
THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact
Let’s Talk About Research Data
Human Subjects Protection Program (HSPP)
THE UNIVERSITY OF ARIZONA

Agenda

This workshop will provide information about research data collection, sharing, protections and related protocol and consent requirements. Federal Data Management Plan and data repository requirements including what needs to be added to the protocol and consent will also be covered. In addition, this session also includes discussion about retrospective data review and touches on PHI, CRDW and GDPR requirements. Links to forms and helpful resources will be provided.

10.0 Research and Data Collection Procedures:

10.1 Select the methods of data collection that will be used in this study (select all that apply):

☐ Anthropometric measures (e.g., height, weight, waist circumference, etc.)	☐ Participant observation
☐ Audio/video recording	☐ Screening data
☐ Benign interventions	☐ Self-health monitoring (e.g., pedometers, food diaries, etc.)
☐ Biological specimens – blood draws	☐ Surveys – paper
☐ Biological specimens – clinically discarded blood or specimens	☐ Surveys – internet (including online and email-based data collection)
☐ Biological specimens (urine/feces, tissue, saliva, skin, hair, nails, nasal swab)	☐ Surveys – telephone
☐ Clinical Data Warehouse (CDW)	☐ Randomization with control and experimental groups
☐ Cognitive or behavioral measures, including daily diaries	☐ Records – billing
☐ Data collected using other communication/electronic devices (e.g., cell phones, pagers, and texting devices)	☐ Records – educational
☐ Data previously collected for research purposes	☐ Records – employee
☐ Deception	☐ Records – lab, pathology and/or radiology results
☐ Instrumentation, equipment, or software not approved by the FDA	☐ Records – mental health
☐ Interviews – focus groups	☐ Records – substance abuse
☐ Interviews – in person	☐ Research imaging protocols
☐ Interviews – virtual/online	☐ Recombinant DNA
☐ Medical records review	☐ Social networking sites
☐ MRI/ultrasound with contrast	☐ Stem cells
☐ MRI/ultrasound without contrast	☐ Radiation Scans (X-Ray, CT Scans, etc.)
☐ Non-invasive instruments (e.g., external sensors applied to the body)	☐ Other activities or interventions – describe: Click or tap here to enter text.

IRB Review of Research Procedures

- As part of the IRB review, all research procedures will be reviewed. Sufficient detail should be provided that would allow the IRB to understand what research participants will be asked to undergo as part of the research study.

IRB Review of Data Collection Tools

- Any data collection tools referenced in the procedures section of the IRB application will need to be submitted. This includes:
  - Interview questions
  - Focus group questions
  - Surveys
  - Any other forward facing data collection document

Check your Understanding

“Our research study will involve two visits to the Bio 5 research lab. Upon arrival, participants will be asked to complete a demographics survey. This survey is expected to take the participant five minutes to complete. We will then have the participant walk on the treadmill for 15 minutes while reading a book of their choice. Lastly, the subjects will be asked to take a questionnaire regarding their exercise routines. This questionnaire is expected to take about 20 minutes to complete. Once completed, the study participant is free to leave. This study visit will be completed a second time a month later. The research procedures will be the same during the second visit.”

Check your Understanding

What Data collection tools will the IRB need as part of their review?

Check your Understanding

“Our research study will involve two visits to the Bio 5 research lab. Upon arrival, participants will be asked to complete a demographics survey. This survey is expected to take the participant five minutes to complete. We will then have the participant walk on the treadmill for 15 minutes while reading a book of their choice. Lastly, the subjects will be asked to take a questionnaire regarding their exercise routines. This questionnaire is expected to take about 20 minutes to complete. Once completed, the study participant is free to leave. This study visit will be completed a second time a month later. The research procedures will be the same during the second visit.”

IRB Review of Privacy and Confidentiality of Data

- The University of Arizona takes seriously its commitment to respect and protect the privacy of individuals that participate in research, as well as, to protect the confidentiality of information.
- The IRB is tasked with ensuring the protection of data and information related to human research protocols.
- Part of the IRB review and approval is to ensure that identifiable private information has the appropriate data security standards.

Human Subjects Data & PHI

- All research data must be protected!
- Access to records requires permission or a waiver consent/authorization.
- Human Subjects Data and Protected Health Information (PHI) are categorized as RESTRICTED and must be stored on a UA Approved SECURE Storage Platform.
- Restricted data must also be encrypted when it is being shared. https://it.arizona.edu/documentation/uaconnect365-email-encryption. Identifiable data sharing must also be approved by the IRB.
- A contract will be needed when disclosing PHI (including limited data sets) outside the UA: UAHSContracts@arizona.edu

14.7 Indicate where data will be stored:

☐ Box@UA	☐ OnCore
☐ Box@UA Health	☐ PACS medical imaging software
☐ Clinical Data Warehouse (CDW)	☐ Password Protected Drive
☐ Cloud Server	☐ REDCap
☐ Department Drive	☐ Transmitting/receiving subject data to/from an outside group
☐ Department Office	☐ UA Records Management & Archives
☐ Encrypted Drive	☐ Banner Server/Platform, specify:
☐ External Drive (hard drive, USB, disk)	☐ Soteria
☐ Google Suite for Education	
☐ HIPAA Research Computing Service	☐ Other, specify: Click or tap here to enter text.

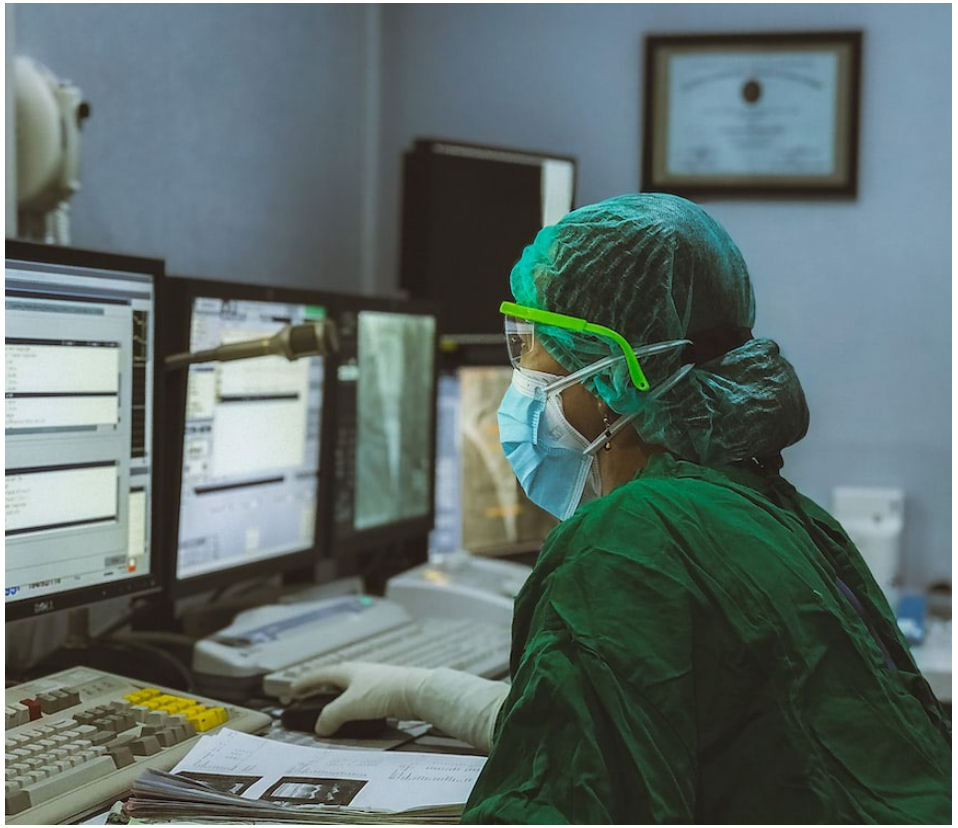
HSPP Guidance: Data Security and Records Retention
https://research.arizona.edu/sites/default/files/Data%20Security%20and%20Records%20Retention%20v2021-09.pdf

Human Subjects Data & PHI

- As part of the IRB review, we will need to understand:

  - Where data will be stored
  - In what format will the data be stored (identifiable, de-identified, coded, etc.).
  - What security controls will be in place to ensure data is and remains protected.
  - How long will the data be stored? (see Data Security and Records Retention guidance)
  - **Will data be shared outside of the institution or with researchers external to the study team? if yes, how?**
  - **Will data be kept for future use and/or stored in a repository?**

Sharing Data



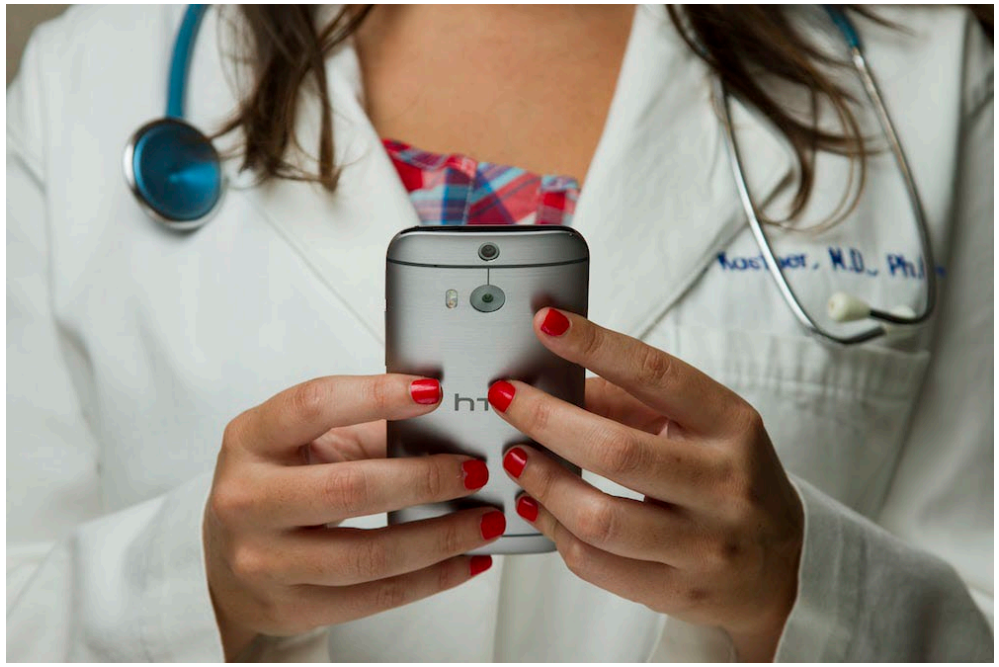
- If you plan to share data (including identifiable data), the consent should explain the details surrounding data sharing:

"The data collected as part of this study, including blood samples, will be shared with investigators at the University of Texas for data analysis. The University of Texas is a collaborating partner in this study. Information released to this site will not include any information that can directly identify you."

- If you plan to share Protected Health Information, HIPAA regulations require the recipient to be listed as a party records will be disclosed to:

"The data collected as part of this study, including blood samples, will be shared with investigators at the University of Texas for data analysis. The University of Texas is a collaborating partner in this study. Information released will include your name, DOB, and medical condition.

Sharing Identifiable Protected Health Information



It is anticipated there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you are giving permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, to comply with regulations, and to help ensure that the study has been done correctly. These other groups may include:

- *Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies*
- *Banner University Medical Group and Banner Health*
- *The University of Arizona (UA) and the UA Institutional Review Board*
- *The sponsor and/or funder supporting the study, their agents or study monitors*
- *Your primary care physician or a specialist taking care of your health*
- ***The University of Texas***

Future Use of Research Data

- When a protocol includes future use, the IRB will require the consent form to describe the potential future use in layman's terms.

For example:

"Your de-identified samples and data will be stored for future unspecified research. This data may be shared with researchers both inside and outside of the institution."

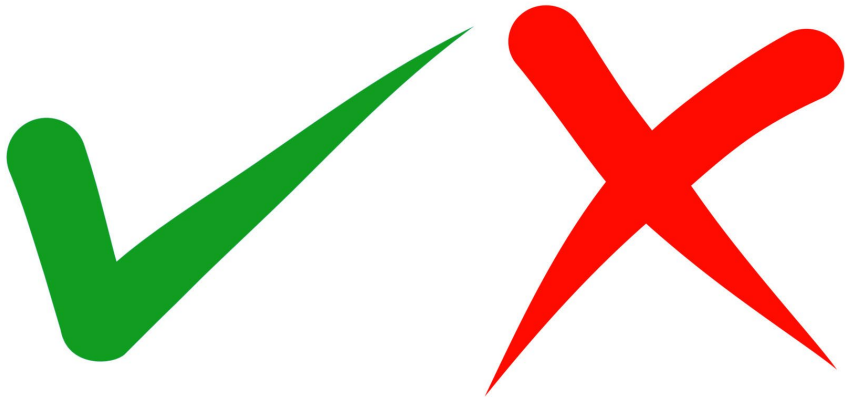
- If the data sharing is optional, an opt-in or opt-out checkbox or initial line on the informed consent document.
- If data will not be used/stored for future use, the consent form must also state so. The revised common rule no longer allows the consent to remain silent on the issue.
- Bottom line: IRB will always honor the original consent for future use of data requests.

Check your Understanding

“The blood specimens collected as part of this research study will not be retained for future research. Once the data analysis has been completed, your blood will be discarded.”

Check your Understanding

Will the IRB allow future reuse of this data if the purpose of the secondary research is similar to the original study? (i.e., both projects analyze the blood for diabetes outcomes)



NIH/Federal Funding Data Sharing Requirements

- Effective January 25, 2023, NIH will require a Data Management & Sharing (DMS) Plan for all funded/supported/conducted research that results in the generation of scientific data.
- Most federal funders are leaning towards this requirement!

Benefits Include:

- Accelerates research discovery
- Enhances research rigor/reproducibility (accountability)
- Provides increase to data accessibility
- And most important to the IRB: this rule increases respect to all research subjects by decreasing duplicative effort from future research participants.

Additional Resources for Investigators

University of Arizona Libraries NIH Data Management and Sharing Policy Website.
https://data.library.arizona.edu/data-management/nih-data-management-sharing-policy-2023

DMPTool
Build your Data Management Plan

- Assistance with writing a DMSP.
- Contains templates, samples, etc.
- A **Data Management Checklist** is also available on the **RII website**.
- https://research.arizona.edu/compliance/human-subjects-protection-program/resources-investigators/data-management

ReDATA
University of Arizona's
Research Data Repository

- **FREE** Data Repository.
- Meets all data archiving and sharing requirements.
- Assists with maintenance, quality control & compliance.

https://data.library.arizona.edu/data-management/services/research-data-repository-redata

IRB Review of Data Management Plans

15.4 Data Management Plan: Please discuss the data management plan, if required by your funder. For additional resources, reference the HSPP Data Management webpage. If your sponsor/funding agency requires a Data Management Plan, please upload the approved copy in eIRB. This section and the informed consent form should contain all pertinent information including:

- **What data/metadata will be shared (imaging, survey; raw data or derived; protocol, data form; etc.)**
- **What repository will be used (if known)**
- **How will data be stored (in a de-identified or identifiable format)**

The IRB will review the DMP to ensure the IRB application and informed consent document contains the necessary information.

IRB Review of Retrospective Data Review Submissions

- Retrospective Record Review: evaluates data that is **existing** at the time the protocol is submitted to the IRB for initial approval.
- The human subject definition extends to a subject's identifiable private information. As such, the IRB must review research proposing to use **identifiable data**, including data from medical records (HIPAA protected data).
- Identifiable data and biospecimens are those that include information where the identity of the individual "is or may readily be ascertained by the investigator."
- A retrospective data review's protocol should specifically the timeline of data to be reviewed. (i.e., data will be reviewed from October 2020 to July 2021).
- A waiver of consent and PHI authorization can be granted oftentimes for retrospective records review if the study meets the waiver criteria and data is existing at time of submission to the IRB.
- See "Records Review" guidance & Protocol for Human Subjects Research Retrospective Data Review

Access to Records

Medical Records

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

Educational Records

- Educational records are protected under FERPA regulations.
- Use of an educational record for research purposes requires signed informed consent to use.
- Waivers of FERPA are only allowed for a “legitimate educational interest.” Research doesn’t fall into a legitimate educational interest.

Employment Records

- Access to records of employees of the University of Arizona (e.g., staff or faculty) requires the written consent of the employee.

De-identified Records

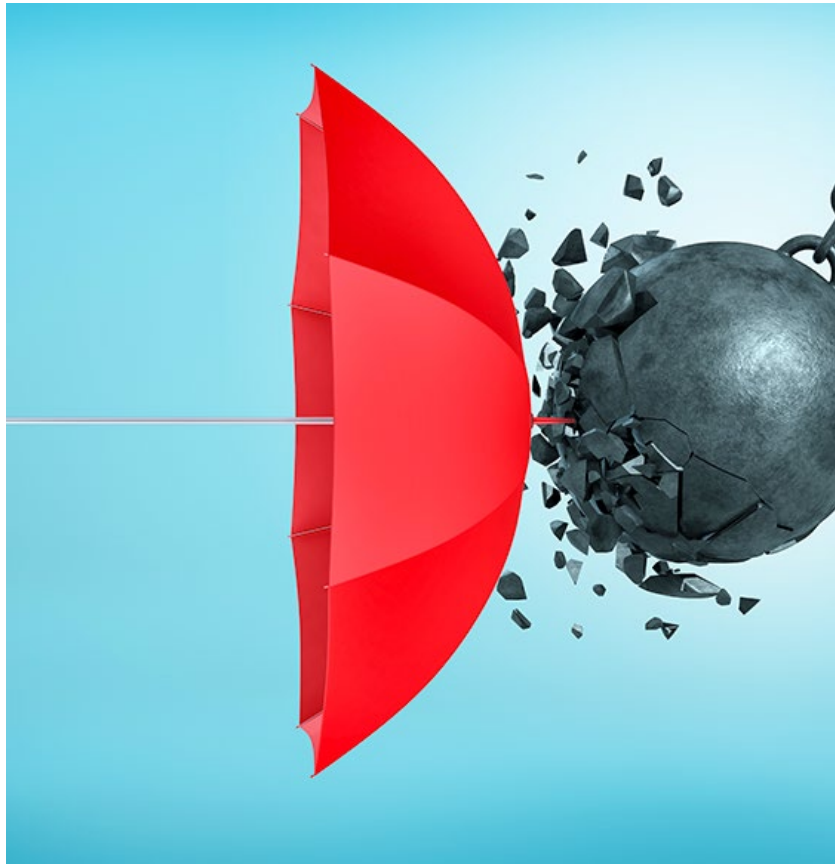
- If de-identified data is **shared** with an investigator (by someone **not** on the research team (honest broker)), the records are not considered to be regulated/belong to a human participant. IRB oversight is not needed. Ensure the data being accepted is OK to reuse (review original consent or contracting terms (if they exist)) prior to use of the data. When in doubt, reach out to the IRB for confirmation.

The Data Warehouse

- Two data warehouses exist that researchers may use to obtain data for a research project:
- **Banner Clinical Research Data Warehouse (CRDW):** Contains data from Cerner (September 19, 2017 – present date).
- **UA Clinical Data Warehouse (CDW)** - Contains data from EPIC (November 1, 2013 - September 18, 2017).
- If you are obtaining **de-identified** data from these warehouses, IRB oversight is not needed. Instead, a submission of research determination would be the required form for review.
- Submission guidelines are found here: https://research.arizona.edu/compliance/human-subjects-protection-program/collaborative-activities-banner-health

European Union General Data Protection Regulation Requirements (GDPR)

- The GDPR is a regulation designed to harmonize data privacy laws across the Europe Union.
- Projects are subject to GDPR regulations when “personal data” or coded data on individuals **located** in the EU will be collected.
- GDPR regulated data requires the use of an GDPR consent addendum (found on the HSPP website).
- There must be an executable plan to remove data in the event a participant requests to have his/her data removed.
- Personal Data is any information relating to an identifiable person.
- See “GDPR” guidance.



HSPP Resources

- **HSPP Website:** https://research.arizona.edu/compliance/human-subjects-protection-program
- **HSPP Forms:** https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index
- **HSPP Guidance Documents:** https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers
  - Access to Records
  - Data Security and Records Retention
  - Certificates of Confidentiality
  - Federal Data Management Plans (DMPs) **NEW!**
  - European Union General Data Protection Regulation Requirements (GDPR)
  - Honest Broker
  - Repositories - Storing Research Information For Future Use

Contact Information

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Questions?


BREAKOUT ROOMS?
CHAT?
PRIVACY?
VIRTUAL BACKGROUNDS?
ZOOM-BOMBING?
SECURITY?
HIPAA COMPLIANCE?
RECORDING?
PASSWORDS?