

Emory HIPAA Policy Frequently Asked Questions

- **When would HIPAA apply to research studies conducted at Emory University?**
For studies conducted at **Emory** and affiliates, **Grady** and **Children’s Healthcare of Atlanta (CHOA)**, HIPAA will apply **only** to studies involving the **use of personal health information (PHI)**, which also **provide treatment** (as part of the research study) **billed** to an insurance company, Medicare/Medicaid or another government benefits program. For studies conducted at the **Atlanta VA (AVAHCS), or CHOA**, that will obtain PHI from patients’ medical records or via interview/surveys **HIPAA will always apply**. Even if the only interaction at these sites are interviews where PHI is collected (no data is collected from the medical record), HIPAA will still apply.
- **My study is not providing 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 under covered entities. Certain studies may obtain PHI from the subject’s medical record. For these types of studies, researchers will need an authorization from the study participant to obtain that PHI from the Covered Entity that holds the medical record, or a waiver from the IRB to access the medical record without authorization (e.g. for retrospective chart reviews).
- **Our study is providing treatment and billing as part of the study (we described this in the protocol) but the treatment is done per the standard of care and it is not dictated by the research. Does HIPAA apply?**
No, because the treatment and billing are not done as part of the research study.
- **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 educational 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 are the Emory Psychoanalytic Center and [ECTRL](#)
- **What research studies will be covered by this new policy?**
 - Studies created in [eIRB](#) on or after September 1, 2016
- **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 locations 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 is under the old HIPAA policy, but I am going to submit my study for IRB renewal. Will my study now be under the new policy?**
 - No. Only new studies **created** on or after September 1, 2016, will be under the new policy.

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

What ICF/HIPAA Template a Study Team Should Use (if any)?



Note: If a study team (*) is accessing the medical record but not collecting PHI, a partial HIPAA waiver will suffice. If informed consent is needed, it should be free of language assuring people their information is covered under HIPAA. Use this template: [Emory Biomedical Consent Template-HIPAA does not apply.](#)

(*) [Emory HIPAA policy](#): applies for studies under the Emory covered entity, Grady and CHOA (but not the AVAHCS) in which treatment of subjects and billing for such treatment is taking place. Remember: if you extract data from the medical record to store in the research record, you may need an authorization for this process even if not treating or billing for study purposes.