

Emory Healthy Brain Study: Study Participation Concerns

Emory University's School of Medicine recognizes that the Tuskegee Study and other abuses have been and continue to be a source of mistrust and a potential barrier to participation in research studies, particularly in the African American community. The Emory Healthy Brain Study staff firmly believes this, and other historical atrocities, should never be forgotten or trivialized. With this sentiment in mind, our study staff works to ensure participants are fully informed and comfortable before, during, and after completion of study procedures. Below are some of the precautions in place to prevent events like Tuskegee from reoccurring in research today:

Informed Consent

To enroll in our study, all participants must participate in our informed consent process. Participants meet with study staff virtually and in-person to review the entire consent form for our study. All procedures and associated risks are discussed in detail, and participants can ask questions before consenting to our study. Participants do not have to participate and can withdraw at any time without any penalty.

Institutional Review Board

Our Institutional Review Board takes our study protocol and participant safety very seriously. The mission of the Institutional Review Board is:

- a. To safeguard and promote the dignity and well-being of participants in research conducted at or by Emory by assuring their rights, safety and welfare are protected;
- b. To provide timely and high-quality review and monitoring of human subjects research; and
- c. To facilitate excellence in human subjects research by providing accurate guidance and education to Emory investigators, IRB members, and research officials.
- d. To ensure compliance with all regulatory and ethical obligations involved in Human Subjects Research conducted at or by Emory.

Study Results – Clinically significant abnormalities

In general, we will not give you any individual results from the study of the samples you give us. Research results will not be revealed to you or to your family now or in the future unless it affects your medical care. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. We do not release research results because it takes a while to discover the meaning of those results. If we become certain about the meaning of the research results, we will try to make that test available. If the test becomes available, we will make you aware of this test.

Our staff understands and respects any hesitancy toward participating in research, especially due to the history of research in the United States. It is our hope that with transparency, comprehensive information, and ethical practices and safeguards in place, we can build and strengthen trust between our potential participants and study team.

References: <https://www.irb.emory.edu/about/index.html>