“The new year will be like the old one if you keep on doing the same old things.”

unknown
A Word From Our Chief Scientific Officer

Steven Smith, MD – Chief Scientific Officer, SVP
IRB Items

• Moving Forward –
  • IRB Fees
  • Steps toward Accreditation through AAHRPP

• Reportable New Information Form

• Confirm Credentials prior to IRB submission
Steps towards Accreditation

AAHRPP (Association for the Accreditation of Human Research Protection Programs)

The Human Research Protection Program (HRPP) is a shared enterprise and responsibility. The HRPP succeeds when all individuals in the organization including key committees, leadership, clinicians, staff and students fulfill their roles and responsibilities described in this plan.

Stay Tuned……
Reportable New Information Form

• Great results with the new form!

• Form will remain as is as we move forward with accreditation.
**Confirm Credentials prior to IRB Submission**

*Why is this important?*

Incomplete requirements have a **significant** impact on IRB processing and approval.

<table>
<thead>
<tr>
<th>Type</th>
<th>Submission Date</th>
<th>Ready for approval</th>
<th>Current status 1/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>New study - Expediteable</td>
<td>9/18/13</td>
<td>11/5/13</td>
<td>Pending – incomplete requirements</td>
</tr>
<tr>
<td>Change Request - Revision to add personnel</td>
<td>11/14/13</td>
<td>11/14/13</td>
<td>Pending – incomplete requirements</td>
</tr>
</tbody>
</table>
Before submission of a New Study or Change Request to add research personnel:

1. Provide IRBNet access to personnel
2. Confirm personnel have completed requirements
How do I confirm another person’s requirements are complete?

- **Before** you submit a package, click on Link/Un-Link Training Records
- Find the team member and check that CITI Basic, HIPS, & GCP courses and their CV have been Accepted
  - In order to find the team member in this list, he/she must have IRBNet access to the study.
Radiology Pricefile
Students Conducting Research at Florida Hospital

Student enrolled in a university or college

STUDENT:
Research participation as part of a course/degree requirement

VOLUNTEER:
Research participation in order to gain research experience only
(Please see ORA Guidance Doc for Volunteers on ORA website)
If FH Employee is a Student...

- FH Employees who are students can conduct research ONLY if there is a research agreement on file with the employee’s educational institution.
- If the student is a FH employee, s/he may serve as the PI of a research project with the condition that at least one other FH employee must be on the research project team.
- Contact the ORA with questions....
- [https://drupal02.floridahospital.org/researchadmin/content/guidance-documents](https://drupal02.floridahospital.org/researchadmin/content/guidance-documents)
Our Purpose

• To establish a program of clinical excellence in Surgical Oncology at Florida Hospital

• To develop a referring center for patients with complex GI malignancies
Florida Hospital Orlando
Surgical Oncology Team

J. Pablo Arnoletti, MD
Sebastian de la Fuente, MD
Mission

• Clinical excellence
• Research
• Education: students, residents, fellows
• Community programs
• International referral program
Research Mission

• Generation of knowledge
• Formulation of hypothesis
• Biorepository
• Translational research
• Clinical Trials
• Publish results
Ongoing research projects

1. Retrospective Review of Post-operative Analgesia in Patients undergoing Pancreatic Resection
2. Transversus Abdominis Regional Plane Blocks for Postoperative Analgesia following Pancreatic Resections
3. Implementation of Fundamentals of Laparoscopic Surgery in Costa Rica
4. General surgery resident participation in complex pancreatic procedures
5. Regionalization of hepato-pancreato-biliary cancer treatments within the state of Florida according to the American College of Surgeons Commission on Cancer Accreditation
6. Tumor stage at presentation and access to surgery is not influenced by race in pancreatic cancer patients
7. Hospital Readmissions Rates Following Open and Laparoscopic Cholecystectomy
8. Prospective Studies Using Peri-Ampullar and Pancreatic Tumor Tissues
9. Validation of Robotic Surgery Simulator Training for Abdominal Surgery
10. Pancreatoscopy for identification of intra-pancreatic lesions during surgery
11. Assessing Implications in Regionalization of Complex Cancer Care in Distances Patients Travel
12. Patient Perspective on Pancreatic Surgery Complications and Outcomes
13. Regionalization of Pancreatic Cancer Treatment Within the State of Florida
14. Postoperative imaging following pancreatic resection
15. Gait Speed as an Incremental Predictor of Mortality and Major Morbidity in Elderly Versus a Younger Cohort of Patients Undergoing Pancreatic Surgery
Collaboration with other investigators

• Prospective Studies Using Gastrointestinal, Liver, and Colorectal Tumor Tissues – Atallah

• Registry for Endoscopic Procedure Outcomes – Varadarajulu

• Peripheral Blood K-Ras Analysis as a Molecular Biomarker of Cancer Risk and Relapse – Chang

• FHCI-TR Study: Improving Hispanic Clinical Outcomes - Equal Access & Identifying Treatment Disparities – Decker

• FHCI-TR Study: Tissue Array Development- Cancer Biomarker Studies – Litherland
Presentations at national meetings

Completed projects

1. Rectal Cancer Course of Treatment using the American College of Surgeons National Cancer Data Base (NCDB) – Presented AHPBA 2012

1. Evolution of laparoscopic Colectomies Over Time using the National Inpatient Sample Registry – Presented SAGES 2012

1. Discharge Patterns of Patients that Underwent Esophagogastrectomy using the National Inpatient Sample Registry – Presented SSO 2012

2. Incidence of Pancreatic Cystic Lesions over Time using the National Inpatient Sample Registry – Presented AHPBA 2012


Publications in peer-reviewed journals

Completed projects


Degrees/Certifications

- Sue Nelson (Orthopaedic Research) received her BSN in December
- Kelly Behm (CV Research) completed her Ph.D. in nursing with specialized training in genetics
  - Dissertation studied transitional experiences in individuals with Turner’s Syndrome

Department Kudos

- NSI and CVI – recognized for going above and beyond enrollment expectation in December 2013 by “Sapphire – a Carotid Stenting Post-Marketing Trial”
- Cardiovascular Research - 2nd national lead enroller in an Aortic Valve study with a total of 51 patients enrolled.
  - Kudos to Dr. Accola, Beverly Mansker, and Tracey Purvis
Acknowledgements

Papers accepted/Published
• John Francis and international collaborators had paper accepted to *Cancer Research*
• “An antibody-drug conjugate that targets tissue factor exhibits potent therapeutic activity against a broad range of solid tumors”

Patents
• Rick Moro has patent filing for a new method of assessing diastolic function called
• “The Moro Index”

Research Day
• Participants & Attendees
• Jeffrey Chui, winner of Poster Presentation
ORA Reminders/Announcements

• Please submit COI documents and other ORA documents to our department mailbox at FH.Research.Administration@flhosp.org

• A schedule of all classes offered by the ORA is available on the ORA website under the calendar tab.
Questions/Comments?

Thank you for your attendance at Research Matters!