



Reporting Local Information

Investigators must report the following information to the IRB within ten (10) business days of discovery, except as otherwise noted. All reportable items must be submitted on a F224, reportable information form. Non-local items requiring changes to the protocol should be reported on a F213: Amendment to Approved Human Research.

Events to Report

<p>1. Unanticipated Problems (UP) involving Risks to subjects or others:</p> <ul style="list-style-type: none"> a. Are unanticipated; b. Are related or possibly related to participation in the research; and c. Suggest that human subjects or others are at increased risk of harm. <p>NOTE: UPs that involve a death must be <i>reported to the IRB within 24 hours</i> of discovery.</p>
<p>2. Information that indicates a new or increased risk (change in the frequency or magnitude of risks or benefits):</p> <ul style="list-style-type: none"> a. An interim analysis or monitoring report b. Published paper or presentation
<p>3. Withdrawal, restriction, or modification of drug/device/biological approval from the FDA or Sponsor.</p>
<p>4. A breach of confidentiality involving a subject (e.g. unapproved use or disclosure of PHI)</p>
<p>5. Changes to the protocol made without prior IRB review to eliminate an apparent immediate hazard to subjects.</p> <p>NOTE: Changes made to eliminate risk must be <i>reported to the IRB within 5 business days</i> of discovery.</p>
<p>6. Complaint of a subject that indicated unexpected risks or that cannot be resolved by the study team.</p>
<p>7. Audit, inspection, or inquiry by a Federal Agency (FDA 483, FDA Warning letters, FDA Audit reports, Notice of Disqualification, OHRP Determination letter, Debarment or Restricted list)</p>
<p>8. Medical license suspension, restrictions or revocations, or any licensure or credentialing issues involving PI, co-PI, sub-I, or research staff.</p>
<p>9. Incarceration of a subject enrolled in a protocol not approved to enroll prisoners.</p>
<p>10. Protocol violations due to investigator or research staff</p>
<p>11. 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 [<i>including a supplementary plan or application</i>], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.]</p>
<p>12. Any other problem that the PI believes needs to be reported promptly to the IRB.</p>
<p>13. Any conflict of Interest previously undisclosed or managed.</p>

INSTITUTIONAL REVIEW BOARD TIPS AND TRICKS



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What is the purpose of an IRB?

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To protect the rights and welfare of subjects participating in research activities on or behalf of an organization that is engaged in human research.

The Elements of the Belmont Report

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Respect for Persons

Protecting autonomy, having courtesy and respect for individuals as persons, including those who are not autonomous (e.g., infants, the mentally retarded, senile persons)

- Each person has individual rights
- Obtain informed consent, protect privacy, maintain confidentiality

Beneficence

Maximizing good outcomes for science, humanity, and the individual research participants while avoiding or minimizing unnecessary risk, harm, or wrong

- Provide benefit, protect from harm, limit risk
- Risk-benefit assessment, standard procedures used

Justice

Ensuring reasonable, non-exploitative and carefully considered benefits among persons and groups

- Equitable selection of subjects
- Includes all groups that may benefit but does not single out one group

How does an IRB protect subjects?

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45 CFR 46.111

- Risks are minimized
- Benefits are maximized
- Subject selection is equitable
- Informed consent is appropriately sought and documented
- Privacy and confidentiality are maintained, as applicable

What are the types of review?

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Projects are classified into three categories

- Exempt → low risk
- Expedited → minimal risk
(no more risk than
everyday life)
- Full Committee → greater than
minimal risk

How to submit a good application?

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Submit early, consult often!

- ✓ Who
- ✓ What
- ✓ Why
- ✓ When
- ✓ Where
- ✓ How

Common Misconceptions

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Statements

1. IRBs are just red tape
2. IRB approval is all that is needed to conduct good research
3. IRBs are killing patients due to delays
4. IRBs do not know anything about research

Fact

1. IRBs are required under the law
2. PI is responsible for conduct of study
3. Delays do happen
4. IRBs are comprised of experts in research

Shared Responsibilities

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- Risks are minimized by using sound research design
- Risks are reasonable in relation to benefits
- Selection of subjects is equitable
- Individuals are adequately informed, including any changes that may impact their participation
- Privacy and confidentiality are maintained
- Appropriate safeguards are included in the study to protect the rights and welfare of subjects.

Investigator Responsibilities

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- Submit completed paperwork at time points requested
- Conduct the study according to the approved IRB protocol
- Obtain and document consent
- Maintain adequate study records, including IRB paperwork
- Submit **ALL** changes to the protocol prior to implementation
- Submit unanticipated problems or noncompliance
- Ensure staff, collaborators, or colleagues have training and credentials and know their obligations

How do problems happen?

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Poor communication

Poor research practice

Poor investigator oversight

What can happen?

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1. Institutions legal liability and reporting obligations to the federal government.
2. Investigators have reputation and, at times, monetary liability

Common Pitfalls

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- Failure to submit renewal paperwork for re-approval
- Materials submitted too late for review
- Current templates not used
- Insufficient detail provided about the study
- Not all attachments submitted
- Signatures not obtained
- Additional approvals not obtained

Current Regulatory Issues

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- Working with collaborating IRBs – Ceded review or Deferral of IRB oversight
- Informed Consent complexity
- Common Rule Changes

Current Ethical Issues

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?? - Does conducting public health practice or quality improvement in the community require IRB approval?

?? - Can biospecimens be used for research activities without the consent of the person from whom the specimen came? What about information?

?? - What is considered *private* information in the context of social media?

Stay Connected

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- Visit our website at:
<http://rgw.arizona.edu/compliance/human-subjects-protection-program>
- Contact us at: vpr-IRB@email.arizona.edu

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