
THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact
Your Study is Approved, Now What?
Post Approval Responsibilities Workshop
Human Subjects Protection Program (HSPP)
THE UNIVERSITY OF ARIZONA

Fall 2022 HSPP Workshop Series

1. Ethical & Regulatory Foundation of Human Subjects Research & IRB Review
2. A Step-by-Step Guide to Successful IRB Submissions
3. Informed Consents & Waivers (October)
4. Let's Talk About Research Data (November)
5. Your Study is Approved, Now What? (December)

HSPP Training: https://research.arizona.edu/compliance/human-subjects-protection-program/hspp-training/irb-training-opportunities

Agenda

- PI & Advisor Responsibilities
- Modifications (MODs)
- Continuing Reviews (CRs)
- MODCRs
- Reportable New Information (RNIs)
- Study Closure & Transfer
- Deferred Studies
- Compliance & Audit Readiness
- HSPP Resources

What are the PI Responsibilities after IRB approval?

[Type your responses into Chat]

PI & Advisor Responsibilities

PI Responsibilities Outlined in eIRB

Submit

IMPORTANT! Before you click "OK" below, please verify that the correct funding source is linked on the Study Funding Sources Smart Form. Linking the correct funding source has significant implications to the COI disclosure process. You CANNOT change the funding source after you click "OK" until after the submission is approved by the IRB.

By signing below you are verifying that:

- You certify that the information you provided in this submission is correct and complete.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with the Belmont Report and institutional requirements: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
- You have read and acknowledge the HSPP guidance on Principal Investigator Responsibilities: https://research.arizona.edu/sites/default/files/Principal%20Investigator%20Responsibilities%20after%20IRB%20Approval%20v2021-09.pdf.
- You acknowledge it is the responsibility of the Principal Investigator (PI) to ensure the correct personnel are listed as an Investigator on the Sponsored Projects Institutional Proposal or Award for Sponsored research. All other personnel not listed on the Institutional Proposal or Award are responsible for ensuring that they have submitted all appropriate disclosures and are in compliance with the University's Conflicts of Interest and Commitment Policy: https://policy.arizona.edu/ethics-and-conduct/conflicts-interest-commitment-policy-interim.

PI Responsibilities HSPP Guidance
https://research.arizona.edu/sites/default/files/Principal%20Investigator%20Responsibilities%20after%20IRB%20Approval%20v2021-09.pdf

PI Responsibilities

- **The Principal Investigator (PI) is ultimately responsible for the conduct of their research.**

- Research **responsibility may be delegated** to co-investigators and research staff, but the **PI must maintain oversight and retain ultimate responsibility** for the conduct of those to whom they delegate to.

PI Responsibilities Cont.

- **Conduct the study in accordance with the IRB-approved protocol.**
- Ensure that **informed consent is obtained and documented** in accordance with IRB-approval.
- **Submit changes for approval prior to implementation** (as applicable).
- If the project requires a Continuing Review, **ensure that the project is renewed prior to the expiration date**, **or concluded** if it is already completed.
- **Report all non-compliance** per the Reportable New Information (RNI) guidance.
- **Transfer the study** when the PI leaves the institution and the study is not concluded.
- **Maintain adequate records** of research data and outcomes, regulatory documents, reportable items, and communications with the IRB and the sponsor.

Research Records Retention

- Store original signed consent and/or PHI authorization documents for at least **6 years** past the time the study is concluded.
- For studies involving minors, store original signed consent and/or PHI authorization documents for at least **6 years after the youngest participant turns 18**.
- Check with the funding agency/sponsor about additional requirements.

Inform Staff & Participants

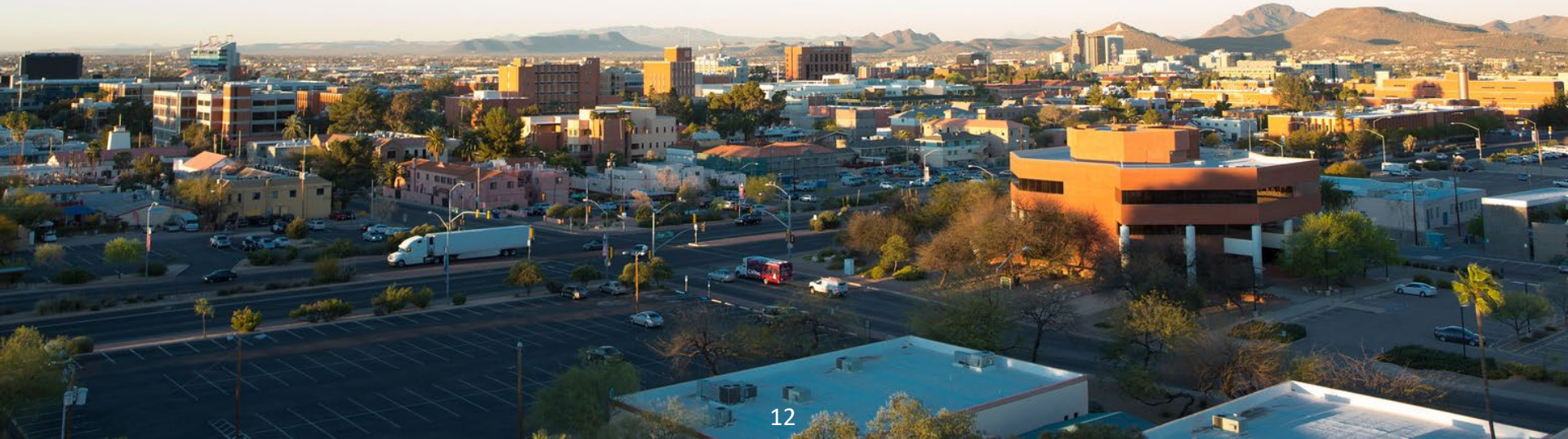
- **Ensure that participants are kept fully informed about any new information that may affect their willingness to continue to participate** in the research study.

- Ensure that all **research staff and collaborators** assisting in the conduct of the research study **continue to have the appropriate training and credentials to conduct the research**; **and are appropriately informed** about
  - the study procedures;
  - informed consent requirements;
  - adverse event reporting requirements; and the
  - data collection and record-keeping criteria.

Advisor Responsibilities

- **Oversee and monitor the conduct of the research** by communicating regularly with the Principal Investigator;
- Assist with the **resolution of any problems or concerns** encountered during the research; and
- **Assure that the UA IRB is notified in the event of an adverse event or unanticipated problem.**
- Advisors/Co-Investigators are also **responsible for the conduct of the research in addition to the PI.**

Modifications (MODs)



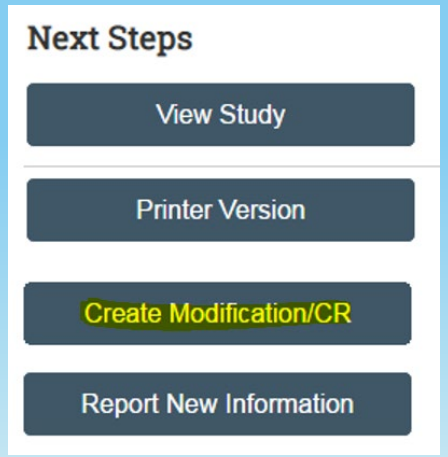
Modifications (MODs)

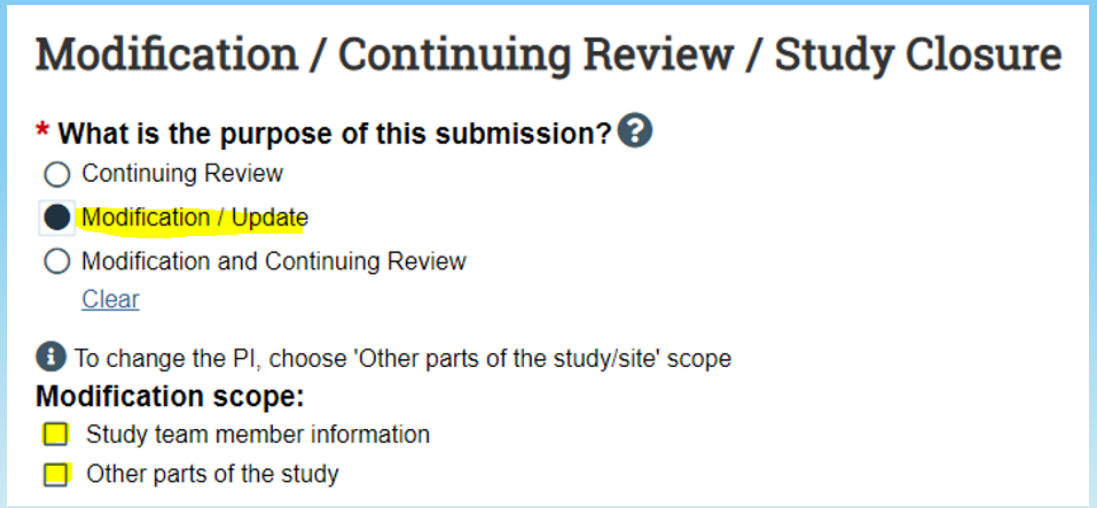
The IRB must review and approve all changes prior to implementing the change!

- **Submit a Modification** for changes to previously approved research, including (but not limited to) changes in:
  - Protocol, consent and subject facing materials,
  - study title,
  - key personnel and collaborators,
  - number/type of participants,
  - study procedures and eligibility criteria,
  - recruitment materials and locations,
  - data collection, security and storage, etc.

- The only **<u>exception</u>** is when a change must be made to eliminate an immediate hazard or harm to a participant, in which case the IRB needs to be notified with an RNI within 5 days of the incident.

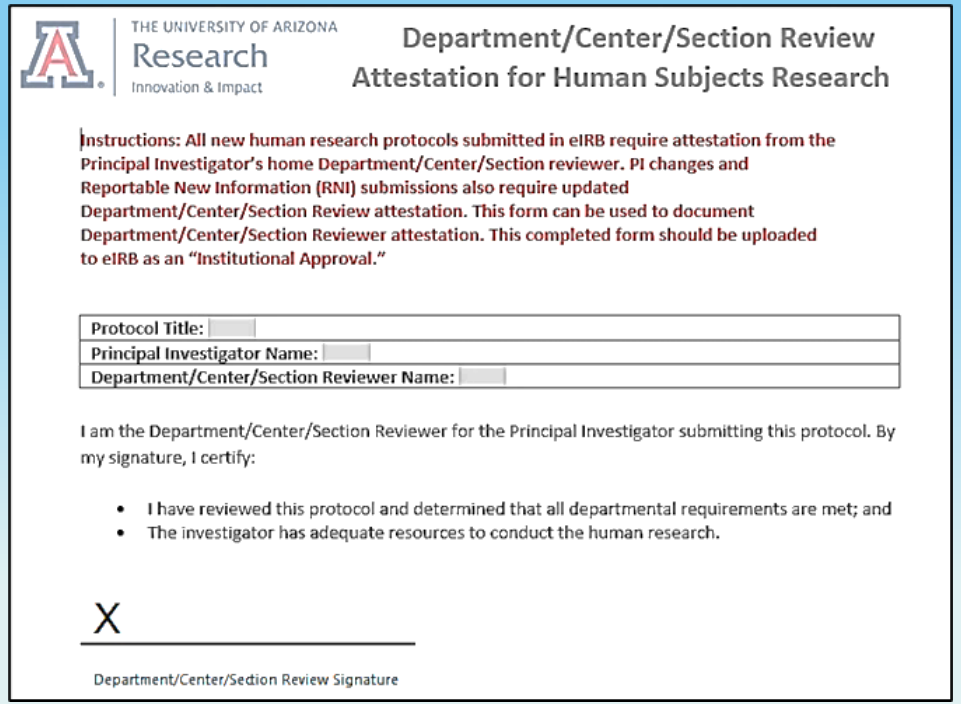
Modification Submissions in eIRB





- For staff Only Mods check the **“Study team member information”** box.
- For Modifications that don’t involve staff changes check the **“Other parts of the study”** box.
- For PI changes or when adding a Responsible Physician, **check both** boxes.

Department/Center Attestation



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Department/Center/Section Review Attestation for Human Subjects Research

Instructions: All new human research protocols submitted in eIRB require attestation from the Principal Investigator's home Department/Center/Section reviewer. PI changes and Reportable New Information (RNI) submissions also require updated Department/Center/Section Review attestation. This form can be used to document Department/Center/Section Reviewer attestation. This completed form should be uploaded to eIRB as an "Institutional Approval."

Protocol Title:
Principal Investigator Name:
Department/Center/Section Reviewer Name:

I am the Department/Center/Section Reviewer for the Principal Investigator submitting this protocol. By my signature, I certify:

- I have reviewed this protocol and determined that all departmental requirements are met; and
- The investigator has adequate resources to conduct the human research.

X _____

Department/Center/Section Review Signature

Departmental signature is needed for:

- All New Projects
- PI changes
- Reportable New Information (RNI)

PI Change Modifications require a new Department/Center/Section Review approval.

Submit: The HSPP Attestation Form, an email approval, or a Comments logged in eIRB.

Modifications for Exempt & Min.Risk 2018 Research

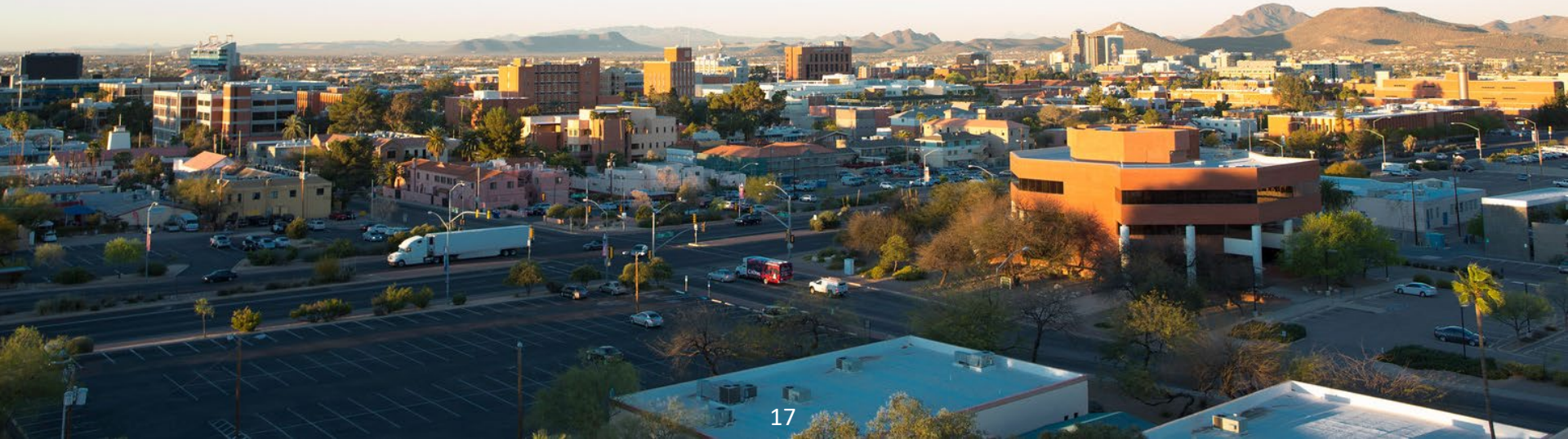
Major changes to study scope, data storage, adding or removing funding, adding/removing Banner or adding a vulnerable population **need IRB approval prior to implementation**.

Minor changes to **Exempt/Minimum Risk 2018** research **do not need to be reviewed**.

- Minor changes include simple revisions to already approved language (e.g., rewording survey language to make a statement clearer, adding new survey questions in line with the already approved purpose and questions, or updating recruitment materials to reflect new contact information).
- For modifications that do not require IRB review, download the relevant approved documents from eIRB, make the necessary changes, and save them separately in a regulatory folder within your protected departmental drive.

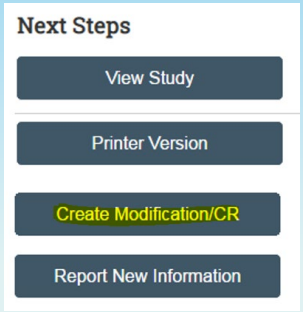
Exempt and Minimal Risk Research Guidance Document:
https://research.arizona.edu/sites/default/files/Exempt%20Minimal%20Risk%20Research%20updated%20v2022-08.pdf

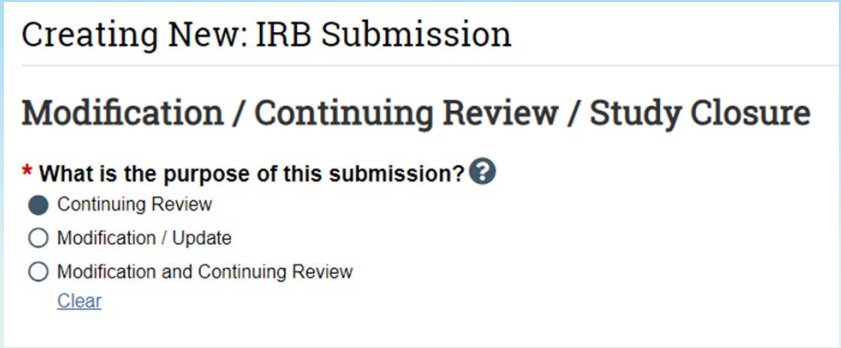
Continuing Reviews (CRs)



Continuing Review Requirements

- Any project that requires an annual/periodic review must submit a Continuing Review in eIRB to renew the project before it expires. (Expiration dates are listed in eIRB and on the Approval letters).
- **Submit** the Continuing Review Renewal **30-45 days before your expiration date** to allow ample time for review and approval. (FC studies also need to upload the CR supplement)
- The project will enter a **Lapsed state if** a Continuing Review is **not approved** before the expiration date, **and all research activities must pause until reapproval**.





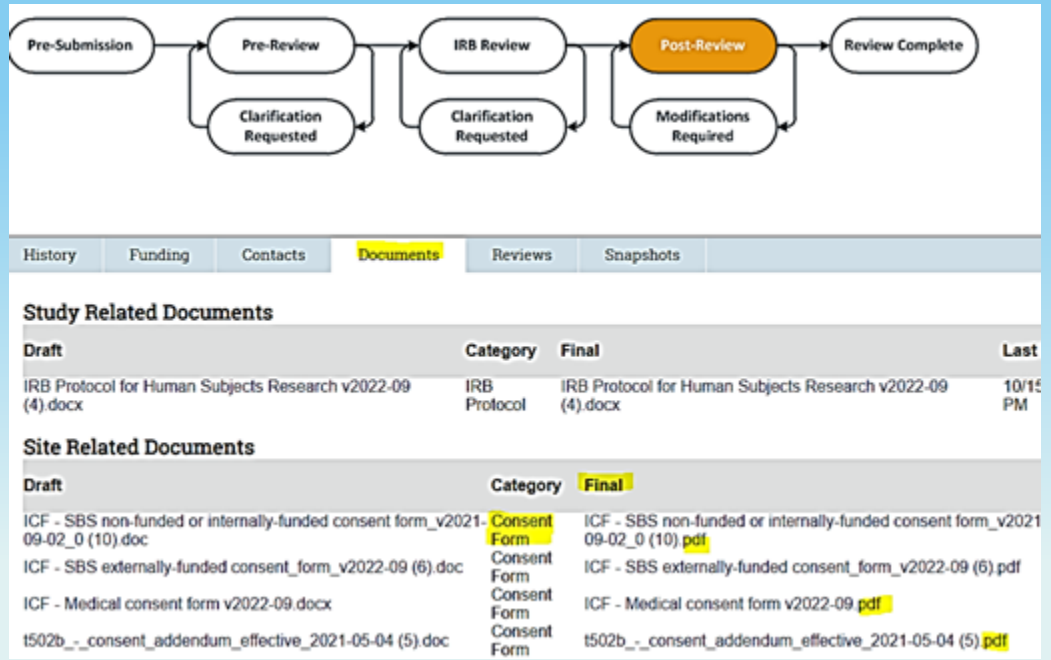
Continuing Review Guidance Document
https://research.arizona.edu/sites/default/files/Continuing%20Review%20of%20Human%20Research%20v2022-08.pdf

CR for Exempt/Min. Risk 2018 Studies

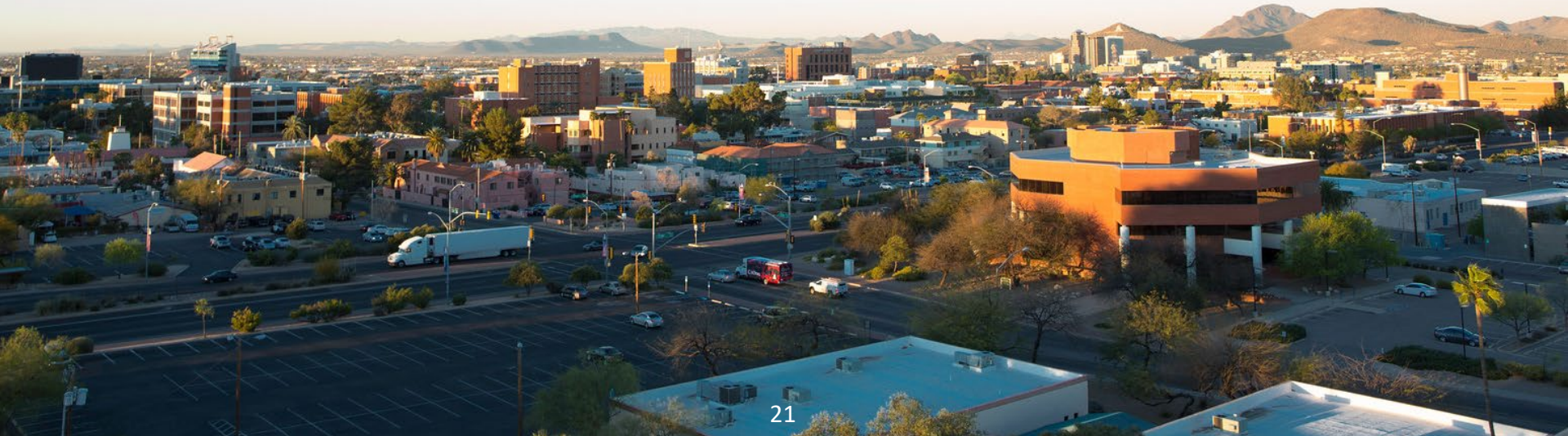
- Most **Exempt and Minimum Risk 2018** studies don't need a Continuing Review unless they fall under the Institutional Continuing Requirements listed below.
- The University of Arizona **requires Continuing Review for certain types of exempt research** including:
  - Research that received a **limited IRB review**;
  - Projects involving **Native Americans**;
  - Principal Investigator (PI) has received **serious or continuing non-compliance** determinations in the past two (2) years;
  - Projects that involve **deception** but do not receive the subject's prior authorization to be deceived before engaging in the deception;
  - A **Conflict of Interest (COI) Management Plan** exists;
  - **FDA regulated research** eligible for expedited review under expedite category 1 on approved drugs or devices;
  - Projects deemed **Expedited Category 9**; or
  - **As determined by the IRB** on a project basis depending on the risks in the research project.

Restamping Consent Documents

- **Consents are re-stamped during the Continuing Review.**
- Make sure to **download the stamped consent forms** located on the main study workspace in the “Final” column of the Study Documents tab.
- Let the HSPP know if you can’t locate the stamped consents or if you find an error.

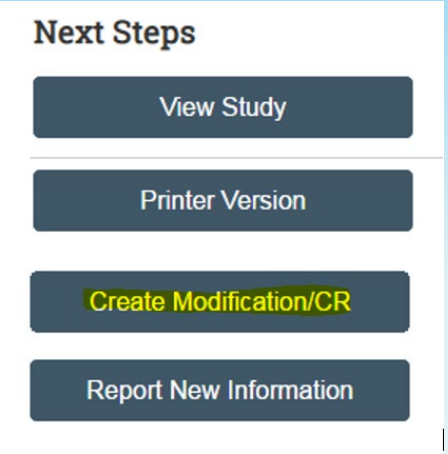


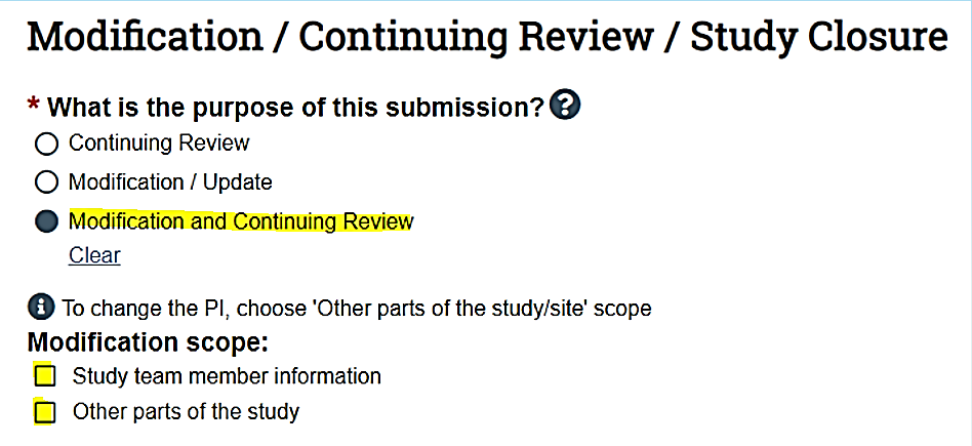
MODCRs



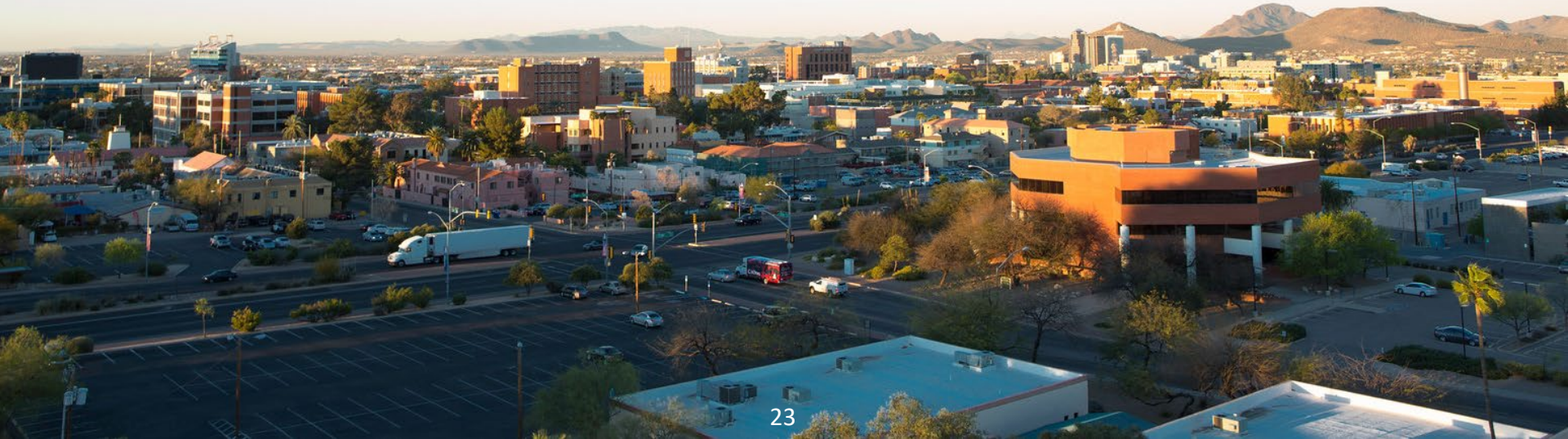
Combined MOD & CR

- It is **highly recommended** to select the “Modification and Continuing Review” option when submitting a Continuing Review for an active/ongoing study.
- This allows you and the IRB to make the necessary updates to the study documents.





Reportable New Information (RNIs)



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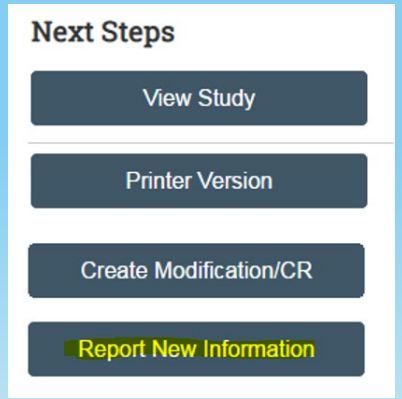


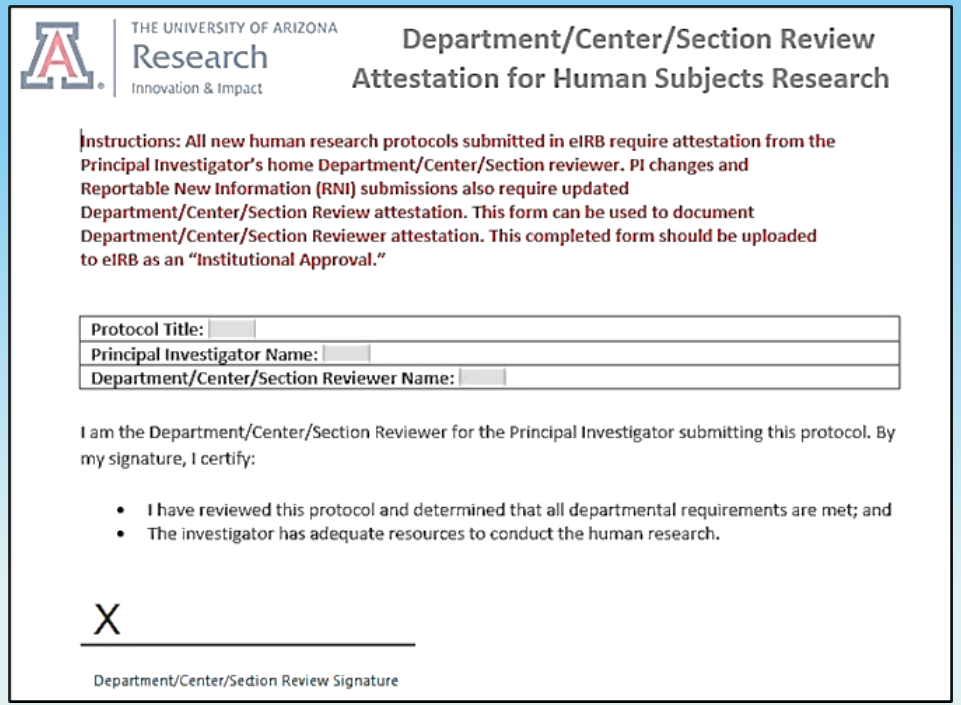
Reportable New Information Guidance
https://research.arizona.edu/sites/default/files/Reportable%20New%20Information%20v2022-08.pdf

- **Protocol violations by the investigator or research staff.**
- **Unanticipated Problems (UP) involving Risks to subjects or others**. **[Participant death must be reported to the IRB within 24 hrs].**
- Information that indicates a **new or increased risk** (change in the frequency/magnitude of risks).
- A **breach of confidentiality involving a subject** (e.g., unapproved use or disclosure of PHI).
- **Complaint of a subject** that indicated unexpected risks or that cannot be resolved by the study team.
- **Any problem that the PI believes needs to be reported.**
- **Changes to the protocol made without prior IRB review** to eliminate an immediate hazard to subjects. **[Must be reported within 5 business days of discovery].**

FDA & Medical Studies

- **Withdrawal, restriction, or modification of drug/device/biologics** approval.
- **Audit, inspection, or inquiry by a Federal Agency** (FDA 483, FDA Warning letters, FDA Audit reports, Notice of Disqualification, OHRP Determination letter, Department or Restricted list).
- **Medical license suspension, restrictions or revocations, or any licensure or credentialing issues involving PI, co-I, sub-I, or research staff.**
- **Unanticipated adverse device effect (UADEs):** Any serious effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.]

Department/Center Attestation



THE UNIVERSITY OF ARIZONA Research Innovation & Impact

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Principal Investigator Name:
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I am the Department/Center/Section Reviewer for the Principal Investigator submitting this protocol. By my signature, I certify:

- I have reviewed this protocol and determined that all departmental requirements are met; and
- The investigator has adequate resources to conduct the human research.

X _____

Department/Center/Section Review Signature

Departmental signature is needed for:

- All New Projects
- PI changes
- Reportable New Information (RNI)

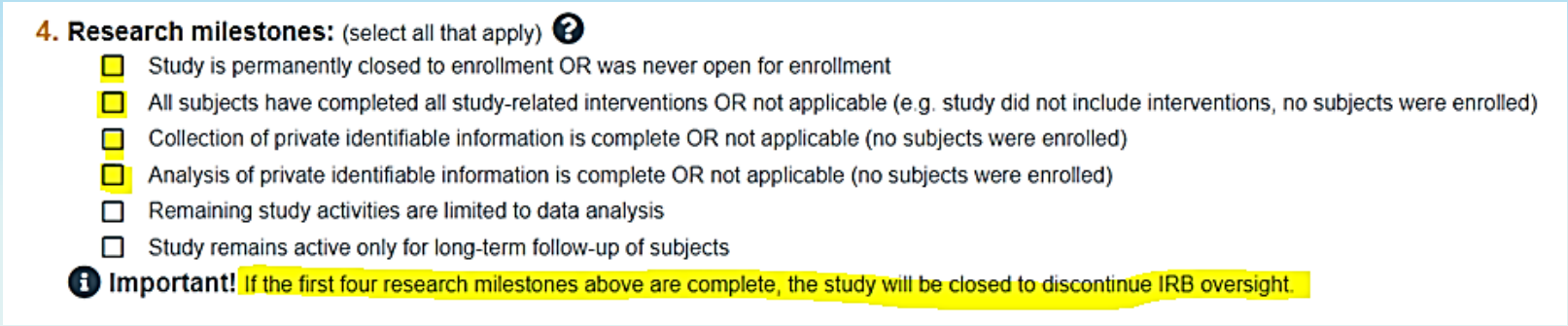
You can use:

- The HSPP Attestation Form
- Email approval
- Comments logged in eIRB

Study Closure & Transfer

Study Closure

- **Investigators, including students, are responsible for concluding their Human Subject's Research Studies** as soon as possible after the project is completed and there are no remaining human subjects research activities.
- **This process is the same for all studies including Exempt & Minimum Risk 2018.**
- To close the study, **submit a Continuing Review in eIRB.**



4. **Research milestones:** (select all that apply)

- ☐ Study is permanently closed to enrollment OR was never open for enrollment
- ☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ☐ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

Study Transfer

When a PI leaves the UA, the study must be concluded or transferred to a new eligible PI.

To Transfer the Study to a NEW PI:

1. Submit a Modification to change the PI to a new Investigator.

- If the old PI is not available to sign, the assigned PI Proxy (if applicable) can submit the Modification on behalf of the old PI and attach a letter/email from the old PI that shows that they agree to the change.
- If there is no assigned PI Proxy and the study will remain open, the submission can be copied in eIRB and updated to reflect the new Investigator.

2. Upload a letter/email from the old PI that shows that **they agree to the transfer**.

3. Upload a letter/email from the new PI that show that they are **aware of the transfer** and that they **agree to take over the PI responsibilities**.

PI Transfer Continued

Additional documents that are usually needed with the PI transfer Modification:

- Department/Center/Section Review approval;
- CV of the new PI (and medical license if applicable);
- Revised Protocol;
- Updated Consent Forms (if applicable);
- Updated Recruitment Materials (if applicable);
- Updated Participant Materials (if applicable);
- Any other changes that the new PI would like to make;

HSPP Guidance for Concluding [Transferring] Human Subjects Research Studies:
https://research.arizona.edu/sites/default/files/Concluding%20Human%20Research%20v2021-09_1.pdf

Deferred Studies

Deferred Studies

Submissions & Reportable Items Required for Deferred Studies (UA is not the IRB of Record)

Modifications:

- Key personnel/PI change.
- Alteration of Banner required consent language/PHI.

Reportable New Information (RNI):

- Reports of any **local** unanticipated problems involving risks to participants or others.

Continuing Review/Study Closure:

- The Renewal Letter or Closure Approval from the IRB of Record uploaded to eIRB.

Compliance & Audit Readiness

HSPP Quality Assurance Program

- The UA HSPP is responsible for ensuring that UA affiliated faculty, staff, and students are in compliance with University, sponsor, state and federal regulations.
- Our mission is to support UA researchers in conducting ethical research, ensure the protection of research participants; and monitoring compliance with all applicable federal, state, and local laws and regulations;
- One way we meet these goals is by conducting ongoing oversight of human research activities.
- The QA program aims to ensure that research staff have the necessary guidance to successfully conduct research; and provide the research community with education, support, tools, and other resources needed to perform compliant research.

Routine/Not For Cause Audits

- Review our **HSPP Quality Assurance Program webpage** .
- Review the HSPP **Audit Preparation Guidance**.
- Use the self-assessment tools from the HSPP Website:
  - **Self-Assessment Review Checklist**
  - **Protocol Adherence Assessment Checklist**
  - **Inclusion/Exclusion Adherence Assessment Checklist**
  - **Consent Documentation and Process Adherence Assessment Checklist**
- Volunteer for or request a not-for-cause audit by the IRB, by sending a request to **VPR-IRB@arizona.edu**.

HSPP Resources

HSPP Resources

- **HSPP Forms:** https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms
- **Modifying Approved Research** https://research.arizona.edu/sites/default/files/Modifying%20Approved%20Research%20v2021-09.pdf
- **Continuing Review of Human Research** https://research.arizona.edu/sites/default/files/Continuing%20Review%20of%20Human%20Research%20v2022-08.pdf
- **Concluding/Transferring Human Subjects Research Studies:** https://research.arizona.edu/sites/default/files/Concluding%20Human%20Research%20v2021-09_1.pdf
- **HSPP Guidance Documents:** https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers

List of HSPP Guidance Documents

- Abbreviated IDE Requirements
- Access to Records
- Adverse Event Flow Chart.pdf
- Amazon Mechanical Turk (MTurk).pdf
- Arizona State Law
- Audit Preparation Guidance (NEW!)
- Case Reports
- Certificates of Confidentiality
- Classroom Research and Independent Projects
- Clinical Trials
- Compensation of Subjects
- Concluding Human Research
- Continuing Review of Human Research
- Corrective and Preventative Action Plans (NEW)
- Data Security and Records Retention
- Deception Research (NEW!)
- Enrollment and Accrual of Study Participants
- Exempt Minimal Risk Research
- Federal Data Management Plans (NEW)
- Fees for Human Research
- Flexible Review
- GDPR
- Honest Broker (NEW!)
- HSPP Process Changes for eIRB
- Informed Consent
- Investigator Roles and COI Disclosures in eIRB (NEW!)
- Investigational Device Exemptions (IDE)
- Investigational New Drugs (IND)
- Limited IRB Review
- Modifying Approved Research
- Other Approvals Required
- PI Eligibility
- Pre-Screening of Potential Subjects
- Principal Investigator Responsibilities after IRB Approval
- Record Reviews (NEW!)
- Recruitment and Advertisements
- Reportable New Information
- Repositories - Storing Research Information for Future Use
- Research in K-12 Settings (NEW!)
- Research Involving Children
- Research Involving Cognitively Impaired Adults
- Research Involving Native Americans or Indigenous Populations
- Research Involving Neonates
- Research Involving Pregnant Women
- Research Involving Prisoners
- Return of Incidental Findings (NEW!)
- Single IRB Review
- Social Media and Research (NEW!)
- Sponsor Investigator
- TMS & tDCS Brain Stimulation Guidance (NEW!)
- What is Human Research
- Zoom Security Guidelines

Contact Information

Simona Janisch

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vpr-irb@arizona.edu

HSPP Webpage:

https://research.arizona.edu/compliance/human-subjects-protection-program

HSPP Office Hours

HSPP Virtual Office Hours are held every other Thursday from 10 am – 11 am.

No registration is required

Remaining 2022 Dates

- December 22

Use this link to join :
https://arizona.zoom.us/j/86232995912

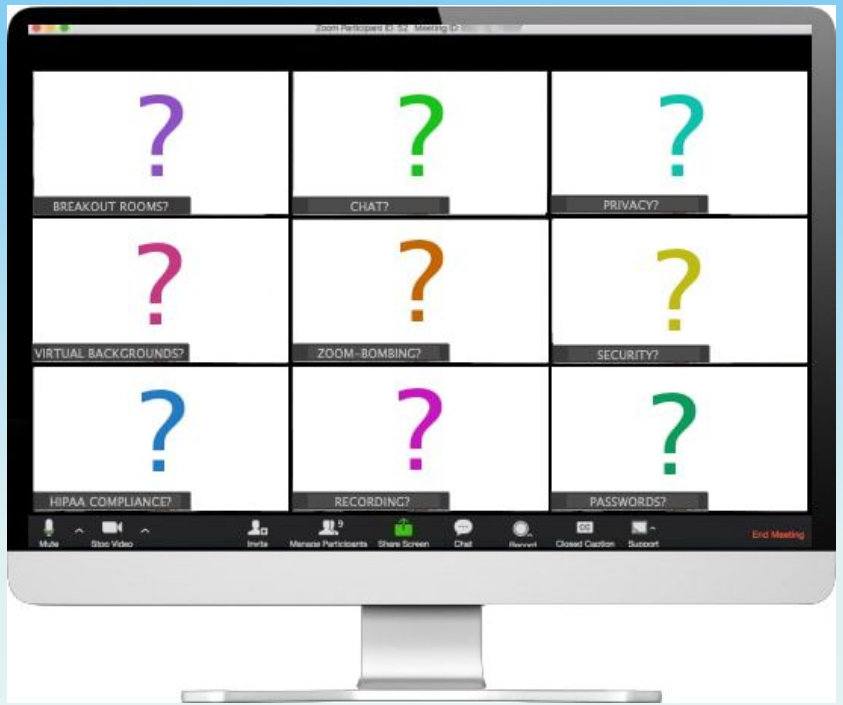
Stay in the Loop

Subscribe to the HSPP listserv:

- Send a blank email to: list@list.arizona.edu
- In the subject line, enter: subscribe UA-IRB Firstname Lastname
- Delete any signature line and/or confidentiality statement that you may have in your e-mail.

Subscription Instructions: https://it.arizona.edu/documentation/how-subscribe-and-unsubscribe-list.

Questions?


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