THE UNIVERSITY OF ARIZONA Research & Partnerships

Access to Records

Medical Records

Information contained in a medical record is considered Protected Health Information (PHI) and is protected under the Health Insurance Portability and Accountability Act (HIPAA). Written permission to access PHI for research purposes must be obtained from the patient before access to the record is permitted.

Alternatively, a waiver or alteration of PHI for research purposes may be granted by a designated Privacy Board or IRB if authorization will not be obtained from the patient. The University of Arizona IRB is authorized to make a determination of a waiver or alteration of PHI for access to PHI for research associated with our affiliated academic hospitals (e.g., BUMC-T, BUMC-P, and BUMC-S). For access to PHI from another Covered Entity (e.g., medical practice or hospital), it is up to the individual Covered Entity to serve as the Privacy Board for use and access to PHI at their facilities for research purposes.

To obtain a waiver or alteration of PHI, the investigator must include protocol-specific justification for why access to PHI is needed without written authorization of the patient. This request must be submitted to the IRB for review and approval via the *Appendix for Waiver or Alteration of Consent or PHI*.

Educational Records

Educational records are protected under The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99). FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when they reach the age of 18 or attend school beyond the high school level.

The Registrar at the University of Arizona defines what information is considered "directory information." Information regarding which data elements are directory information can be found at www.registrar.arizona.edu/FERPA. Written permission from the student is required to access non-directory information.

Informed Consent

If educational records are accessed for research purposes, the informed consent form should:

- Specify the records that will be disclosed
- State the purpose of the disclosure
- Identify to whom the disclosure will be made
- Include the following language:

  Education records used by this research project are education records as defined and protected by Family Educational Rights and Privacy Act (FERPA). FERPA is a federal law that protects the privacy of student education records. Your consent gives the researcher permission to access [list educational records] *for research purposes.*

Access to Records

Students as Research Participants

Research involving one's own students raises specific human subjects protection concerns, primarily due to the inherent power imbalance between instructor and student. Even when participation is presented as voluntary, students may feel pressured to take part out of concern that declining could affect their grades or their relationship with the instructor.

If any research personnel have access to student grades, they must be blinded to participant identity for all research-related activities and **cannot** access educational records or student artifacts (e.g., coursework, class assignments, exams, etc.) for research purposes until after final grades are posted. In addition, these project personnel cannot be involved in recruitment, consenting, or identifiable data collection or analysis of their own students to avoid the potential for undue influence or coercion.

If extra credit is used as an incentive, students must be offered an alternative assignment of equivalent effort and value so that participation is not required to earn credit. Safeguards should also be in place to minimize coercion, such as separating research participation from course grading decisions and, when feasible, using a third party to manage recruitment and credit assignment.

In this instance, a neutral third party not affiliated with the study must serve as an "honest broker" and be responsible for recruiting and consenting students, as well as collecting identifiable data (including educational records) and hold those items until final grades are posted. This individual must have no vested interest in the study, must not be engaged in the research in any way, and may not be included as a study team member or listed as an author on any resulting publications. The honest broker will also need to serve as the point of contact for students who wish to withdraw from the study prior to posting of final grades. If the project personnel/instructor wishes to analyze data in real time, the honest broker can de-identify the data and share it with the project personnel/instructor.

Access to Records

Access to department specific records may be granted by the individual department. Permission for use of large-scale University of Arizona student records (undergraduate, graduate, and professional) is granted by the Registrar's Office. The request for release of information and a copy of the protocol must be submitted to the Registrar for a determination of whether the release of information is appropriate under FERPA.

Registrar
PO Box 210066
reghelp@email.arizona.edu

Employment Records

Access to records of employees of the University of Arizona (e.g., staff or faculty) requires the written consent of the employee per ABOR Policy 6-912. The policy permits

administrative access to personnel records only for authorized purposes. Research which typically is not considered an authorized purpose unless authorized by the President of the University

Access to employment records of another organization requires permission from that organization and according to their own policies.

Substance Use Disorder Patient Records

Substance Use Disorder (SUD) Part 2 regulations apply when a patient has been referred for treatment or diagnosed with a SUD. Patient-identifying information may be used or disclosed for scientific research purposes if the data holder is a HIPAA-covered entity or business associate, and the use or disclosure complies with 45 CFR 164.512(i).

Any individual conducting scientific research using patient-identifying information related to SUD:

- Is fully bound by Part 2 and will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part.
- Must not redisclose patient identifying information.
- May include data under this part in research reports only in deidentified form.
- Must maintain and destroy patient identifying information.
- Must retain records in compliance with applicable federal, state, and local record retention laws.
- Must develop and use consent forms that meet Part 2 requirements, specifying: 1) who can receive the records, 2) the purpose of the disclosure, and 3) an expiration date for the consent.
- Must retain data in a University of Arizona or Banner Health approved database such as REDCap or UA Box Health.
- Must conduct regular audits to assess compliance with Part 2 regulations, including record access logs and documentation of disclosures.