longer subject to HIPAA or breach notification requirements

What studies are no longer covered ?

- ▶ Note: If other institutions are involved, HIPAA may still apply
 - ▶ E.g. CHOA, VA, other collaborating covered entities

How this works?

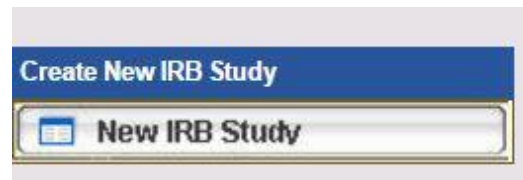


When are the changes effective?

- ▶ Even though the changes to the Emory policy were approved, the changes are not yet effective
- ▶ We are anticipating that the effective date will be near the beginning of the new fiscal year
- ▶ Why the delay? We need to make sure the eIRB application is updated (including software development and testing), to ensure consistent application of the new policy

What determines if the new vs. old policy applies to your study?

- ▶ Studies created in eIRB after the effective date will be under the revised Emory HIPAA policy
- ▶ What do we mean by “create”? When one clicks the “new study” button and then saves at least the first page of the new application:



- ▶ Regardless of when the study is submitted: if the study was created before the effective date, it will under the old HIPAA policy
- ▶ Rationale: We have to have a consistent standard to apply if/when ORA audits us for HIPAA compliance and this is the standard that was feasible in the electronic system

What about if I have created but not submitted my study?

- ▶ You will have two options.
 - ▶ You may submit the study and it will remain under the old HIPAA policy; or,
 - ▶ You may create a new study (using the Copy function if desired), withdrawing the old one
- ▶ Remember, revised “HIPAA determination” questions will only appear in eIRB for studies created after the system is updated, and the revised policy becomes effective.

eIRB: new questions in HIPAA section

- ▶ The questions under the HIPAA section in the IRB submission currently say:

HIPAA Determination

The "RWHSC" is comprised of the School of Medicine (SOM), School of Nursing (SON), School of Public Health (SPH), Yerkes Primate Center (YPC), Student Health Services (SHS), Psychological Center (PC), University Counseling Center (UCC), and the Oxford College Student Health & Counseling Center.

For a list of PHI identifiers, go to http://www.irb.emory.edu/documents/phi_identifiers.pdf

- 1.0 * Will you be receiving or disclosing any information about a person's health, healthcare or payment for healthcare that has any associated identifiers?
- Yes No Clear
- 2.0 * Is there any person on the study (Study Staff) that is part of the "RWHSC Covered Entity"?
- Yes No Clear
- 3.0 * Will any protected health information (PHI) be provided by any component of the "RWHSC Covered Entity"?
- Yes No Clear

eIRB: new questions in HIPAA section

- ▶ For studies created after the policy effective date, the questions will read similar to:

HIPAA Covered Component/Covered Entity Determination

There are HIPAA Covered Components within the following units: School of Medicine (SOM), School of Nursing (SON), School of Public Health (SPH), Student Health Services (SHS), Oxford College Student Health Services, Emory Clinical & Translational Research Lab (ECTRL), Psychoanalytic Institute, Autism Center, and the Department of Psychology.

For a list of PHI identifiers, go to http://www.irb.emory.edu/documents/phi_identifiers.pdf

Part I: Are you in a Covered Component for the purposes of this study?

1.0 * Is this study conducted or partially conducted at the Atlanta VA Medical Center, or another non-Emory institution that has defined itself as a covered entity?

Yes No

2.0 * Is anyone on the study team a Workforce member of the Emory SOM, SOPH, SON, or SHS, Oxford Student Health Services, Autism Center, ECTRL, Psychoanalytic Institute or Department of Psychology?

Yes No

eIRB: new questions in HIPAA section

3.0 * Is medical treatment provided as part of your current study?

Yes No [Clear](#)

4.0 * Is any treatment described in the protocol being billed, electronically, to an insurance company or a benefits program (e.g., Medicare/Medicaid)?

Yes No [Clear](#)

Part II: If study is not being conducted in a Covered Component, do study still require a HIPAA authorization or waiver of authorization?

5.0 * Is study getting protected health information from a covered entity (e.g., a retrospective medical records study)?

Yes No [Clear](#)

What other resources will be available?

- ▶ We will have an updated HIPAA authorization template
- ▶ We will have a decision tree to help you determine if your study will be covered by HIPAA (the eIRB system will guide you as well)
- ▶ A copy of this webinar and slides will be available after this presentation
- ▶ The Office of Compliance will present these changes at the next OCR Lunch and Learn!

Additional Questions?

► Please contact us at:

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