**The IRB Protocol for Determination of Human Research should be used when it is unclear if the proposed activities require review by an Institutional Review Board (IRB). This form is required if the proposed study involves the following activities:**

* **Access to an electronic medical record;**
* **Use or disclosure of Protected Health Information (PHI);**
* **Requests for data or specimens from the Banner Clinical Research Data Warehouse (CRDW);**
* **The project is or will be supported by federal funds that involves people;**
* **The information will be used to support an application to the FDA or involves the use of a test article in a human;**
* **IRB certification for access to materials from dbGap; OR**
* **The project involves Native American/Alaskan Native or international indigenous populations.**

**The red text is instructional and should be deleted prior to submitting this form to the IRB.**

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| --- | --- | --- |
| **Basic Information** | | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Principal Investigator’s Department/Unit:** |  |

# Funding Information

**Please indicate all sources of funding for the project, including gift funds, departmental funds, or other internal funding. For each funder, list the name of the funder, and the institutional proposal number or the award number that you received from Sponsored Projects. For externally funded projects, the information below should match the Study Funding Sources in eIRB.**

|  |  |
| --- | --- |
| **No Funding** | |
| **Federal Funding**, including flow-through federal funding (i.e., NIH, NSF, DoD, etc.) | Name of funding source: |
| Institutional Proposal or Award Number: |
| **Industry Funding** | Name of funding source: |
| Institutional Proposal or Award Number: |
| **Foundation Funding** | Name of funding source: |
| Institutional Proposal or Award Number: |
| **Department Funding** | Name of funding source: |
| **Gift Funding** | Name of funding source: |
| **Other** | Name of funding source: |

# Determination of “Research”

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| **45 CFR 46.102(l)**: Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.  A **systematic** approach involves a predetermined system, method, or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/  or biospecimens, and analysis either quantitative or qualitative.  Activities **designed to develop or contribute to generalizable knowledge** are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable). |

Does the proposed activity involve a **systematic** approach?

Yes

No

Is the intent of the proposed activity to **develop or contribute to generalizable knowledge**?

Yes

No

**If Yes to BOTH questions the study is Research. Proceed to Section 3.0: Determination of "Human Subject."**

**If the answers to one or both questions are NO, skip Section 3.0 and proceed to Section 4.0: Determination of "Human Subjects" per FDA Regulations.**

# Determination of "Human Subject"

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| **45 CFR 46.102(e)**: **Human subject** - a living individual about whom an investigator (whether faculty, student, or staff) conducting research: (1) obtains information or biospecimens through **intervention** or **interaction** with the individual; and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or  generates **identifiable** private information or identifiable biospecimens.  **Intervention** includes both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes.  **Interaction** includes communication or interpersonal contact between investigator and subject.  **Identifiable** is where the identity of the subject is or may be ascertained by the researcher or will be associated with the information. The research could involve the use of coded data/specimens.  **Private Information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). |

Does the activity involve obtaining information about living individuals through **intervention** or **interaction** with the individuals?

Yes

No

Does the activity involve obtaining **identifiable** and **private information** about living individuals?

Yes

No

**If YES to either question, the research activity is research that involves human subjects. STOP and submit the IRB Protocol for Human Subjects Research.**

**If the answers to both questions are NO, proceed to Determination of "Human Subjects" per FDA Regulations.**

# Determination of "Human Subject" per FDA Regulations

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| **21 CFR 50.3(g)**: **Human subject** - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human, a patient, or involves the use of an individual’s specimen even if there are no identifiers.  \***Test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation.  \*\***In vitro diagnostic products** are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. |

Is this a clinical investigation involving a test article including in vitro diagnostics with a human subject(s) or their biospecimens?

Yes\*

No

**\*If yes, answer questions a. and b.**

Will an individual be a recipient of any test article (i.e., drug, biologic, or medical device) or as a control?

Yes\*\*  No

Will a medical device be used on an individual’s specimen (21 CFR 812.3(p)) (i.e., In vitro diagnostic device)?

Yes\*\*  No

**\*\*Note: The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by FDA, as well as other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. For more information see the FDA Guidance on In Vitro Diagnostic Device Studies - FAQs.**

# Coded private information and/or human biological specimens per OHRP

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| **Coded** means a living individual's identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof and there is a key to link the code to the identifiable information of that individual. Coded data are considered identifiable if the individual who holds the key to link the information or specimens collaborates on other activities related to the conduct of the research. |

Does the activity involve the use of **coded** private information/specimens?

Yes

No **(if no, skip to section 6.0)**

If **Yes**, the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information /specimens pertain because:

The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased.**Provide a copy of this agreement (an informal email exchange is sufficient)**. **OR**

The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased. **Provide documentation of the written policies and operating procedures**. **OR**

There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. **Provide documentation of the legal requirements**.

Were the coded private information and/or specimens previously collected, specifically for the currently proposed project?

Yes

No

# Other Activities

**Select the most appropriate check boxes below that describes the proposed research activities. If none of the activities apply, leave this section blank.**

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| [**Program Evaluation/Quality Improvement/Quality Assurance**](https://research.arizona.edu/sites/default/files/What%20is%20Human%20Research%20v2021-09.pdf): The proposed activity will assess, analyze, critique, and improve current processes of program or health care delivery in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements in a program or health care delivery in a specific setting without the intent to generalize findings. |
| **De-identified Data Analysis:** The researchers on this activity will be provided with an existing de-identified dataset. Please note: confirmation from the data owner is necessary to confirm data is truly de-identified. In addition, a list of the data elements must be submitted for review. |
| [**Course-Related Activities**](https://research.arizona.edu/sites/default/files/Classroom%20Research%20and%20Independent%20Projects%20v2021-09.pdf): The proposed activity is limited to course-related activities designed specifically for educational or teaching purposes. |
| [**Case Reports**](https://research.arizona.edu/sites/default/files/Case%20Reports%20v2021-09.pdf): The proposed activity is a case report or case series of no more than three (3) cases describing an interesting treatment, presentation, or outcomes. |
| **Oral History**: The activity is limited to oral history activities, such as open ended interviews that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings. |
| **Public Use Datasets**: The activity is limited to analyzing information contained within a publicly available dataset (Meaning, any person can find and use the data). NOTE: This does not include reviewing or analyzing information from social media. |
| **Journalism/Documentary Activities**: The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis. |
| **Purchased cell lines**: The activity involves commercially available, de-identified non-human embryonic cell lines. |
| **[Limited Data Set](https://research.arizona.edu/sites/default/files/hipaa_data_reference_guide_12.21.2016.pdf)**: A limited data set is a data set that is stripped of certain direct identifiers specified in the Privacy Rule. A limited data set may be disclosed to an outside party without a patient’s authorization only if certain conditions are met. **Please review the**[**Data Use Agreement (DUA)**](https://research.arizona.edu/compliance/HIPPA-privacy/data-use-agreements/faqs)**from the HIPAA Privacy Program.** |
| **dbGap**: Receipt of data from dbGap that requires IRB approval, but the data you will receive is coded or de-identified. |
| **Preparatory to Research**: The activities are limited review of protected health information (PHI). No PHI is to be extracted from the covered entity by the researcher in the course of the review. |
| **PHI of Decedents**: The use or disclosure is solely for research on the PHI of decedent, the PHI is necessary for research purposes and if requested the Principal Investigator will be required to provide documentation of the death of the individual(s). |
| **Public Health Surveillance**: In general, public health surveillance involves collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease. The activity must be conducted, supported, requested, ordered, required, or authorized by a public health authority. The activity must be limited to that necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). |
| **Native American/Alaskan Native**: The activity involves access to tribal resources (e.g. cultural artifacts, environmental samples, or people), but the activity is not intended to produce generalizable knowledge. |

# Summary of Activities

**Provide a concise description of the purpose or objectives of the project**:

**Describe the proposed methods and study procedures**:

# Describe the subject population, or the type of information/specimens to be studied:

**Select the appropriate box indicating where the information/specimens were or will be collected/obtained (i.e., identify the source of data/specimens)**:

**Note: Provide a separate list of the specific data points, variables, and/or information that will be collected and/or analyzed (i.e., data abstraction form).**

|  |
| --- |
| Banner University Medical Center- Medical Records  **For** [**Collaborative Activities with Banner Health**](https://research.arizona.edu/compliance/human-subjects-protection-program/collaborative-activities-banner-health)**, review the additional information needed for Non-Research Projects** |
| Data Warehouse, specify: |
| Business Associate or Collaborator |
| Other, explain: |

**Items needed for approval, as applicable:**

* Advisor approval (if the PI is a student or resident)
* If applicable, list of data elements to be received or obtained
* If applicable, documentation explaining that the PI cannot ascertain the identify of individuals from coded private information/specimens
* Site authorizations
* Data collection tools