**Why are records considered human research?**
Researchers do not have to interact with a person to involve humans in research. A *Human Subject* is defined as a living individual about whom the researcher will intervene or interact, OR will obtain his/her identifiable information. Research that is looking at records typically accesses identifiable information, and therefore, the research is subject to IRB review. Access to records can be restricted, similar to the case of medical, education, or judicial records. Other records can be obtained by the general public.

**What is identifiable information?**
Identifiable information includes information where the identity of the individual can be ‘readily ascertained or associated with the individual.’ Some of this information may also be considered private (where the person can reasonably expect that no observation or recording is taking place, and which is provided by the person for a specific purpose and which the individual can reasonably expect will not be made public).

**What is a ‘retrospective’ record review?**
There are many terms used when discussing record reviews – retrospective, prospective, existing, exempt, and expedite are just a few. The terms are not synonymous. What is the difference?

The IRB regulation has two categories that apply to record reviews.

1) Exempt category 4 requires that only ‘existing’ data be used for the research, and the information cannot be recorded by the investigator in a manner that people can be identified. ‘Existing’ is defined by the federal government as ‘existing before the research is proposed to an institutional official or the institutional review board.’ The signature date of the PI on the HSPP Form is used to determine what is ‘existing.’ The data cannot be recorded by the PI in a manner that people can be identified.

2) Expedite category 5 is for identifiable data analysis. The category does not specify that the data have to be existing. In theory, this is for any other data analysis not subject to exempt category 4.

To add to the confusion, researchers commonly identify their work as either retrospective or prospective. Retrospective and prospective have no definition in the regulations. It generally means the project is classified as either exempt or expedite. Not all expedite research is solely prospective. This would be misleading to assume that an expedite study cannot also be retrospective.
Case Study:
A typical request to the IRB goes something like: 'Over the next two years I will look at records on individuals with X disease or for X reason. By the time I look at the record the information will exist, and therefore, I am requesting a retrospective records review.'

The logic is flawed due to how 'existing' is defined by the federal government. Anything that is not already in existence at the time the submission is made to the HSPP cannot be considered exempt. Therefore, the activity is expedite (and prospective) and must follow the regulatory requirements for consent or a waiver must be obtained.

Exempt means everything is there already and you just want to look at it. There is no renewal and the IRB does not have to document waiver of consent requirements (there may still be HIPAA waiver requirements).

Expedite means everything is not there yet (or is there but identifiable), there is a renewal requirement, and the project is bound by the regulatory requirement for consent. Consent must be either obtained or waived.

Do I need to provide a date range for a record review?
The IRB must know when you will be collecting records so the IRB can determine if the data are 'existing' and whether the project can be made exempt. The project should specifically state when the review will start and when, if at all, the review will end.

Remember, the requirements for a determination of exemption are 1) the data all exist and 2) the information is not recorded by the investigators in a manner that subjects can be identified. If there is no end date, the data do not exist, and therefore, the project is considered expedite. Conducting expedite research requires informed consent or a waiver of consent for any information not already existing.

NOTE: The IRB will not approve a moving date range. It is not appropriate to seek an approval with a waiver of consent and then continue to request an amendment every six months for review of records for the last six months. If you know you want to collect information into the future, then the IRB needs to approve the project as such.

Why is consent needed for some record reviews and not for others?
It's complicated! In short, whenever possible the IRB adheres to the Belmont Report principle of 'respect for persons.' This principle says that people should have a say in what happens to them and their information. In addition, some records have a legal or regulatory requirement for consent.

In keeping with the spirit of the Belmont Report, anything prospective should get consent unless the study can justify meeting the requirements for a waiver. Waiving consent has to meet all the following requirements:
Record Reviews

- Minimal risk;
- Will not affect rights/welfare;
- Could not be practicably carried out; and
- Subject will be given more info if appropriate.

Bullet #3 causes a lot of confusion. Practicability of getting consent is not based on it being hard to get consent, or inconvenient for the researcher. Instead, it is based on the subject being available or reachable, and what is the right thing to do. If a patient is in the hospital or visiting the researcher routinely, then the individual is available. Sometimes a waiver can be justified but it truly is case specific.

**Common record requests and requirements**

**Medical Records**

Information contained in a medical record is considered Private Health information (PHI) and is protected under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA outlines 18 specific elements that are automatically deemed identifiable. Written permission to access PHI must be obtained from the owner of the record before access to the record is permitted.

A waiver or alteration of PHI must be granted by a designated Privacy Board or IRB if consent will not be obtained from individuals. The University of Arizona IRB is authorized to make these determinations for access to information for BUMG and associated covered studies and covered investigators. The investigator must include protocol-specific justifications for waiving consent and/or PHI Authorization.

**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 s/he reaches the age of 18 or attends a school beyond the high school level. Written permission to access non-directly information is required before access to the record is permitted except in certain limited circumstances.

The organization that owns the record is charged with protecting the FERPA information. At the University of Arizona, the Registrar is the designated individual with defining “directory information.” Information regarding which data elements are eligible to be considered directory information and from which the University's list is selected can be found at [www.registrar.arizona.edu/FERPA](http://www.registrar.arizona.edu/FERPA). Access to records from schools other than the UA must have site authorization from the district who owns the records.

Access to department specific records may be granted by the individual department. Site authorization for use of large-scale University of Arizona student records (undergraduate,
graduate, and professional) is given 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
REG-reghelp@email.arizona.edu

A copy of the written site authorization to access student records for information beyond the above directory information must be submitted with the appropriate form.

**Employment Records**

Access to records of employees of the University of Arizona (e.g. medical residents, 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 (which typically do not include research) unless authorized by the President.