Sharpening Research Compliance: Heightened Awareness with a Self-Guided Risk-Assessment
Conflict of Interest

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I do not have any conflicts to report.
A Wild Boar was engaged in whetting his tusks upon the trunk of a tree in the forest when a Fox came by and, seeing what he was at, said to him, “Why are you doing that, pray? The huntsmen are not out today, and there are no other dangers at hand that I can see.” “True, my friend,” replied the Boar, “but the instant my life is in danger I shall need to use my tusks. There’ll be no time to sharpen them then.”


Moral: Preparedness is the best guarantee for peace.

Objectives

- Employ risk assessment philosophies and principles to heighten awareness of risks in clinical research.

- Empower research teams to weigh and prioritize self-identified risks in order to create meaningful action plans.

- Form a self-guided risk assessment tool to encourage risk preparedness and sharpen research compliance.
How Do You Define Risk?

Spotting the Huntsmen
Risk Definitions

Risk

The chance of loss. Uncertainty as to whether loss will occur. Uncertainty about an event that could produce loss.

Risk Assessment

How an organization understands and attempts to quantify the potential magnitude or materiality of each identified risk.

Risk Management

The process of making and carrying out decisions that will help prevent adverse consequences and minimize the negative effects of accidental losses on an organization.

Risk Appetite

The amount of risk an organization is willing to assume for a return it hopes to achieve.

Expected Enterprise Value

Risk Level

Insufficient Risk-Taking

Optimal Risk-Taking

Excessive Risk-Taking

“Sweet Spot”

How Do We Measure?

- Vulnerability
- Impact
- Likelihood
- Frequency
- Detectability
- Mitigation
- Controls
- Consequences

Identify the Variables

Personalize

Quantify

Calculate
What Could Go Wrong?

- Volume
- Activity
- Complexity
- Scrutiny
- Accountability
- Investments
- Pressure

Identify the Risks

- Human Subjects Research Protection
- Research Operations and Administration
- Research Integrity
How Do You Make Risk Meaningful?

Knowing Your Tools
Fostering Risk Preparedness

Engage in in-person dialogue about risk: Research Compliance Rounding.

Change attitudes and beliefs: is your program a partnership or a catch-me-if-you-can system?

Meet teams where the work happens: encourage research teams to identify vulnerabilities themselves.

Identify compliance questions, distinguish real from perceived areas of risk, and celebrate compliance successes.

What Kind of Program Do You Want?

Preparedness vs. Counteraction
Research Compliance Rounding

• Rounding sessions have three objectives:
  ✓ build relationships and learn collaboratively;
  ✓ assess vulnerability and efficiency; and
  ✓ recognize strong compliance practices while fostering a culture of ethics.

• Rounding sessions open discussions about what’s going well, and what areas could be improved:
  ✓ grant and clinical trial accounting
  ✓ effort reporting
  ✓ clinical trial billing
  ✓ research misconduct
  ✓ privacy and security
  ✓ human subjects protection
Trust: What Will You Do with the Information You Obtain?

Trust happens when we:

• disclose early and often that reportable issues like patient harm or research misconduct must be addressed immediately;
• use risk assessment data to guide education and to partner with research teams to create meaningful mitigation plans.

Distrust happens when we:

• arrive solely to enforce and discipline;
• target teams for for-cause audits based on their self-guided risk assessments.
Risk Management: Avoiding Meaningless Mitigation Efforts

To quote an FDA Warning Letter, an Investigator acknowledged a need for:

- “adequate oversight of study staff, training of study staff, and protocol adherence.”
- “principal investigators [being] aware of their obligations”; and
- “PIs and staff [understanding] the importance of following the protocol SOPs; and for PIs and staff [being] trained”.

Indicated corrective actions had been or would be implemented.
Risk Management: Avoiding Meaningless Mitigation Efforts

To quote the FDA's response, the Agency could not “undertake an informed evaluation because [the investigator]”:

✓ “did not include any corrective actions that [she], as a clinical investigator, [had] taken to prevent similar violations in the future.”

✓ “did not provide details on how [she] personally [plans] to prevent similar violations in any future studies.”

Concerned corrective actions did not reflect actions personally taken.

How Do You Implement a Risk Assessment?

Preparedness as the Guarantee for Peace
Calculating Risk

Likelihood

The probability that specific events, factors, or situations will adversely affect an outcome.

Detectability

The probability that a risk could be identified before it has an adverse effect.

Controls

The probability that a risk might be mitigated. The possible precautions that could most effectively reduce an adverse outcome.

Risk

The combination of likelihood, detectability, and controls that could result in an adverse or unfavorable outcome contrary to the objective.
Scoring Risk Variables: Likelihood

1. least likely/unlikely for a failure to occur
2. slightly likely for a failure to occur
3. moderately likely for a failure to occur
4. significantly likely for a failure to occur
5. extremely likely for a failure to occur
Scoring Risk Variables: Detectability

1. very detectable
2. slightly risky that a failure would not be detected
3. moderately risky that a failure would not be detected
4. significantly difficult to detect prior to failure
5. undetectable or extremely difficult to detect
Scoring Risk Variables: Controls

1. no formal controls in place
2. process not audited or tested with limited policy and procedure guidance
3. periodically audited/tested, corrected action plans developed and tested for effectiveness, limited performance metrics established
4. routinely audited/tested and policies/procedures exist surrounding this category
5. automated controls that are highly effective
Example: Risk in Informed Consent

An allergy research coordinator enrolling participants for an investigational treatment study wants to assess risk in her informed consent process.
Example: Decide What Could Go Wrong

The coordinator identifies the following risks:

- The wrong version of the consent form could be used to consent a participant.
- Parent/guardian signatures may be missed or incorrect on the signature page(s).
Example: Evaluate Risk

The coordinator stores her consent forms in her desk and determines it is somewhat likely she could use the wrong version of the consent form. She determines it is very likely that a parent enrolling in the study might incorrectly sign or date the consent form. She assigns "likelihood" a 4 on the risk scale.

This coordinator is the only coordinator assigned to this study. She performs the consent process and then documents and files the consent form. She assigns "detectability" a 4 on the risk scale.
5 Undetectable
4 Very Difficult
3 Difficult
2 Moderately
1 Easily

(negative scores may be considered "Mild")

Detectability

Likelihood

(1 = Easily Mild Risk, 2 = Moderately Mild Risk, 3 = Difficult, 4 = Very Difficult, 5 = Undetectable)

(1 = Rare, 2 = Unlikely, 3 = Possible, 4 = Likely, 5 = Almost Certain)

Critical Risk
Significant Risk
Moderate Risk
Mild Risk

Rarity
Unlikely
Possible
Likely
Almost Certain

Assessment Matrix:

- 1 = Easily Mild Risk
- 2 = Moderately Mild Risk
- 3 = Difficult
- 4 = Very Difficult
- 5 = Undetectable

- 1 = Rare
- 2 = Unlikely
- 3 = Possible
- 4 = Likely
- 5 = Almost Certain

(Rare Unlikely Possible Likely Almost Certain)

L: 1 2 3 4 5
D: 1 2 3 4 5

Critical Risk
Significant Risk
Moderate Risk
Mild Risk

Top Right Quadrant: Critical Risk
Bottom Left Quadrant: Mild Risk
Example: Evaluate Controls

The coordinator identifies the following controls:

- Every morning the coordinator verifies that she has the most recent version of the consent form filed in her desk according to her IRB approval.
- Additionally, she asks a research colleague to review each page of the consent form during the initial visit before she scans it into Epic and documents the consent process.

Given these precautions, she assigns her "controls" a 4 on the risk scale. Considering controls reduces her overall risk score for informed consent.
5 Undetectable
4 Very Difficult
3 Difficult
2 Moderately
1 Easily
(negative scores may be considered “Mild”)

Detectability

Likelihood

Rare Unlikely Possible Likely Almost Certain
The Research Compliance
Self-Guided Risk Assessment at Children’s Hospital Colorado
Use the Camera in Your Smartphone to Scan

https://redcap.ucdenver.edu/surveys/?s=KMJEY4RJ87
Self-Guided Risk Assessment For Research

Thank you for participating in the Self-Risk Assessment for Research. We will make every effort to keep your individual responses confidential throughout our risk assessment process, although we may need to contact you with follow-up questions or to obtain more specific information about a risk you identify.

Please provide your name: John Example
Please provide your title: Clinical Research Coordinator
Please provide your department: Neurology
Please provide your email: example@examplehospital.org

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Self-Guided Risk Assessment For Research

Human Subject Research Protection

Examples of areas of risk in human subject research protection include Informed consent, Institutional Review Boards (IRBs), HIPAA, and sensitive data.

Can you identify any areas of risk in Human Subjects Research Protection?

* must provide value

Yes

No

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## Human Subject Research Protection

Examples of areas of risk in human subject research protection include informed consent, Institutional Review Boards (IRBs), HIPAA, and sensitive data.

### Can you identify any areas of risk in Human Subjects Research Protection?

*Must provide value*

- Yes
- No

Please select each area where you can identify risk. For each category you select, you will be asked to rate the risk category for likelihood, detectability, and controls.

- **Likelihood:** The probability that specific events, factors, or situations will adversely affect an outcome.
- **Detectability:** The probability that a risk could be identified before it has an adverse effect on an outcome.
- **Controls:** How risk is mitigated; the possibility to exercise some control to reduce risk.

Your scoring of these three areas will yield a total risk score for that category.

*Must provide value*

- Informed consent/assent
- Documentation of informed consent/assent in Epic
- Institutional Review Board
- HIPAA Privacy and Security Monitoring and Training
- Sensitivity of Data
- Other Human Subjects Research Protection

## Informed Consent/Assent

Please rate the risk category of Informed Consent/Assent for **Likelihood** according to the following scale:

1: least likely/unlikely for a failure to occur
2: slightly likely for a failure to occur
3: moderately likely for a failure to occur
4: significantly likely for a failure to occur
5: extremely likely for a failure to occur

*Must provide value*

Please rate the risk category of Informed Consent/Assent for **Detectability** according to the following scale:

1: very detectable
2: slightly risky that a failure would not be detected
3: moderately risky that a failure would not be detected
4: significantly difficult to detect prior to failure
5: undetectable or extremely difficult to detect

*Must provide value*

Please rate the **Controls** for Informed Consent/Assent risk according to the following scale:

1: No formal controls in place
2: Process not audited or tested with limited policy and procedure guidance
3: Periodically audited/tested, corrected action plans developed and tested for effectiveness, limited performance metrics established
4: Routinely audited/tested and policies/procedures exist surrounding this category
5: Automated controls that are highly effective

*Must provide value*

Overall risk score for risk category of Informed Consent/Assent:

\[
\text{Overall risk score} = (\text{likelihood score} + \text{detectability score}) - \text{controls score}
\]
Self-Guided Risk Assessment For Research

Summary of Results

Below you will see the overall risk prioritization score for each risk category you identified.
The table below illustrates how each category may be prioritized:
Use Risk Prioritization Scores to:

1. Identify the “Huntsmen”
   - Build relationships
   - Start a conversation

2. Sharpen your “Tusks”
   - Tailor education
   - Develop guidance

3. Create “Peace”
   - Encourage meaningful mitigation plans
   - Foster a risk-prepared culture
Go Sharpen Your Tools!

https://ResearchRiskAssessment.childrenscolorado.org