

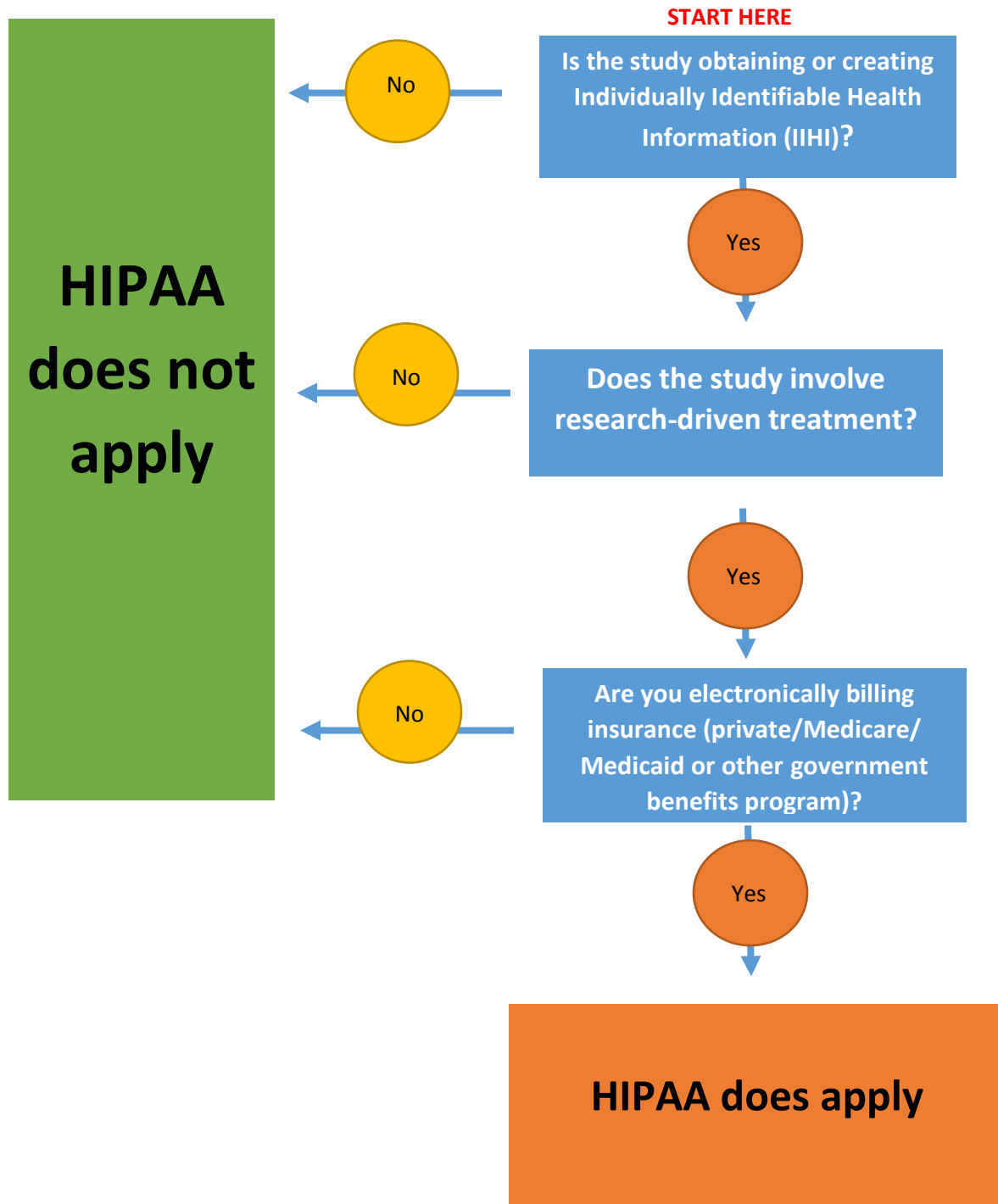
Emory HIPAA Policy Changes: Frequently Asked Questions

For additional information about the changes, please reference this recorded [webinar](#) or [slides](#).

- **When would HIPAA apply to research studies conducted at Emory University?**
For Emory-only studies, HIPAA will apply only to studies involving the use of Individually Identifiable Health Information (IIHI), which also provide treatment (as part of the research study) billed to an insurance company, Medicare/Medicaid or another government benefits program. For studies also conducted at the VA, CHOA or other external covered entities, HIPAA will always apply.
- **What are the Emory schools/groups under the HIPAA covered entity (as of 2/23/2017)?**
School of Medicine, School of Nursing, Student Health Services at Emory University, and the Emory Clinical and Translational Research Lab (ECTRL). The Emory University Health Plan is also a covered component, but it is governed by separate privacy and security policies.
- **What schools are no longer under the covered entity?**
The School of Public Health, Emory Autism Center, Oxford College Student Health Service and the Emory University Psychoanalytic Institute
- **What research studies will be covered by this new policy?**
Studies created in [eIRB](#) on or after September 1, 2016
- **What do you mean by “created” in eIRB?**
A study is created in our system after completing and saving the first page of the submission.
- **I created my study already but I have not submitted the study. What are my options if I know it would no longer be covered by HIPAA?**
You may withdraw your draft and create a new study application (you could use the copy function to avoid duplicating your work), or you could complete your already-created application which would remain under HIPAA
- **My study is only observational/chart review. I am not providing treatment or billing, but I am getting information from the medical record. HIPAA does not apply to me, right?**
HIPAA will not apply to data that is part of the research record. Certain studies, such as observational studies and chart reviews, record 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, alternatively, a waiver from the IRB to access the medical record without authorization (e.g. for retrospective chart reviews).
- **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](#).

HIPAA DECISION CHART



Note: Studies conducted at the AVAMC, CHOA, or other non-Emory Covered Entity will be covered under HIPAA, regardless of study type.