

Emory HIPAA Policy Frequently Asked Questions

- **When would HIPAA apply to research records for studies conducted by Emory University?**
 - For studies conducted at **Emory** and affiliates **Grady** and **Children’s Healthcare of Atlanta**, HIPAA will apply **only** to the research records of studies involving **treatment** (as part of the research protocol) which is **billed** to an insurance company, Medicare/Medicaid or another government benefits program.
 - For studies conducted at the **Atlanta VA (AVAHCS)** that will obtain PHI from patients’ medical records or generate health information via research procedures, **HIPAA will always apply**.
 - For studies at other covered entities not listed above, HIPAA applicability would depend on the contract or data transfer agreement terms, and we would likely need to consult with Emory’s Privacy Officer for guidance.
- **My study does not involve study-driven treatment or billing. I am only collecting data from the medical record. HIPAA does not apply to me, right?**

HIPAA always protects medical record information stored within covered entities, or within covered “components” of hybrid entities like Emory. If your study needs to access or use PHI from a covered entity’s medical records, you will need HIPAA authorization from the study participants, or a waiver from the IRB to access the medical record without any authorization (e.g. for retrospective chart reviews). In this scenario, after you copy the PHI into your research records *at Emory*, it would no longer be covered by HIPAA (VA studies would differ)
- **Our protocol describes treatment which is billed to insurance but the treatment is done per the standard of care and it is not at all dictated by the research. Our study just adds a couple observational tests that are paid for by the study. Does HIPAA apply?**

Probably not, if the treatment and billing are not “study-driven.” However, if you *assign* people to one or more routine treatments when they join the study, then the treatment would be considered “study-driven” and HIPAA would apply to your research records. For rare borderline scenarios, Emory IRB may need to gather more details and consult with the Emory Privacy Officer.
- **What are the Emory schools/groups under the HIPAA-covered entity (as of 4/11/2021)?**
 - The Emory University Health Plan, which is governed by separate privacy and security policies.
 - Emory University Student Health Services to the extent to which records subject to FERPA are not involved.
 - Emory University School of Medicine health care providers who are providing treatment (or Research that includes treatment) and collecting payment involving HIPAA-covered billing.
 - Emory Autism Center to the extent to which records subject to FERPA are not involved.
- **What schools are no longer under the covered entity?**
 - Emory University School of Nursing
 - Emory University School of Public Health
 - Oxford College of Emory University Student Health Service
 - Other entities no longer included: Emory Psychoanalytic Center and [ECTRL](#)
- **What research studies will be covered by this new policy?**
 - All studies, even ones that started before the Emory covered entity changed.
- **My study is being conducted outside the US, and I am providing treatment to participants. I am planning to bring identifiable health information to the US. Will HIPAA apply to my study or do I need an authorization?**

No, HIPAA does not apply to data collected outside the U.S. A HIPAA authorization is not required either provided that the study does not involve treatment and electronic billing to insurance or a government benefits program within the U.S.

- **My study was initiated under the old HIPAA policy but I am still conducting the study. Will my study now be under the new policy?**
 - Yes. Per outside legal guidance, updates to the covered entity structure become applicable to all research studies.

My study used language saying HIPAA applied to the research records, but now HIPAA would not apply. Do I need to update my consent/authorization form?

Emory IRB is not requiring updates to HIPAA language within consent forms for older studies. This is based on practicability, and the fact that our previous HIPAA language described what happens if data is no longer kept in the covered entity (i.e. it is no longer protected by HIPAA, but other protections are still in place.) That language covers the current situation, where your research records are now “out” of the Emory covered entity.

For additional questions, please contact the [IRB Education and QA team](#) or the [Office of Compliance](#).

What HIPAA or Confidentiality Language to Use?

