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When Things Go Wrong

AAHRPP®
Association for the Accreditation of Human Research Protection Programs, Inc.®

Role of the Institutional Official

- Ensure that Human Research Protection Program
  - Runs smoothly
  - Operates in compliance with federal regulation and guidance
  - Protects research participants
  - Is prepared for the unexpected

Planning for the Unexpected

- Key staff
  – Have the right staff
- Written policies and procedures
  – Standard operating procedures
  – Procedures to deal with an incident
  – Procedures to deal with the media
- Continuity plan
- Stay calm

Three Examples

- Incident of interest to the media
- Allegation or finding of non-compliance
- Interruption in operations of the human research protection program

Incident of Interest to the Media

- Your facility is targeted and publicly criticized by the media or an advocacy organization.
- A research participant dies or experiences serious injury.
- Your facility is alleged or found to be seriously non-compliant with the federal regulations to protect research subjects.
- One of your employees reports an allegation of non-compliance, misconduct, or a problem.

Set Policy (example)

- In the event of an allegation your facility supports the resolution of the incident while maintaining its credibility and integrity.
- Your facility evaluates and investigates, as needed, all allegations.
- Your facility collects as much information as possible to confirm the allegation.
- Your facility involves the interested parties as is appropriate in the investigation.
- When feasible, your facility seeks resolutions to incidents that are positive for all parties involved.

Establish Procedures (examples)

- The individual making the allegation notifies the IO.
  - If the individual making the allegation, notifies another employee, the notified employee notifies the IO.
- The IO evaluates the allegation in consultation with other key senior staff and may determine:
  - The information does not represent an incident that requires further action.
  - The information might represent an incident, but the information is incomplete, in which case the IO seeks more information.
    - The IO may contact the individual making the allegation for more detail or others, as is appropriate.
  - The allegation is an incident, in which case the remainder of this process is followed.

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Establish Procedures (examples)

- The IO contacts his/her superiors to discuss:
  - A plan for addressing the incident; and
  - Whether the incident is reportable to a state or federal agency or other authority.
- Once a plan for corrective action is finalized, the IO notifies the affected parties.
- The IO communicates the incident and corrective actions to those who are affected.
- The IO, in consultation with legal counsel, determines whether the incident must be, or may be, reported to any state or federal agency or other authority.
  - If the incident is reportable, the IO reports the problem to the appropriate authorities.
- When media attention is likely, the IO follows the procedures in SOP XXX – Managing a Response to an Incident that is Reported by the Media.

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When the Media Is Interested

- Stay calm
- You know more about the incident than the reporters know
- Reporters take their cues from the ones providing them with information
- Seek media training
- Never talk to the media unprepared

Set Policy (example)

- In the event that an incident occurs or is likely to occur and is reported by the media your facility conducts activities in support of maintaining its credibility and integrity.
- One spokesperson is used to help your facility control the flow of information and ensure a clear and consistent message. Only the spokesperson may speak to outside entities.
- All inquiries (media and otherwise) regarding an incident are directed to the spokesperson.
- During an incident, staff keep a log of all inquires (media and otherwise), and notes pertaining to the inquiries.

Establish Procedures (examples)

- Contact an Official:
  - When an incident occurs or is likely to occur, the person made aware of the situation notifies one of the following individuals in the following order of priority:
    - IO
    - XXX
    - XXX
  - The person initially contacted, contacts the others listed as is appropriate.
  - In the absence of the IO, the XXX serves in place of the IO for the purpose of this procedure.

Establish Procedures (examples)

- Determine whether incident warrants a response:
  - The IO and other senior staff, legal counsel and Public Relations meet to:
    - *Immediately obtain the most up-to-date and accurate information regarding the incident.*
    - *Determine whether more information is required to understand the incident.*
  - The IO will contact others for information or advice as is appropriate.
- Pull together copies of standard response materials:
  - Public Relations assembles the following standard response materials:
    - *General information on the facility*
    - *A one-page document describing relevant policies and procedures*
    - *A one-page document providing an overview of federal regulations, policies and guidance*

Establish Procedures (examples)

- Develop a Communication Plan
  - The IO and others develop the steps to be taken. These include at a minimum:
    - *Creates a press statement and a set of talking points for the spokesperson that are specific to the incident and include responses to likely questions.*
    - *Designates a spokesperson and providing that individual with the “Guidance on Spokespersons” and general and specific talking points.*
    - *Disseminates to the media the press statement and response materials.*
    - *Communicates with stakeholders as appropriate, such as:*
      - Within the facility
      - Elected representatives
      - Regulatory officials
  - Monitors developments

Establish Procedures (examples)

- Inform staff: The IO Director meets periodically with staff meeting to keep them informed, confident, and aware of the steps being taken to resolve the incident, and coaches staff on how to handle calls, keep a log of all inquires, and where to direct inquiries.
- Conduct a review: After the incident has passed, the IO, with others, reviews the incident to evaluate what elements were handled well and what needs to be improved next time.

Allegation or Finding of Non-Compliance

- Have a policy and procedure for investigating allegations of non-compliance
  - Define non-compliance, serious non-compliance and continuing non-compliance
  - Identify the entity (title of person or office) that performs the investigation.
  - Identify the entity that makes a determination for each allegation of non-compliance whether the allegation has a basis in fact.
  - Identify the entity that makes a determination for each incident of non-compliance whether the non-compliance is serious or continuing.

Non-compliance procedures

- Identify the entity to whom non-compliance is referred if it is determined to be serious or continuing.
- Identify the entity to whom non-compliance is referred if it is determined to be neither serious nor continuing.
- Have serious or continuing non-compliance reviewed by the convened IRB or EC.
- Describe the types of information provided to the IRB or EC for review of serious or continuing noncompliance:
  - a. Describe the specific documents provided to primary reviewers, if a primary reviewer system is used.
  - Describe the specific documents provided to all other IRB or EC members.
- Describe the types of actions the IRB or EC might take.
- Describe the process for reporting serious or continuing non-compliance.

Some Advice

- Expect to see non-compliance, including serious or continuing non-compliance.
- Focus on serious or continuing non-compliance.
  - Address the non-compliance immediately.
  - Delays lead to more non-compliance and increase complexity of the non-compliance.
- If you look for non-compliance, you will find it.
- Strong HRPPs detect and address non-compliance.

Interruption in Operations of the Human Research Protection Program

- Natural acts
  – Flooding
  – Electrical outage
  – Prolonged snow closure
- Fire
- Protests
- Terrorist Attack
- Unstable governments/refugees

Develop a Continuity of Operations Plan

- Carefully assess how your HRPP functions, to determine which staff, materials, procedures and equipment are absolutely necessary to keep the HRPP operating.
  - Review your operations process flow chart.
  - Identify operations critical to survival and recovery.
  - Establish procedures for succession of management.

- Identify the units that you must interact with on a daily basis.
  - Develop professional relationships with more than one vendor to use in case you are unable to provide a service.
  - Create a contact list for existing critical business contractors and others you plan to use in an emergency. Keep this list with other important documents on file and at an off-site location.

- Plan what you will do if your facility is not accessible.
  - Consider if you can run the HRPP from a different location.
  - Develop relationships with other entities to use their facilities in case a disaster makes your location unusable.

- Decide who should participate in putting together your emergency plan.
  - Include co-workers from all levels in planning and as active members of the emergency management team.
  - Consider a broad cross-section of people from throughout your facility, but focus on those with expertise vital to daily HRPP functions. These will likely include people with technical skills as well as managers and executives.

- Define crisis management procedures and individual responsibilities in advance.
  - Make sure those involved know what they are supposed to do.
  - Train others in case you need back-up help.
- Coordinate with others.
  - Talk with first responders, emergency managers, community organizations and utility providers.
- Review your continuity plan annually. Just as your HRPP changes over time, so do your preparedness needs.

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