Network for Clinical Research Professionals (NCRP) Seminar

Disaster Preparedness for Clinical Research Professionals
UPDATES:

- Brainstorming Session About Barriers and Possible Solutions
  - What is a hurdle that you face as a clinical research professional?

- Next NCRP: August 9, 2017 – HSRO Speaker: Khemraj Hirani, MPharm, Ph.D.
  - Overview of the Revised Common Rule: Changes and Implementation of Review Process to Better Protect Human Subjects and Reduce Administrative Burden
  - October 2017 – Topic TBD

- New mandatory training is in development for PIs and study teams – to be rolled out later in Fall

- Revised U-Way will also roll out later this Fall
**UPDATES:**

New IRB 7 Field

- New field for allowing entry of a “Layman’s Description” of your study
- Should be entered with new submissions, amendments/modifications and continuing reviews
- This field will eventually feed directly into the Clinical Research Search Tool as the primary description how to market your study to participants.
UPDATES:

- Update on Clinical Research Professionals Career Ladder Project
- Survey
  - Evaluation of today’s presentation & selecting/requesting future NCRP topics
There are multiple possible natural and man-made disasters that could affect your clinical studies.

- Hurricanes
- Tornados
- Fire
- Floods
- Power failures
- Terrorism, bioterrorism
- Pandemics, plagues, mosquito borne viruses
- Active shooter
- Toxins, poisons
# 2017 FORECAST

## Hurricane Season: June 1st to November 30th

<table>
<thead>
<tr>
<th>Storm Type</th>
<th>NOAA</th>
<th>CSU</th>
<th>AccuWeather</th>
<th>Average Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Named Storms (39 mph and higher)</td>
<td>11-17</td>
<td>11</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Hurricanes (74 mph or higher)</td>
<td>5-9</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Major Hurricanes (Cat 3+) (111 mph or higher)</td>
<td>2-4</td>
<td>2</td>
<td>3</td>
<td>2</td>
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</tbody>
</table>

- **Season Peak:** September 10th
- **Early Season:** Caribbean Generation
- **Secondary Peak:** October 5th
- **Later Season:** Cape Verde Type
Before the Storm...

I AM NOT AFRAID OF STORMS, FOR I AM LEARNING HOW TO SAIL MY SHIP...

Louisa May Alcott
Practitioner Considerations

01. Complete as much study activity as possible in advance of the event.
02. Notify sponsors and stakeholders to discuss any potential impacts on the protocol.
03. Coordinate an alternative site to conduct study visits, if feasible.
04. Establish a process to unblind studies in the case of a disaster.
05. Ensure clear procedures exist to secure and access investigational drugs and devices during a disaster.
Research Participant Considerations

01 Contact the study participants to determine if they need anything from you (contact information, Investigational Product).

02 Ensure that the study participants contact information is current, moreover, if there is an evacuation, do you have an alternative means of contacting them?

03 Do not allow research to take precedence over the welfare of your study participants.

04 Secure all clinical trial research records, both paper and electronic format. Document the process and inform the study team of the method and location.
| Have A Plan | Family – Water, medications, non-perishable foods, cash, fuel, battery powered radio, first aid supplies, 96+ hours of resources, etc.  
Pets – Food, cages, location of nearest shelters that allow pets  
Red Cross – Safe and Well Website |
| Update Contact Information | Update Contact info on WorkDay and/or CaneLink,  
Create a contact in your phone for “UMiami ENN Alert” with the following numbers (in any order):  
800-227-0354  
Text 226787 or 67283 to 40404 – The text “Follow @UMiamiENN” |
| Review Work Plans | Understand the University of Miami’s Hurricane Guidelines  
Review shipping vendor agreements. What are their disaster plans? (contact the study Sponsor if applicable)  
Update the study team contact information  
Review information on the Miami-Dade Office of Emergency Management Website |
What Happens Before the Alert?

Information Flow

- NHC, NWS, County EM Offices
- UM Emergency Management
- University Crisis Decision Team
- Individual Campus Crisis Decision Teams
- University Community

Threat Area
Preservation of Research

Do you need to ship or relocate samples to a safer location?

- Where are they going?
- How long does it take to prepare a shipment?
- Who will be moving the samples?
- Who will verify that my shipment was received?
  - What condition
  - How will it be cared for
  - Document the chain of custody
- When will I receive my shipment back?
- Does the residing location meet all the security and physical needs of my research study?
Understanding when my research is at risk

- Risk Identification Techniques
  - Priority Ladder
  - Priority Cross
# Priority Ladder

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>YES</td>
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<td>YES</td>
<td>YES</td>
<td>1</td>
</tr>
<tr>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>2</td>
</tr>
</tbody>
</table>

Start Here

X
PRIORITY CROSS

Great Loss Potential?

YES | NO
---|---
YES | 1 | 2
NO | 3 | 4

Preventable?

1 = highest priority
4 = lowest priority
Exercise 1

- Category 4 - Hurricane Sebastian is expected to make landfall in Miami within 72 hours.

- You have been tasked with the following:
  - Ship out your research samples to an alternative location
  - Back up sensitive data files that have no replacement
  - Ensure that your research subjects are properly informed regarding the storm

- You have been awake for the last 14 hours on your latest study.

- The University of Miami will issue a campus closure notice within the next 24 hours.

- Use the Priority ladder to determine which of your tasks presents the greatest risk.
# Priority Ladder

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>YES</strong></td>
<td><strong>YES</strong></td>
<td><strong>YES</strong></td>
<td><strong>YES</strong></td>
<td></td>
</tr>
<tr>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
<td><strong>NO</strong></td>
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</tbody>
</table>

*Start Here*

<table>
<thead>
<tr>
<th>1</th>
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<tbody>
<tr>
<td>2</td>
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<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>
DATA IS A PRECIOUS THING AND WILL LAST LONGER THAN THE SYSTEMS THEMSELVES

TIM BERNERS-LEE
The University of Miami provisions all faculty, staff, and students to several cloud-based collaboration services.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Box</th>
<th>Microsoft OneDrive</th>
<th>Google Drive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encrypted</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>BAA</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Storage</td>
<td>Unlimited</td>
<td>Unlimited</td>
<td>Unlimited</td>
</tr>
<tr>
<td>Group Accounts</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Versioning</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Co-Authoring</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mobile App</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Desktop App</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Data Storage – Best Practices

- Always attempt to store data in non-proprietary or open standard formats for long-term software readability (see file formats table).

- Copy or migrate data files to new media between two and five years after they were first created, since both optical and magnetic media are subject to physical degradation.

- Check the data integrity of stored data files at regular intervals.

- Create digital versions of paper documentation in PDF/A format for long-term preservation and storage.

- Non-digital data are fit for the purpose, structurally sound, and free from the risk of general environmental disasters.
<table>
<thead>
<tr>
<th>TYPE OF DATA</th>
<th>RECOMMENDED FILE FORMATS FOR SHARING, RE-USE AND PRESERVATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative tabular data with extensive metadata</td>
<td>SPSS portable format (.por)</td>
</tr>
<tr>
<td>a dataset with variable labels, code labels, and defined missing values, in addition to the matrix of data</td>
<td>delimited text and command (‘setup’) file (SPSS, Stata, SAS, etc.) containing metadata information</td>
</tr>
<tr>
<td></td>
<td>some structured text or mark-up file containing metadata information, e.g. DDI XML file</td>
</tr>
<tr>
<td>Quantitative tabular data with minimal metadata</td>
<td>comma-separated values (CSV) file (.csv)</td>
</tr>
<tr>
<td>a matrix of data with or without column headings or variable names, but no other metadata or labelling</td>
<td>tab-delimited file (.tab)</td>
</tr>
<tr>
<td></td>
<td>including delimited text of given character set with SQL data definition statements where appropriate</td>
</tr>
<tr>
<td>Geospatial data</td>
<td>ESRI Shapefile (essential: .shp, .shx, .dbf; optional: .prj, .sbx, .sbn)</td>
</tr>
<tr>
<td>vector and raster data</td>
<td>geo-referenced TIFF (.tif, .tfw)</td>
</tr>
<tr>
<td></td>
<td>CAD data (.dwg)</td>
</tr>
<tr>
<td></td>
<td>tabular GIS attribute data</td>
</tr>
<tr>
<td>Qualitative data</td>
<td>eXtensible Mark-up Language (XML) text according to an appropriate Document Type Definition (DTD) or schema (.xml)</td>
</tr>
<tr>
<td>textual</td>
<td>Rich Text Format (.rtf)</td>
</tr>
<tr>
<td></td>
<td>plain text data, ASCII (.txt)</td>
</tr>
<tr>
<td>Digital image data</td>
<td>TIFF version 6 uncompressed (.tif)</td>
</tr>
<tr>
<td>Digital audio data</td>
<td>Free Lossless Audio Codec (FLAC) (.flac)</td>
</tr>
<tr>
<td>Digital video data</td>
<td>MPEG-4 (.mp4)</td>
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<tr>
<td></td>
<td>motion JPEG 2000 (.jpg)</td>
</tr>
<tr>
<td>Documentation</td>
<td>Rich Text Format (.rtf)</td>
</tr>
<tr>
<td></td>
<td>PDF/A or PDF (.pdf)</td>
</tr>
<tr>
<td></td>
<td>OpenDocument Text (.odt)</td>
</tr>
</tbody>
</table>
3 – 2 – 1 – Data Management Rule

The 3-2-1 backup rule implies that you should:

- Have at least 3 copies of your data
- Keep these backups on 2 different media
- Store 1 backup offsite
How Does the 3 – 2 – 1 Rule Work?

- **By three copies, I mean your original data and two backups**
  - The more copies of your data you make, the less risk you have of losing everything.
  - One backup is good, it however is just not good enough. If you have only one additional copy of your data, **AT LEAST** make sure it’s located in a different physical location from the original (and as far away as possible!).

- **Keep these backups on 2 different media**
  - Having several backups of your data and keeping them in the same place is **NOT** logical.
  - Why Not? - Typically, a common failure will affect ALL devices.
  - For example, disks from the same RAID are statistically dependent, and often, after one disk failure, you might experience the failure of another disk from the same storage in a short period (often because the devices were bought approximately at the same time and from the same vendor).
  - Tapes, USB drives, CDs, external/internal hard drives, etc.

- **Store 1 backup offsite**
  - Offsite means as FAR AWAY as possible, in another city, state, country or even continent.
  - Even if you have two copies on two separate storage types but both are stored onsite, a local disaster could wipe out both of them. Keep a third copy in an offsite location, like the cloud.
Exercise 2

- Category 4 - Hurricane Sebastian is expected to make landfall in Miami within 72 hours.

- You are the study coordinator for an Investigator-Initiated Trial for which you have enrolled over 100 study participants. You have collected blood samples on all study participants and have paper Case Report Forms (CRFs) and paper source documents only. The study is now closed to enrollment and you have no active study participants.

- What do you do to ensure the stability of the blood samples and the integrity of the source and paper CRFs?
After the Storm

THE BEST WAY TO PREDICT THE FUTURE IS TO CREATE IT...

PETER DRUCKER
After the Storm - Study Recovery Phase

01
Contact the study participants to determine if they need assistance and reschedule visits, if needed.

02
Verify the stability of the study participant’s samples, study drug, data, etc. and if necessary, make arrangements for their return. Inform your supervisor of any damages.

03
Contact the study-sponsor to discuss any impact on the protocol.

04
Resume the protocol timeline as soon as practical.
CAMPUS REOPENING PROCESS

- Campus Damage Evaluation
- Student & Employee Check In
- Prioritizing emergency repairs and debris clearance
- University/ Campus CDT Conference Calls
- Wait for the All Clear to be issued via the ENN by Emergency Management / Public Safety Officials
- Emergency Hotline Remains Staffed
- Long-Term Recovery Operations
- After Action Analysis: What can we do better next time?

UMiami ENN: GABLES CAMPUS Power is being restored in many bldgs. Please wait to return until official clearances are issued. More info Facebook.com/UMLamiENN
Safety precautions for campus reentry

**DON'T** Self Dispatch to the campus if Umiami Emergency Management has not given the ALL Clear Notification

**DON'T** Drive through floodwater. You should drive around water whenever possible because it may be deeper than you think, or contain dangerous objects, hazardous materials you can’t see. If you can’t avoid the water, turn around and find an alternate route.

**DON'T** Enter a building if it has visible structural damage from a storm, or one that smells like gas, has nearby downed power lines, or is flooded.

**DON'T** Immediately attempt to grab external door handles. Use the back of your hand first just in case the handle is “charged”.

**DO** Carefully inspect any freezers or sensitive equipment and document your findings.

**DO** Take photographs of any and all damage to your work location. Report this to UM Risk Management.
FEMA REIMBURSEMENT

• FEMA Reimbursement is lead by Risk Management, but is a responsibility for all units.

• Key Points for Reimbursement
  o Document all actions and expenditures
  o Make decisions consistent with existing plans
  o Before and After Photos
  o Utilize University Disaster Recovery Vendors
  o Coordinate issues through the University EOC
  o Be prepared to submit preliminary costs when requested

Questions regarding FEMA Reimbursement? Contact RiskManagement@miami.edu
RESOURCES

• New Prepare Website
  www.prepare.miami.edu

• University of Miami Emergency Guide
  www.miami.edu/emergency-guide

• Hurricane Preparedness Information
  www.prepare.miami.edu/hurricane

• Preparedness for Clinical Researcher
  www.research.med.miami.edu/clinical-research/clinical-preparedness

• University of Miami Weather Stations
  miamidade.weatherstem.com/umiami

• Follow @UMiamiENN on Facebook and Twitter
Questions & Answers

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