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Elizabeth Buchanan, Karen Hansen and Kelley O'Donoghue
Learning Objectives

1. Create policies and procedures to assist in preserving institutional memory
2. Discuss how documents related to the IRB and HRPP be archived and stored
3. Share strategies for succession planning
4. Explore on-boarding and off-boarding of staff and members to retain institutional memory
Presenter Bio

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Director, Healthcare Research Compliance & Chief Research Compliance Officer
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Unity Health Toronto Providence, St. Joseph’s & St. Michael's Hospital
Think of Our HRP Field

- How many have fewer than 5 FT staff?
- How many have multiple generations represented in your offices or on the IRB?
- Think how much has changed around us!
- And, more broadly:
The Field Itself Has Changed Significantly

- Institutional leadership started paying attention
  - 1999 – Duke, University of Illinois, University of Colorado, University of Pennsylvania
  - 2000 - Virginia Commonwealth University, University of Alabama at Birmingham
  - 2001 - Johns Hopkins

- PRIM&R/ARENA
  - Professionalization

- AAHRPP
  - Standards/Requirements
More changes….

- Privacy, HIPAA
- General Data Protection Regulation (GDPR)
- Revised Common Rule
- State laws
Why is retaining institutional memory important? (and there are so many reasons…)

- Work never stops
  - Always new research protocols, amendments, continuing review

- Not an easy job to learn
  - Regulations vs Guidance
  - Policy
  - Research paradigms
  - Unpredictability
  - Time sensitive review/issues

- Memory is important
  - Continuity important to protecting subjects, quality research, and quick turn around
What Is Mission Critical?

- Ethics
- Compliance
- Deadlines

  - Will drive what is mission critical.
    - E.g., a USDA site visit on day 13.
    - Delegation, Phone Trees, Disaster/Emergency Ops planning
    - Grant Requirements
    - Safety Issues
Institutional Memory

- **Definition:** Set of facts, concepts, experience and knowledge held by a group of people

- **Self test:**
  - What is your license plate number?
  - What was your high school principal’s name?
  - What color is your neighbor’s front door?
Build an explicit strategy
Create a robust set of SOPs
Use technology to create a process to capture institutional knowledge
How to write a stellar SOP

- Standardized format
- Begin with an end in mind
- Define the scope
- Identify the audience
- Review, test, edit
Section 100: Category

<table>
<thead>
<tr>
<th>POLICY:</th>
<th>Number and Title of the SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>This policy pertains to:</td>
<td>the range of activities the SOP applies to (aka &quot;Scope&quot;)</td>
</tr>
<tr>
<td>Responsibility for executing this policy:</td>
<td>the personnel responsible for both performing and complying with the SOP as well as the person responsible for assuring the appropriate personnel are trained on the SOP</td>
</tr>
<tr>
<td>(for most SOPs this will be IRB, IRB Chair, IRB staff, Vice-President Research)</td>
<td></td>
</tr>
<tr>
<td>Approval authority:</td>
<td>Eg. IRB Chair, Vice-President, Research</td>
</tr>
<tr>
<td>Effective date:</td>
<td>month/dd/yyyy of current SOP (i.e. April 15, 2013)</td>
</tr>
<tr>
<td>Supersedes documents dated:</td>
<td>history of all previous version dates</td>
</tr>
<tr>
<td>Approved:</td>
<td>Eg. IRB Chair, Vice-President, Research</td>
</tr>
</tbody>
</table>

1. **PURPOSE** - an explanation of the objective the SOP is intended to achieve

2. **POLICY STATEMENT** - the principles guiding the standard operating procedure

3. **DEFINITIONS** - define terms and acronyms that people reading the SOP may not generally know and that would require clarification. (If a definition exists in the regulations, the regulation definition will be used)

4. **PROCEDURES** - state specifically what to do in order to achieve uniformity of the performance of a specific function (i.e. state what is done not what must, shall or may be done)

5. **REFERENCES** - references to guidelines, regulations, policies, etc. for items, as applicable, will be listed adjacent to the item within the SOP
Data Archiving

- **Data archiving** is the process of moving data that is no longer actively used to a separate storage platform for long-term retention.

- **Archived data** consists of older information that is still important to the IRB and may be needed for future reference, as well as information that must be retained for regulatory compliance.

- May consist of paper and electronic information.
Data Archiving

- Key considerations:
  - Access
  - Usability
  - Redundancy
  - Retrievability
Success(ion) Planning

Succession planning doesn’t start with people. It starts with the requirements of the position.

David Ulrich
## Success(ion) Planning

<table>
<thead>
<tr>
<th>Replacement</th>
<th>Succession</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>Proactive</td>
</tr>
<tr>
<td>Form of risk management</td>
<td>Planned</td>
</tr>
<tr>
<td>Substituting</td>
<td>Renewing</td>
</tr>
<tr>
<td>Narrow approach</td>
<td>Organized alignment</td>
</tr>
<tr>
<td>Restricted</td>
<td>Flexible</td>
</tr>
</tbody>
</table>

- Identify key/critical positions
- Define role on the IRB
- Monitor, evaluate
- Identify gaps

- Competency
- Diversity
- Term limits
Success(ion) Planning

- Needs to be considered at the beginning, not at the end
- Orientation
- Training Manual
  - ‘Living’ document that can be built upon
  - Required reading, acronyms, consent form guidelines, sample reviews, SOPs
  - Document important decisions made by the IRB
Success(ion) Planning

- Remember to think lateral as well as linear!
  - Identify the knowledge, skills and abilities to perform functions and develop a plan to prepare individuals.
  - Cross training will broaden skill sets and increase institutional memory
  - Culture fit is key. You may grow talent internally and you may be forced to look outside. Skills can be taught, whereas attitude has an immediate impact.
On and Off-Boarding at Unity Health Toronto

- Letter of engagement – lists expectations and term up front
- Establish individual member file – include CV, training, etc.
- Recognition and appreciation
  - Annually
  - Solicit feedback (areas for improvement)
On and Off-Boarding at Baystate Health

- In addition to what has already been covered...
- In person training with one of our educators, typically 1-2 hours
  - Review electronic system and where to find helpful tips and guidance such as OHRP decision trees in the electronic library
  - Must observe and IRB Meeting
  - Must complete a paired review with a member of the committee with greater than 1 year experience.
Single IRB Considerations (or Cede)

- Standardize: criteria for single IRB cede, policies you want to see, storage location, document naming convention

- Consider maintaining a local context review:
  - The risk level to the human subjects
  - The number of sites
  - The experience level of the Investigator/study team
  - The level of administrative resources available to the PI/study team to manage/coordinate the project
  - Whether your Investigator holds the funding grant

- Remember, if AAHRPP Accredited the lead IRB must share policies you request (Standard I-9)
For More Information

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Questions?
Thank You