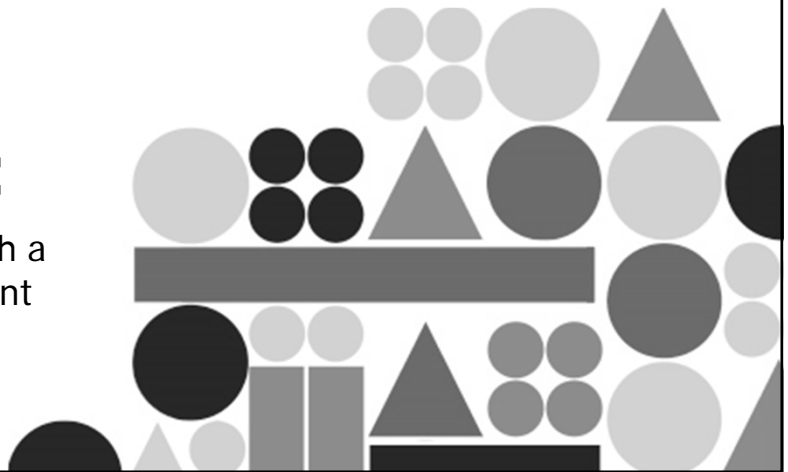


JUNE 9, 2019

Sharpening Research Compliance:

Heightened Awareness with a
Self-Guided Risk-Assessment



Conflict of Interest

David Staley, MA
Research Compliance Officer
Children's Hospital Colorado

I do not have any conflicts to report.

Hannah Gilbert, MS, CCRP
Research Compliance Analyst
Children's Hospital Colorado

I do not have any conflicts to report.

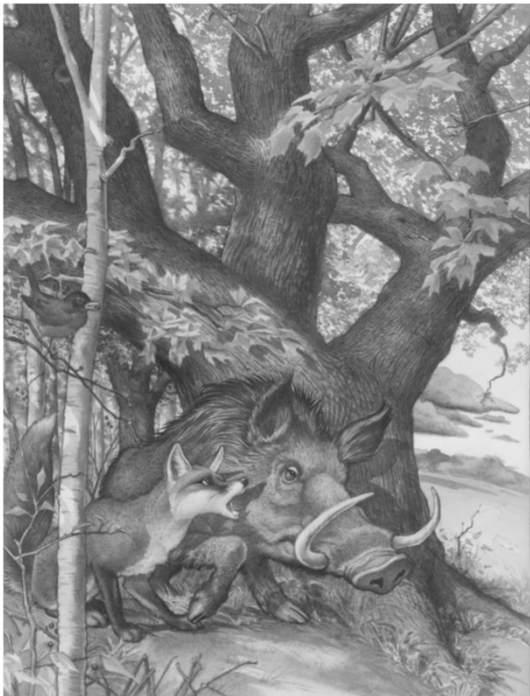




A Wild Boar was engaged in whetting his tusks upon the trunk of a tree in the forest when a Fox came by and, seeing what he was at, said to him, "Why are you doing that, pray? The huntsmen are not out today, and there are no other dangers at hand that I can see." "True, my friend," replied the Boar,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

Aesop, Rackham, A., & Ashliman, D. L. (2003). *Aesop's Fables*. New York: Barnes & Noble Classics.

Santore, C. (2018). *Aesop's Fables: The Classic Edition*. Maine: Appleseed Press.



Moral: *Preparedness is the best guarantee for peace.*

Santore, C. (2018). *Aesop's Fables: The Classic Edition*. Maine: Appleseed Press.



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

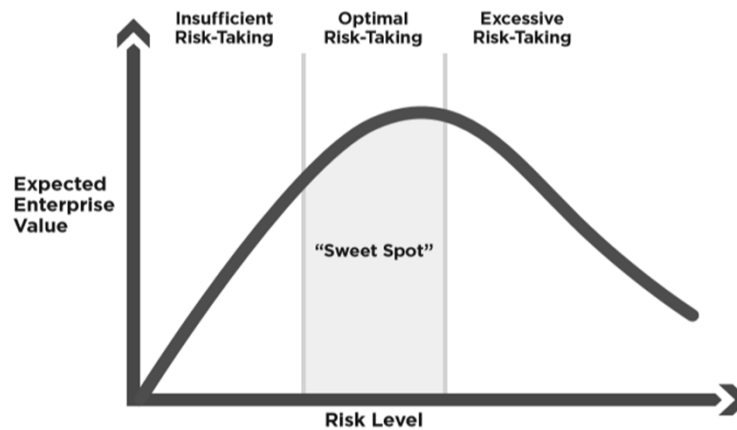
The process of making and carrying out decisions that will help prevent adverse consequences and minimize the negative effects of accidental losses on an organization.



Hagg-Rickert, S., Carrol, R., Muellenberg, E., Kielhorn, T., Rozovsky, F. (Eds.) (2017). *Enterprise Risk Management Handbook for Health Care Entities (3rd ed)*. Washington, DC: American Health Lawyers Association.

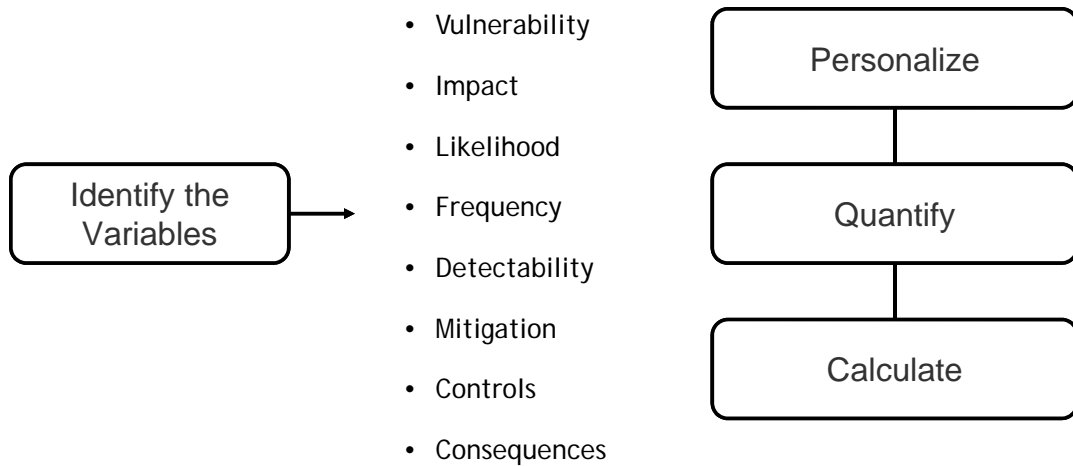
Risk Appetite

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

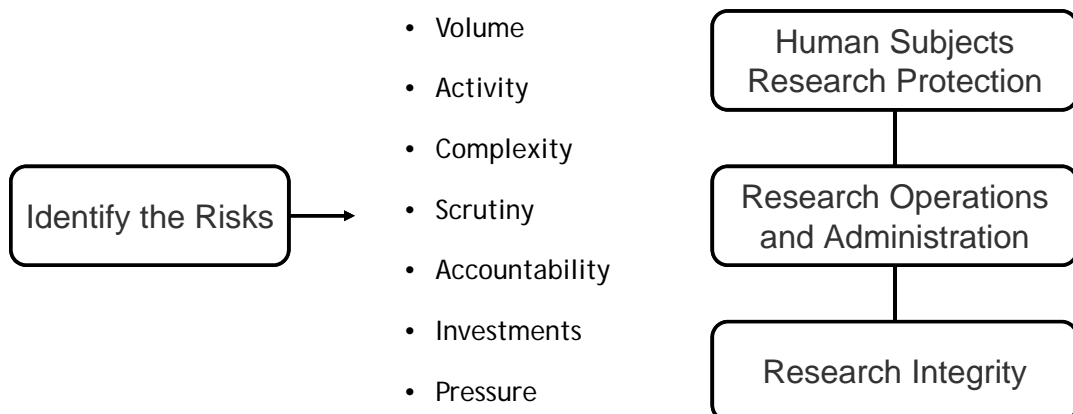


Hagg-Rickert, S., Carrol, R., Muellenberg, E., Kielhorn, T., Rozovsky, F. (Eds.) (2017). *Enterprise Risk Management Handbook for Health Care Entities (3rd ed)*. Washington, DC: American Health Lawyers Association.

How Do We Measure?



What Could Go Wrong?



How Do You Make Risk Meaningful?

Knowing Your Tools



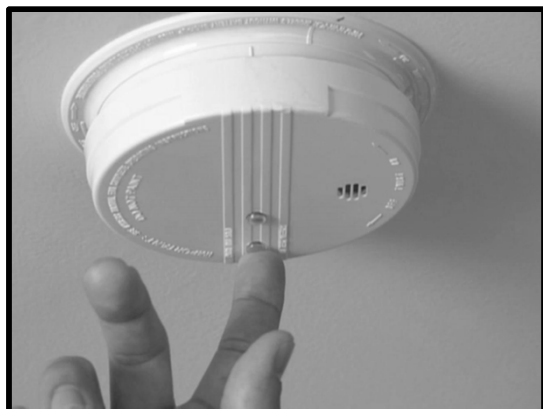
Fostering Risk Preparedness

- 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.



Staley, D., Gilbert, H. (2018). Risk preparedness: The best guarantee for peaceful compliance. *Compliance Today*, November 2018, 76-80.

What Kind of Program Do You Want?



Preparedness

vs.



Counteraction



Research Compliance Rounding

- | | |
|--|--|
| <ul style="list-style-type: none"> • Rounding sessions have three objectives: <ul style="list-style-type: none"> ✓ build relationships and learn collaboratively; ✓ assess vulnerability and efficiency; and ✓ recognize strong compliance practices while fostering a culture of ethics. | <ul style="list-style-type: none"> • Rounding sessions open discussions about what's going well, and what areas could be improved: <ul style="list-style-type: none"> ✓ 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



U S Food and Drug Administration Home Page. (2019). *Warning Letters*. Retrieved from <https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm548678.htm>

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



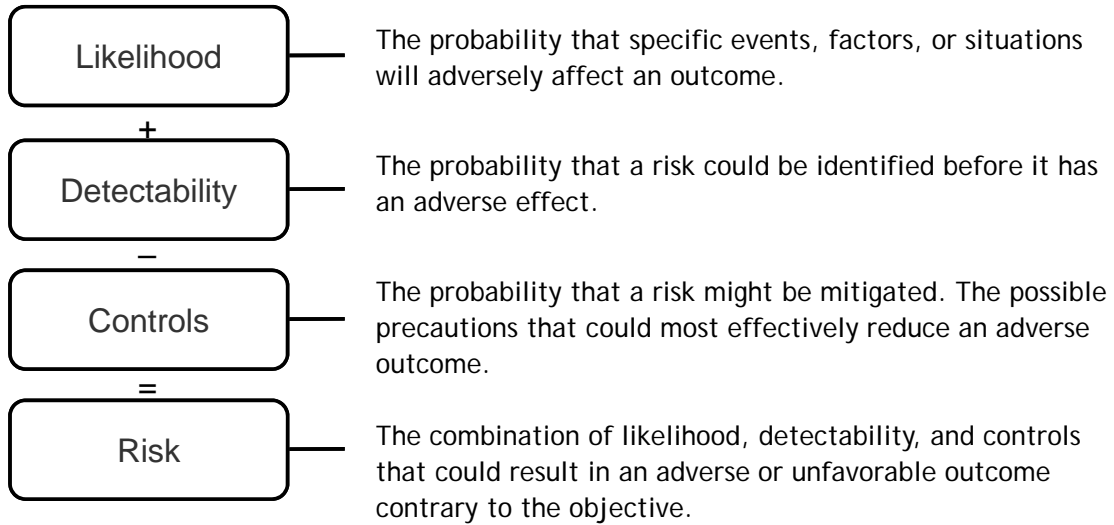
U S Food and Drug Administration Home Page. (2019). *Warning Letters*. Retrieved from <https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm548678.htm>

How Do You Implement a Risk Assessment?

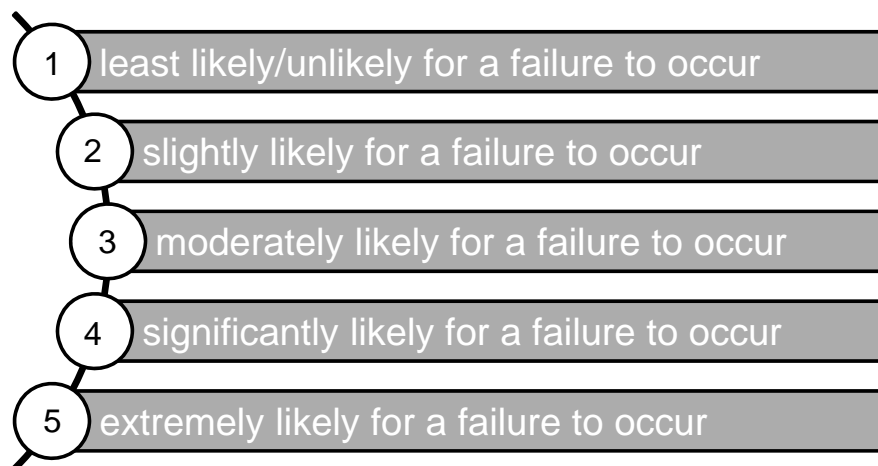
Preparedness as the Guarantee for Peace



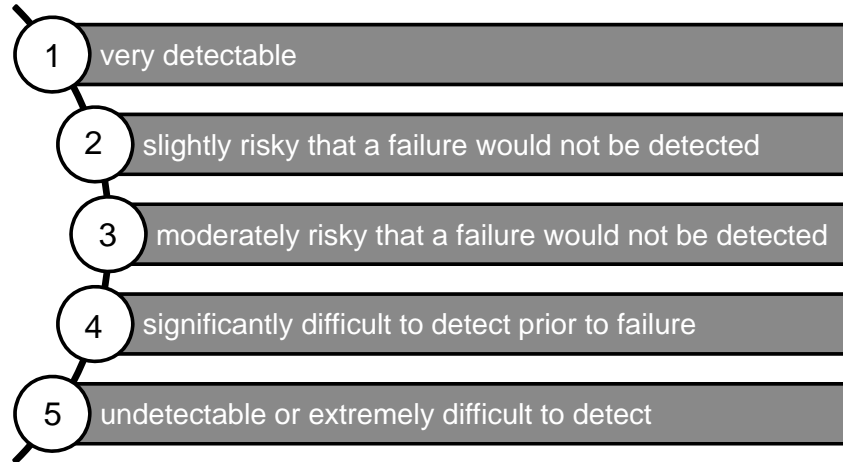
Calculating Risk



Scoring Risk Variables: Likelihood

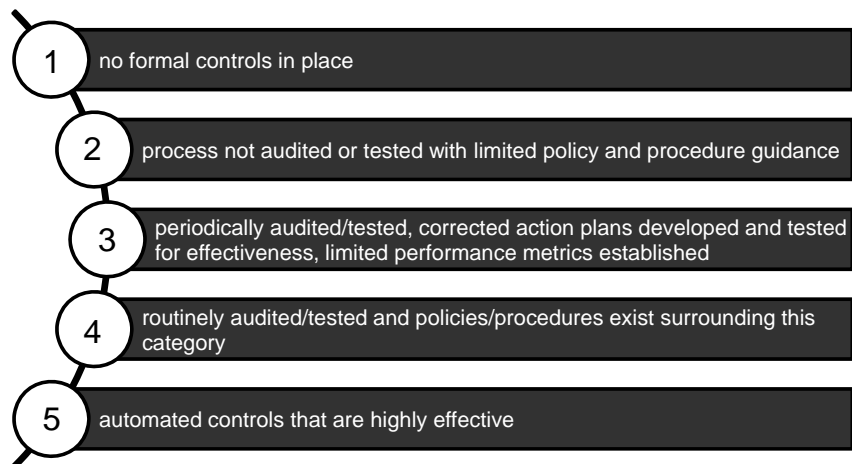


Scoring Risk Variables: Detectability

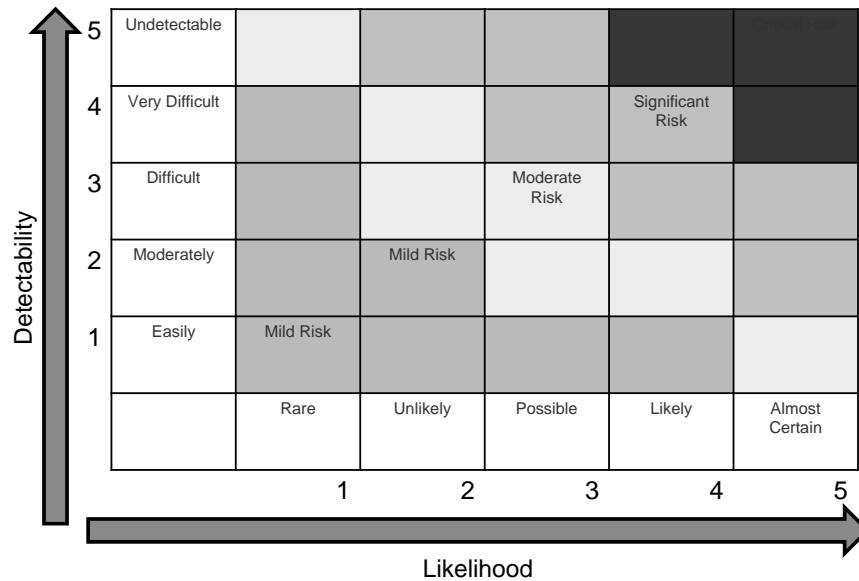
- 
- A vertical scale for Detectability risk, consisting of five horizontal bars of increasing length, each preceded by a numbered circle. The scale is connected by a vertical line on the left. The descriptions for each level are as follows:
- 1 very detectable
 - 2 slightly risky that a failure would 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

- 
- A vertical scale for Controls risk, consisting of five horizontal bars of increasing length, each preceded by a numbered circle. The scale is connected by a vertical line on the left. The descriptions for each level are as follows:
- 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

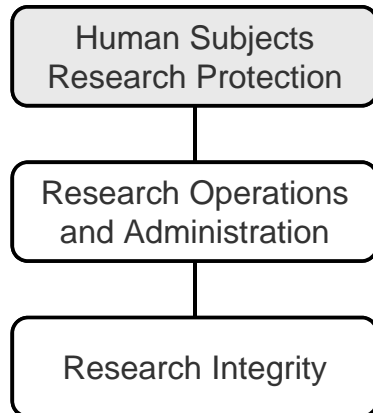
An allergy research coordinator enrolling participants for an investigational treatment study wants to assess risk in her informed consent process.



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

Likelihood

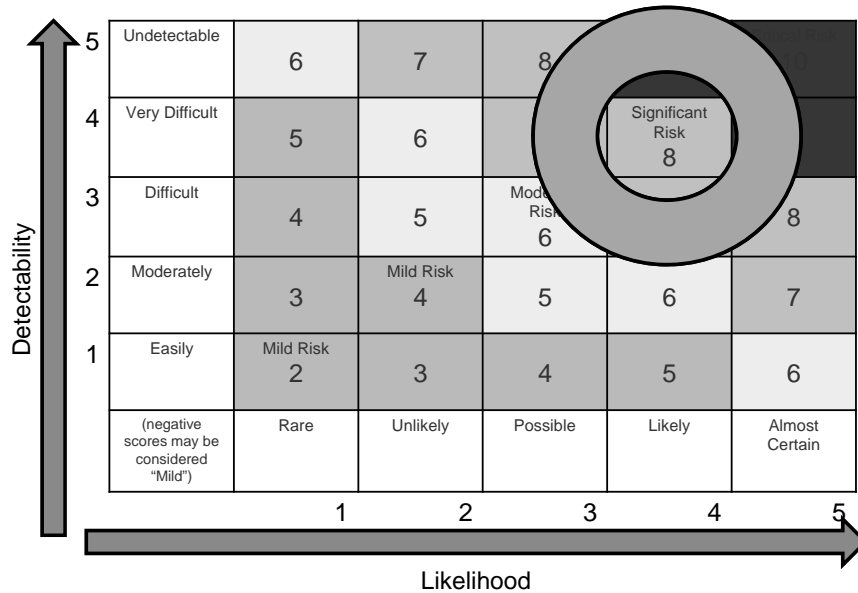
+

Detectability

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.



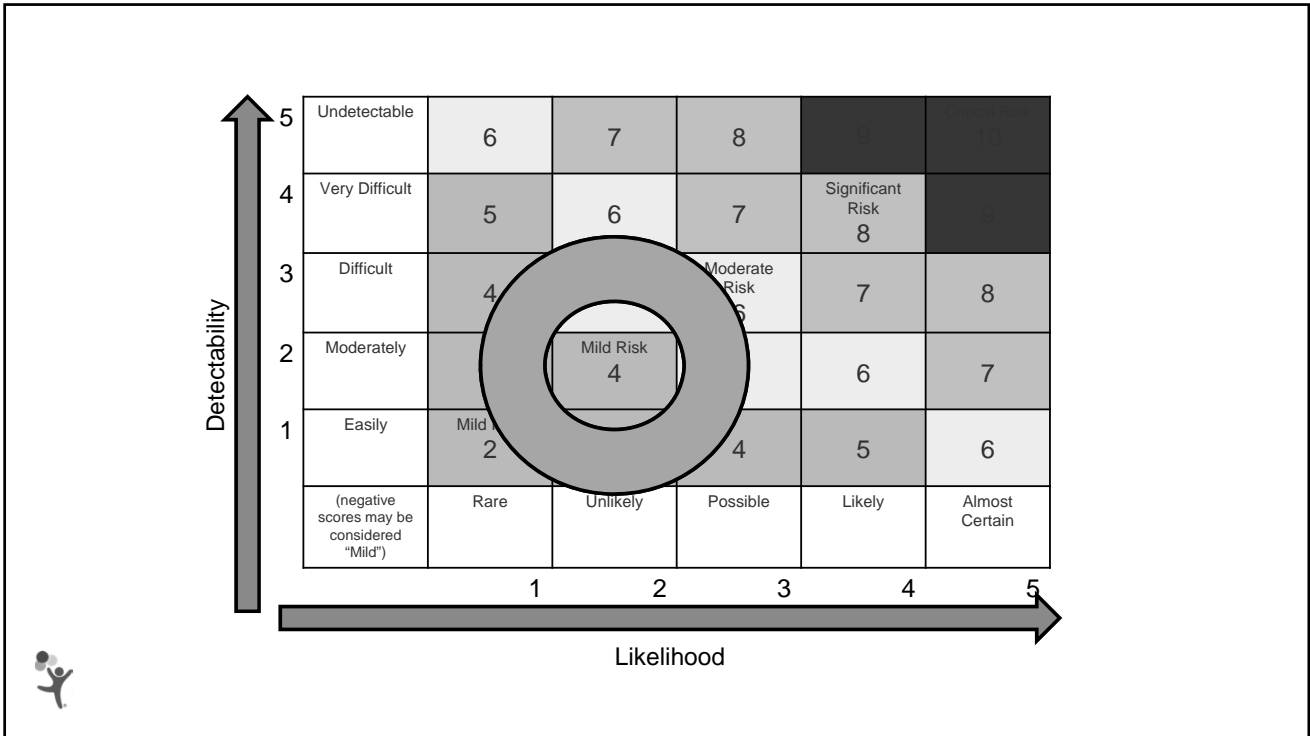


Example: Evaluate Controls

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.



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>

Use the Camera in Your Smartphone to Scan



<https://redcap.ucdenver.edu/surveys/?s=KMJEY4RJ87>



Self-Guided Risk Assessment For Research

This assessment is for example use only. Responses will not be saved.


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 contact you with follow-up questions or to obtain more specific information about a risk you have identified.

Please provide your name:

Please provide your title:

Please provide your department:

Please provide your email:

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Risk

The combination of likelihood, detectability, and controls that could result in an adverse or unfavorable outcome.


The scores you give for each of these categories will be used to calculate that category's overall risk prioritization score.

The table below illustrates how each category may be prioritized:

Impact ↑	5	Critical					Critical Risk
	4	Significant				Significant Risk	
	3	Moderate			Moderate Risk		
	2	Mild/Moderate		Mild Risk			
	1	Mild	Mild Risk				
		Rare	Unlikely	Possible	Likely	Almost Certain	
		Likelihood →					

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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

[reset](#)

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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

reset

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.

Hover your mouse over each category for a definition of 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

4

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

4

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

4

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

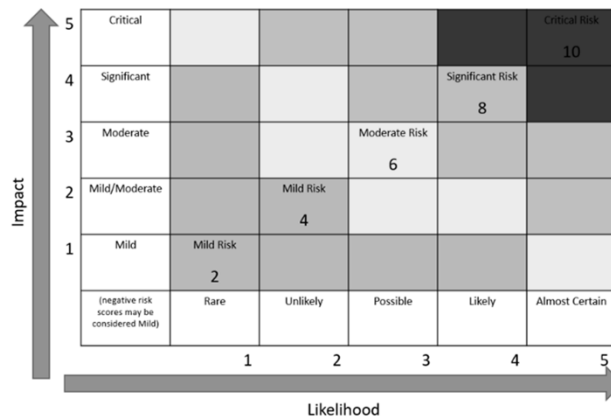
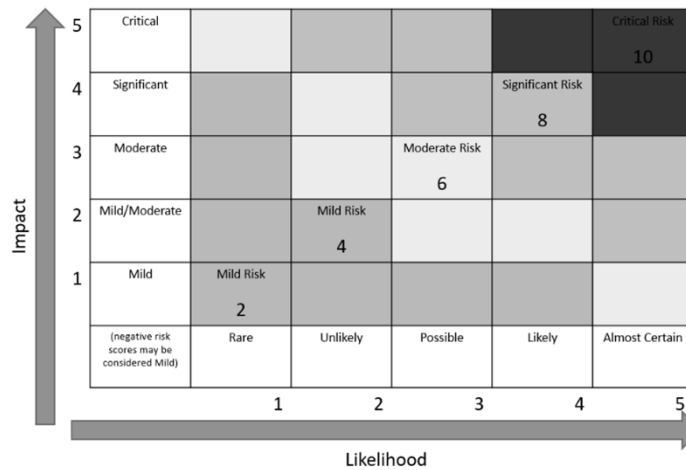
(likelihood score + detectability score) - controls score

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:



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

4

(likelihood score + detectability score) - controls score

Overall risk score for risk category of Institutional Review
Board (IRB):

6

(likelihood score + detectability score) - controls score

Overall risk score for risk category of Protocol adherence:

8

(likelihood score + detectability score) - controls score

Overall risk score for risk category of Effort reporting:

2

(likelihood score + detectability score) - controls score



Use Risk Prioritization Scores to:

Identify the
“Huntsmen”

Sharpen your
“Tusks”

Create “Peace”

Build relationships

Tailor education

Encourage
meaningful
mitigation plans

Start a conversation

Develop guidance

Foster a risk-
prepared culture



Go Sharpen Your Tools!

<https://ResearchRiskAssessment.childrencolorado.org>