**Non-Human Research Project Requirements and Attestation**

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| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Principal Investigator’s UA Department/Unit:** |  |

The purpose of this document is to provide guidance to University of Arizona (“UA”)-affiliated researchers who are planning to create or implement a “non-human subjects research” project utilizing Banner Health (“BH”) data, resources, etc. These “non-human subjects research” projects are generally:

* Quality Improvement/Quality Assurance designed or intended to improve patient care;
* Evaluations and comparisons between a program, process, or system to an established set of standards like standard of care, recommended practice guidelines, or other benchmarks;
* Initiatives to improve the performance of institutional practices or local systems; or
* To bring about improvements in health care delivery.

“Non-Human subjects research” projects using Banner Health data or resources must be approved by the Institutional Review Board (“IRB”). Submit your project using the [IRB Protocol for Determination of Human Research form](https://research.arizona.edu/sites/default/files/IRB%20Protocol%20for%20Determination%20of%20Human%20Research%20v2021-11.docx) and this Attestation form. If the IRB determines a project to be “non-human subjects research,” strict guidelines and regulations, such as HIPAA, must still be followed. HIPAA does eliminate the need for patient authorization for these projects under “healthcare operations” but all other HIPAA requirements and UA policies and standards must be followed.

**Requirements**

* If the project involves a patient or employee survey, please include verbiage similar to: *Your participation is voluntary and participation/non-participation will not affect any current or future treatment or care at Banner Health; Your participation is voluntary and participation/non-participation will not affect any current or future employment at Banner Health*;
* The minimum necessary standard will be followed at all times, only the minimum necessary amount of information will be accessed, used, or disclosure (to or by the minimum necessary persons) to accomplish the intended and approved purpose;
* PHI/PII, confidential, or sensitive information will only be accessed by appropriate/approved parties;
* Approval for the project should be obtained by advisor (if project lead is a student/resident), applicable department/unit leader, and administration to ensure the project will not interfere with patient care, operations, etc. and is supported by UA/BH; and
* If results from the project are to be published externally, outside of UA/BH, and the information includes identifiable information (PHI/PII), patient or employee authorization and approval from the BH Privacy Office are required.

**Attestation**

I, as project lead, attest that all information provided as part of my submission is accurate. If any substantial changes are made that affect the answers above, I will resubmit the project for review. I also understand and agree to abide by the requirements above regarding appropriate and secure access, disclosure, and use of Banner PHI/PII or other confidential/sensitive information.

Signature of Project Lead Date