National Institutes of Health (NIH)

Risk Management Program

A Presentation to IOM

July 2010

Presentation Objective

Provide an overview of risk management and specific information on the NIH Risk Management Program.

NIH Management Philosophy

- At NIH, outstanding management practices support scientific research.
  - Without sound management, the ability to promote sustainable scientific innovation is jeopardized.
  - To ensure sustainable scientific innovation, NIH management engages in activities to manage risk and internal control.

- NIH Risk Management activities focus on areas that support science (such as finance, grants, information technology, radiation safety, animal welfare) **and not the assessment of science itself.**

Risk Management Concepts

- What is risk?
  - Risk is the uncertainty around a future outcome.
  - Risk is the possibility that an event or condition may occur that would negatively impact an organization and its mission.
- What is risk management?
  - Risk management is a continuous process to proactively identify and mitigate risks.
  - Risk management promotes the achievement of the organization's objectives, strategy, and mission.

The Risk of NOT Managing Risks.

- Disruption to research in laboratories
- Loss of trust in the organization
- Resources allocated to low priority activities
- Assumption that "everything is fine"

Examples of Hypothetical Risks

Hypothetical Risks	
Intramural Research	**If** human subject volunteers suffer unnecessary health consequences due to participation in a clinical trial, **then** subjects suffer or die, public trust declines, and clinical trials recruitment declines.
Extramural Research	**If** an organization does not communicate policies, procedures and announcements to its grantee community **then** the community will not understand policy requirements and would not fulfill their responsibilities, which could affect stewardship of Federal funds, compromise public trust, and jeopardize biomedical/behavioral research.
Ethics	**If** an employee participates in a matter in which they have a real or perceived conflict of interest, **then** an organization's public trust may be jeopardized.
Facilities	**If** an organization is unable to maintain proper temperature and humidity controls in research and storage facilities, **then** an organization may lose significant animal assets, scientific sample collections, and other important research materials.
Human Resources	**If** an organization fails to recruit and retain highly qualified candidates and fill vacant positions in a timely manner, **then** the workforce may be unable to support the goals and objectives of the organization mission.

What is NIH Doing About Risks?

- Many activities are in place to mitigate or manage risks at NIH.
- Examples of day-to-day Risk Management activities include:
  - Participating in IRBs to promote good science and protect patients
  - Following animal care and use guidelines to protect the safety of research animals
  - Providing clinical research patients with clear consent forms to minimize misunderstandings
  - Using passwords to protect personal privacy information and maximize data integrity
  - Performing an ethics review to approve or deny an employee's outside activities
- But, how do we know these risk management strategies are working?
  - To find out, NIH developed an agency-wide risk management program.

The NIH Risk Management Program

NIH Risk Management Program: Objectives

- Support the NIH research mission and vision.
- Provide a consistent and cross-cutting look at risks across NIH.
- Identify risks and proactively manage those that present the highest risk to NIH.
- Develop data and information about NIH risks.
- Improve strategic planning with data and information about risks.

NIH Risk Management Program: Methodology

The NIH Risk Management methodology is a customized six-step approach that provides a standard means of addressing risks and assessing internal controls.

1. Organize
- Establish clear ownership of risks.
- Define Risk Management Structure.

2. Identify & Score
- Identify risks within risk management structure using standardized tools.
- Score risks based on Impact and Likelihood.
- Plot results on a Risk Heat Map.

3. Assess
- Evaluate the processes associated with each risk and identify any problems or gaps.

4. Manage
- Develop and execute Corrective Action Plans to address problems or gaps.

5. Monitor
- Update the risks.
- Monitor Corrective Action Plans to verify completion.

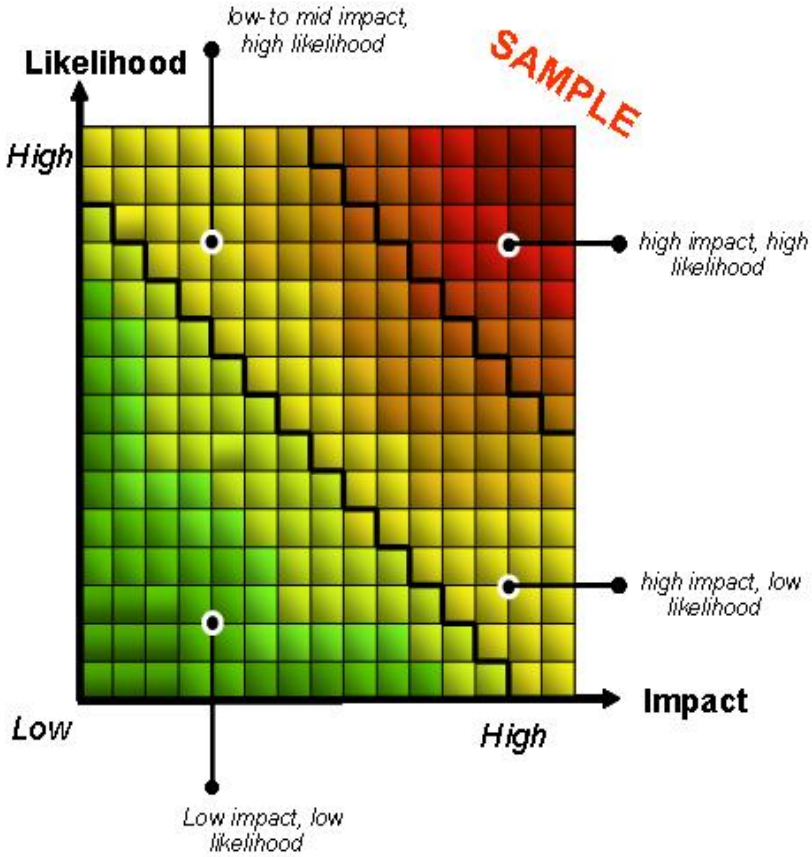
6. Report
- Conduct formal reporting activities semi-annually.

Risk Management Methodology: Organize Phase

- How is this done?
  - Create a culture of awareness by identifying and training personnel with key roles.
  - Segment the organization into discrete units to which you can apply a risk identification methodology.
  - Consult with key subject matter experts to establish clear ownership of risks.

Risk Management Methodology:
Identify & Score Phase

- Purpose is to identify those events (risks) that could jeopardize achievement of the mission of an organization, and then score them.
- Risk owners and key subject matter experts identify and score risks using standardized tools.
- Risks are scored based on two dimensions:
  - The Impact that a risk could have on the organization.
  - The Likelihood of the risk occurring.
- Identified and scored risks are plotted on a Risk Heat Map according to their scores.
- *Hypothetical Red Risk*: If an inexperienced Researcher removes tissue samples from an organization without patient authorization, then the Researcher's interests in personal gain could undermine the rights of human subjects, creating a conflict of interest.



Risk Management Methodology: Assess Phase

- Purpose is to evaluate the processes associated with each risk and identify any problems or gaps.
- The evaluation of the processes and controls uses a 3-tiered approach (high, medium, and low risk) so that NIH focuses its resources on the risks with the highest scores.
- Results of risk assessments – any identified control gaps and deficiencies from the Assess phase – determine the activities in the Manage step.
- *Hypothetical Example*
  - Risk Statement: **If** an inexperienced Researcher removes tissue samples from an organization without patient authorization, **then** the Researcher's interests in personal gain could undermine the rights of human subjects, creating a conflict of interest.
  - Assessment: Determine whether all researchers have completed the required Human Subjects Research Training course.
  - Results: 15 percent of the population of researchers in our sample did not take the required training. Recommend that the business owner formally track the completion of the training course.
  - Next steps: The business owner would need a plan to correct the problem.

Risk Management Methodology: Manage Phase

- Purpose is to develop and execute Corrective Actions Plans (CAPs) to address problems and gaps identified during the Assess phase.
- NIH periodically reviews remediation activities to ensure corrective actions are being taken.
- *Hypothetical Example*
  - Corrective Action Plan steps include:
    - Developing a more stringent tracking mechanism to determine completion of the training course for new and existing research staff.
    - Communicating to the research community that the training is required.
    - Developing a policy to restrict researchers from participating in protocols until training has been completed.
  - Next steps: monitor the status of corrective actions to ensure they are implemented.

Risk Management Methodology: Monitor Phase

- Purpose is to:
  - Periodically re-score identified risks because of changes that might affect their Impact and Likelihood
  - Identify and score new risks
  - Monitor the status of corrective action plans

- Periodic re-evaluation of changes in risks, controls and CAPs are key elements of this phase.

- *Hypothetical Example*
  - Three months later, select an additional sample to determine whether researchers are completing the required Human Subjects Research training.
  - If all researchers are now taking the training, determine whether to rescore the risk to reflect a lower risk rating.

Risk Management Methodology: Report Phase

- Purpose is to provide risk management data and information to program stakeholders.

- Semiannual reporting is currently planned.
  - What risk assessments have been completed?
  - What are the results of those risk assessments?
  - Based on results of risk assessments, what is the nature and extent of risks at NIH?
  - Can some risks be closed because they are no longer risks?

- *Hypothetical Example*
  - The risk has been assessed and corrective actions completed.
  - The program stakeholder has assurance that researchers are properly trained.

Questions and Discussion

Contact:

Suzanne Servis, Director

Office of Management Assessment, NIH

(301) 496-1873

Website: http://oma.od.nih.gov