RESEARCH MATTERS

January 19, 2016

DEVOTIONAL & PRAYER

CHRISTINA JACKSON
FHRI UPDATES

- PI Forum
  - Tuesday, February 2nd 7:00 a.m. – 8:00 a.m.

- CTMS Clinical Conductor
  - Launch Meeting with BioOptronics last Friday

- CREATION Health - 2016 Tour de Cure for the American Diabetes Assoc.
  - March 13th
  - Ride 10 miles or more…
RESEARCH SERVICES, SURVEY RESULTS
OVERALL FEEDBACK – ROB H.

- Purpose of Survey
  - To obtain a baseline snapshot in time of feedback from Clinical Research teams regarding the key services within Research Services

- Who Participated

- Overall results with % that met or exceeded and % that were below expectations
THANKFULLY, YOU ARE NOT CATS...

And here we have the results... 46% don't give a darn, 34% couldn't care if their life depended on it, and 20% slept through.
WHO PARTICIPATED?

- Faculty Researcher/Investigator/Scientist
- Department Director/Manager/Supervisor
- Research Coordinator
- Regulatory
- Research Assistant

- 33%
- 29%
- 27%
- 10%
- 1%
UNDERSTANDING OF REQUESTOR NEEDS

- Met or Above: 74%
- Below or Poor: 26%
FUNCTIONAL/TECHNICAL EXPERTISE OF STAFF

- Met or Above: 78%
- Below or Poor: 22%
ACCESSIBILITY AND COURTESY OF STAFF

78% Met or Above: 22% Below or Poor:
UNDERSTANDING AND EXPLANATION OF RESEARCH REQUIREMENTS

Met or Above: 67%
Below or Poor: 33%
OVERALL SATISFACTION WITH THE PROCESS OF REVIEW AND CLEARANCE/APPROVAL

Met or Above: 65%
Below or Poor: 35%
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<thead>
<tr>
<th>Overall Satisfaction - Average</th>
<th>NA</th>
<th>Excellent</th>
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## OVERALL SATISFACTION - GRANTS

### Understanding Needs

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### Functional/Technical Expertise of Staff

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### Accessibility and Courtesy of Staff

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### Timeliness of Response/Problem Resolution

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## OVERALL SATISFACTION - GRANTS

### Consistent Application of Policy/Procedures

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### Understanding and Explanation Research Administration Requirements

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### Communication

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### Process

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RESEARCH SERVICES – SURVEY RESULTS
GRANTS

- **Summary**
  - On average, satisfaction % are consistent for each area
  - Lowest scoring area is with regards to **PROCESS**
    - Grants Team has been in the process of developing new / updating old procedures prior to and in response to survey results.
    - The Team anticipates that once procedures have been implemented / refined and communicated effectively to customers, understanding of these processes will increase overall satisfaction

- **Strategies**
  - Develop training materials
  - Increase transparency in the grants administration process
  - Continue to keep abreast of new policy requirements / updates
94 Respondents, but 8 consistently responded “n/a” to ORA Qs

N = 86 (94 Respondents, but 8 consistently responded “n/a”)

- 30.8% Faculty
- 29.8% Directors/Managers/Supervisors
- 26.6% Coordinators
- 1.2% Regulatory
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<tr>
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<tbody>
<tr>
<td>Understanding of Requestor's Needs</td>
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<td>77.9%</td>
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<td>22.1%</td>
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<tr>
<td>Functional/Technical Expertise of Staff</td>
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<td>86.0%</td>
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<td>14.0%</td>
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<tr>
<td>Accessibility and courtesy of staff</td>
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<td>86.0%</td>
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<tr>
<td>Consistent Application of policy/procedures</td>
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<td>72.1%</td>
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### ORA – OPPORTUNITIES

#### Classes/Workshops/Training

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<tr>
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#### Timeliness of Response, problem resolution, or other services

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#### Understanding/explanation of ORA requirements

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#### Overall satisfaction with the process of study review and clearance

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#### Overall satisfaction with communication relating to research and scholarly activity

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Summary

- Expertise and accessibility of ORA Staff are seen as strengths
- Stakeholders may not understand the “why” behind ORA processes and requests – ORA needs to provide more information/education
- Continued improvement with the process of study review & clearance as well as other problem resolution is needed

2015 & 2016 Strategies

- Continue development of Onboarding Education
- Monitor and publish metrics for contract review and budget review
### IRB - STRENGTHS

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<thead>
<tr>
<th>Understanding/explanation of IRB requirements</th>
<th>N/A</th>
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INSTITUTIONAL REVIEW BOARD (IRB) SURVEY RESULTS

IRB - Key Take-Aways

- **Strengths**
  - Timeliness of Response/Resolution to Problems
  - Staff Expertise

- **Opportunities for improvement (OFI's)**
  - Communication
  - Education
  - Timeliness for review of minimal risk studies

- **2016 Strategies**
  - Continue development of educational offerings and investigator guidances
  - Monitor review times for expedited/exempt review
  - Random monthly surveys
Study Spotlight

Clinical Excellence and Research
Sandra Galura
Nurse Research Residency Program
Clinical Excellence and Research

Nurse Research Residency Program

Sandra Galura PhD, RN
Nurse Research Residency

**Purpose:** To support clinical nurses and facilitate the development and implementation of nursing research that aligns with Florida Hospital’s Strategic Innovation Agenda.

**Objectives:** Upon completion of Nursing Research Residency Program, residents will:

1. Develop skills necessary for clinically relevant research project.
2. Identify and utilize Florida Hospital research support services.
3. Integrate the research process into clinical nursing practice.
4. Disseminate research findings internally & externally to professional organizations.
Integration of Data to Establish a Standard Operating Procedure for the Diabetic Patient Undergoing Hyperbaric Oxygen Therapy

Katherine George RN, BSN, CHRN, CWS
Hyperbaric oxygen therapy:

- Adjunct clinical therapy used to treat multiple medical conditions including diabetic foot infections and wounds
- Patient placed in a full body pressurized chamber
- Atmospheric pressure > 1.5 to 3 times normal
- Patient breathes 100% oxygen
  - Normally we breathe ~21% @ sea level
- Benefit: increases oxygen available to tissues for healing
Problem

- No HBO Standard Operating Procedure for diabetic population
- Safe minimal BGL pre-HBO $\geq 100$ mg/dL
- HBO glycemic management, no standard protocol
- HBO nutritional options, not standardized
- Risk of seizures
- Risk of operational delays
- Documentation in electronic health record, inconsistent
Background/Scientific Rationale

Glycemic Physiology

- Hyperbaric environment reduces blood glucose levels (BGL) in all patients undergoing HBO therapy
- Hypoglycemia increases the risk of oxygen induced seizures associated with HBO therapy
- Problem is exacerbated in the diabetic patient
Objectives & Research Design

• Objectives
  – Determine impact of blood glucose
    • Seizure events
    • Nutritional interventions
    • Operational delays

• Research Design
  – Retrospective, descriptive review
    • Electronic health records
    • Department logs
    • January 1-May 31, 2015
Population/Sample

• Population/Sample
  – All diabetic patients undergoing HBOT
  – Convenience sample
  – 100 patients
  – 1175 dives

• Inclusion
  – Admitted between January 1, 2015 and May 31, 2015
  – Age, all inclusive
  – Gender, all inclusive

• Exclusion
  – Did not receive HBOT
Blood Glucose Levels

Pre-HBO

- N=1175 dives
- Range = 53 - 439
- Mean = 178
- ≤100 = 43

Post-HBO

- N=1162 dives*
- Range= 56 - 414
- Mean= 165
- ≤100 = 91

* No BGL documentation = 13
Interventions BGL $\leq 100$ mg/dL

Comparison of Means Pre-Post

$4=\text{Combination of food & hypoglycemic med kept patients most stable, without decline of BGL}$
HBO Practice Change Study Recommendations

- Utilize Florida Hospital Hypoglycemic Protocol BGL $\leq 120$ mg/dL
- Employ American Diabetic Association snack options post medication
- Eliminate routine use of fruit juices as snack during HBO therapy
- Ensure HBO documentation of interventions in the EHR
Post Study/Current State

- Increased minimal BGL from 100 mg/dL to ≤120 mg/dL
- Drafted HBO Standard Operating Procedure specific to diabetic population
- Modified HBO power plan to include a standard meal time (not concierge)
- Added Glycemic Management Intervention tab to HBO Procedure Form
- Linked HBO documentation to Glycemic Management in I-net
- Process improvement for documentation in Electronic Health Record, ongoing
HBO pilot approved by Nursing Pharmacy Committee 01/14/16; potential to be extended to other procedural areas
Acknowledgements

• Glycemic Management Program
  – Mary Gaines, Director
  – Damon Tanton MD

• Hyperbaric Medicine and Wound Care Center
  – Maria Dominico BSN, RN, CWCN, CHRN
  – Robin Ortega MS, RN, CWCN, CHRN, Nurse Manager

• Office of Research Administration
  – Julie Pepe PhD

• Clinical Excellence and Research
  – Sandra Galura PhD, RN, CPAN
  – Dianne Ross PhD, RN
  – Lynn Rowe PhD, RN
  – Hong Tao PhD, RN
References


Florida Hospital (2014). *Glycemic management plans*. Orlando, FL. Florida Hospital System.


References


Thank you

Katherine George BSN, RN CHRN, CWS
Hyperbaric Medicine and Wound Care Center

2015 Nurse Research Residency
Clinical Excellence and Research

FH.Nursing.Research@flhosp.org
COI UPDATES

1. Updated P&P and SOP
2. SFIs: Helpful Hints…
3. Training Requirements
Can be found on SharePoint

UPDATED COI P&P AND SOP
How is it determined if a management plan is necessary?

- The SFI-related entity is the sponsor of a research study.
- The SFI-related entity provides funding for a research study.
- The SFI-related entity manufactures, makes, or provides an article, device, drug, or service being evaluated or used in a research study.
CHANGES IN CONFLICT OF INTEREST TRAINING

EFFECTIVE JULY 1, 2016.

This affects all researchers including your investigators!
COI training certification is good for 4 years.

- If you completed your training in 2012, you will need to renew!

Effective July 1, 2016, the COI training requirement will be met by completing the COI Refresher module through CITI Training.

- This will take approximately 40 minutes.
- After completion, you will scan your completion record to the ORA mailbox at FH.Research.Administration@flhosp.org.

Attendance at an ORA training will satisfy your COI training requirement for the next 4 years.

- Sessions will be offered in April, May, and June of this year.
- These sessions will run approximately 15 minutes.

ORA can also provide a session in your department if there will be a minimum of 10 people in attendance.

COI training must be current for all study team members on a project.

- If it is not, the study must be placed on Administrative Hold.
INVESTIGATIONAL DRUG SERVICES

- Jeff Carrico, Pharm. D., B.C.P.S.
  - Directory of Pharmacy
QUESTIONS/COMMENTS?

THANK YOU FOR YOUR ATTENDANCE AT RESEARCH MATTERS!