Definitions

CITI Training

CITI training is an online training program designed to educate faculty, students, and individuals involved in research about issues regarding human subject research. Healthcare and academic institutions performing research purchase a membership to gain access to this training. Certificates and required courses can be viewed at https://citiprogram.org. Contact your facility research compliance officer to obtain login information.

Clinical Trials

Clinical trials are designed to evaluate and test new interventions that include but are not limited to: drugs, cells and biologic products, surgical procedures, radiological procedures and devices. Approved studies for trials involving direct treatment or patient care require written patient authorization and study approval by an Institutional Review Board (IRB). Clinical trials may also use de- identified patient materials to evaluate new instrumentation for a diagnostic company or microbial isolates to evaluate new antimicrobial agents *in vitro*. These do not require patient authorization but do, under most instances, require IRB review.

Client, Internal vs. External

An internal client is defined as a Principal Investigator or Study Lead that is affiliated with SQL/LSA, Banner Health, and/or the University of Arizona. Whereas, an external client would be anyone not affiliated with one of the institutions mentioned above.

Laboratory Data/Analytics

Laboratory Data/Analytics is the practice of obtaining laboratory information to address clinical questions. Examples include gathering retrospective data for a research study submission, to evaluate treatment and testing methodologies, or to identify factors associated with specific outcomes. If the request for information is related to a scholarly activity, select Data Analytics under the Scholarly Project header.

Material Transfer

A Material Transfer manages the transference of laboratory specimens or materials where the recipient's intended use is for the purposes of research. A material transfer agreement outlines obligations and rights of the provider and recipient in regard to the transferred materials and any derivatives. Note: test results acquired from transferred specimens cannot be used for medical treatment nor billed to the originating patient or their insurance.

Material Transfer Types:

- Surveillance: Specimens associated with Public Health-related epidemiological monitoring of health and wellness.
- Internal Clients: Transfer of deidentified waste-stream specimens between Banner Health and/or Sonora Quest facilities.
- External Clients: Transfer of deidentified waste-stream specimens between the Banner Health/Sonora Quest Laboratories and outside entities.

Purchased Laboratory Services

If clinical laboratory testing is needed for research purposes (not patient care) and SQL/ LSA laboratory is not involved in any other part of the research other than providing testing services, call your SQL Sales representative or the SQL Sales Department at 602-685-5285 to set up a research-specific account.

Scholarly Projects	A project designed and performed by an academic institution that is executed under the guidance of a qualified mentor. Scholarly activities requiring laboratory support fall under two categories, Clinical Research and Data Analytics. Clinical Research is defined as any scientific or technical research performed within a clinical laboratory at Banner Health or Sonora Quest Laboratories, whereas Data Analytics is the exclusive request of scientific and clinical data for activities such as quality improvement, clinical practice, or education.
Clinical investigations regulated by the Food and Drug Administration (FDA)	Clinical investigation regulated by the FDA means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. Click here to view Title 21 Part 50 Click here to view Title 21 Part 50
Research regulated by the Office for Human Research Protections (OHRP)	Research is regulated by the OHRP if the research is conducted or funded by the Department of Health and Human Services. **Click here to view 45 CFR 46**
Anatomic Pathology	Select Anatomic Pathology when research study requires support and/or testing from the following departments: Histology, Cytology, or Flow Cytometry. Examples are but not limited to: tissue, tissue blocks, slides, specialized slide staining, cytology fluid testing, and Flow Cytometry analysis. If only data analytics of Anatomic Pathology data is needed, select Laboratory Data/Analytics.