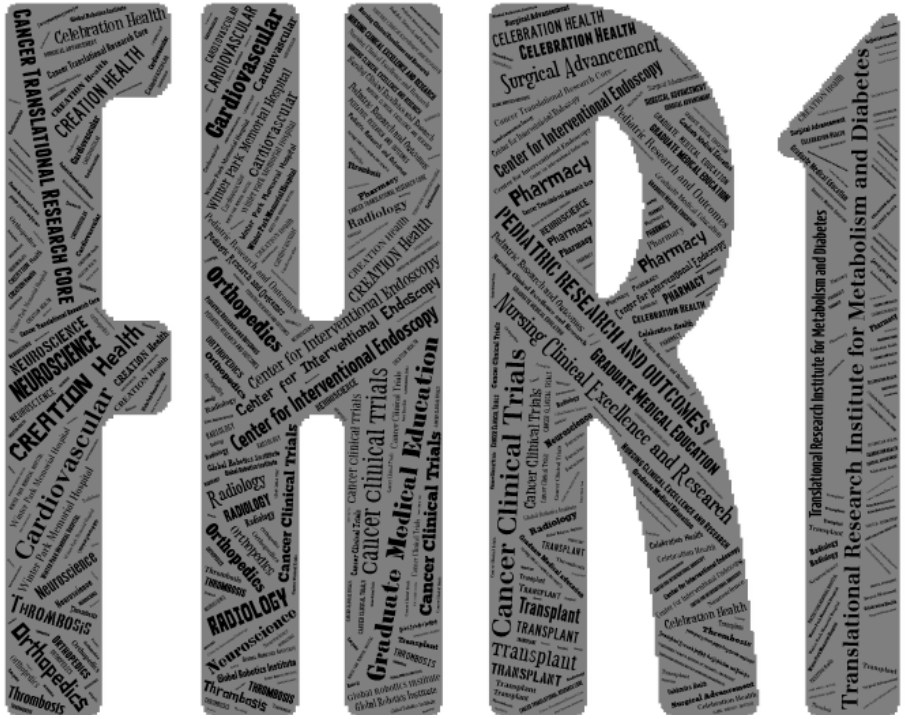


Research Matters

September 25, 2017

Welcome

Rob Herzog, VP Research Operations

Devotion

Pam Jennelle, MS, CAHIMS

Center for CREATION Health Research

Project Manager

Finding Meaning and Thriving at Work

2 out of 3 U.S. workers are bored, detached or jaded at work

We cannot let this be true with the important work of our mission.

Happiness Traps: How We Sabotage Ourselves at Work

MCKee, Annie (2017). Harvard Business Review.

- Ambition – winning at all costs
  - Negatively affects colleagues to be in competition with you
- Doing what is expected instead of what you want
  - Hiding who you are and what is important to you in order to ”fit in”
  - Be in the right setting for YOU
- Overwork
  - Stress and fatigue affect people skills, creativity, and cognitive speed
- Some research-based solutions:
  - Meaningful work, enduring hope, workplace friendships

ACRP Local Chapter Update

Sue Nelson, Ortho
Jessica Hyacinthe, OSP
Carole Coyne, Radiology

The mission of the Central Florida Chapter shall be to provide a readily accessible mechanism for regional program development for clinical research professionals to foster professional interaction, continuing education, problem-solving, and discussion of professional issues as a chapter of the Association of Clinical Research Professionals.

Chapter Events

May 25, 2017

Webinar Replay: “How Does the Recent ICH-GCP E6 Update Affect You”

August 24, 2017

Webinar Replay: “Medicare Coverage Analysis for Clinical Research”

September 29, 2017

Item Writer Training

October 26, 2017

Professional Development Event

November TBA

Career Development speaker

December TBA

Open Member Meeting and Holiday Party

Spring 2018

ACRP Certification Exam Prep Class and/or Study Groups

COME JOIN US TO MAKE THIS CHAPTER A SUCCESS WHILE PROMOTING THE RESEARCH PROFESSION!!!

September 29th

Item Writer Training

The North Central Florida (NCFL) and Central Florida (CFL) ACRP Chapters presents the upcoming

Item Writing Training

What is an item writer?

A trained, currently certified clinical research associate or coordinator, or principal investigator (CCRA, CCRC, or CPI), content expert writing items for one of the four Academy Certification exams (CCRA, CCRC, CPI, and CP).

What are the requirements to be an item writer?

- ⇒ Hold current ACRP Certification (CCRC, CCRA, CPI)
- ⇒ Be familiar with ICH / GCP Guidelines and the Declaration of Helsinki
- ⇒ Attend in-person Item Writing training
- ⇒ Participate in three (3) writing assignments each year.
- ⇒ Follow the Item Writing Guidelines provided in the *Item Writing Guide*
- ⇒ Complete each assignment by the stated deadline.
- ⇒ Maintain confidentiality of draft items and test development materials.
- ⇒ Agree to refrain from participating in any training designed to prepare candidates for certification during service as an Item Writer (plus 2 years after).

Friday, September 29, 2017

8:30 AM—Registration
9:00 AM—Training Session 1
12:00 PM—Lunch
1:00 PM—Training Session 2
3:00 PM—Closing remarks

UF Research and Academic Center at Lake Nona
6550 Sanger Road, Orlando, Florida 32827

ACRP CHAPTER EXCELLENCE AWARD WINNER ACRP

For more information, please contact Alie Trainor (President, NCFL Chapter): awickham@ufl.edu

To register online, please visit: Item Writer Training Event Registration Page

October 26th – Professional Development Speaker

"Lead and Succeed in Your Clinical Research Team"

(Presented at the 2017 ACRP Annual Meeting and Expo)

- OBJECTIVES:
  - Identify the leadership behaviors and characteristics needed in your clinical research team and build a personal plan to cultivate your leadership qualities.
  - Open up new opportunities for yourself as you explore the elements of your personal style and leadership presence.
- SPEAKER: Hilary Anne Smallwood
- LOCATION: Ramada Kissimmee Gateway

Event details will be emailed in September. Registration will be available online.

Central Florida Chapter of ACRP

CONTACT US:

- Website: http://community.acrpnet.org/communities/community-home?CommunityKey=440ceeea-04f0-4517-a56f-e3a45a35decd
- Email: CFLACRP@gmail.com

2017 CENTRAL FL CHAPTER LEADERSHIP

• Membership Committee Chair	Jessica Hyacinthe
• Event Committee Chair	Carole Coyne
• Treasurer	Charmaine Garcia
• Secretary	Susan Nelson
• Vice President	Kristan Anderson
• President	N'Diris SAM Barry

Thank you for supporting your local ACRP chapter!

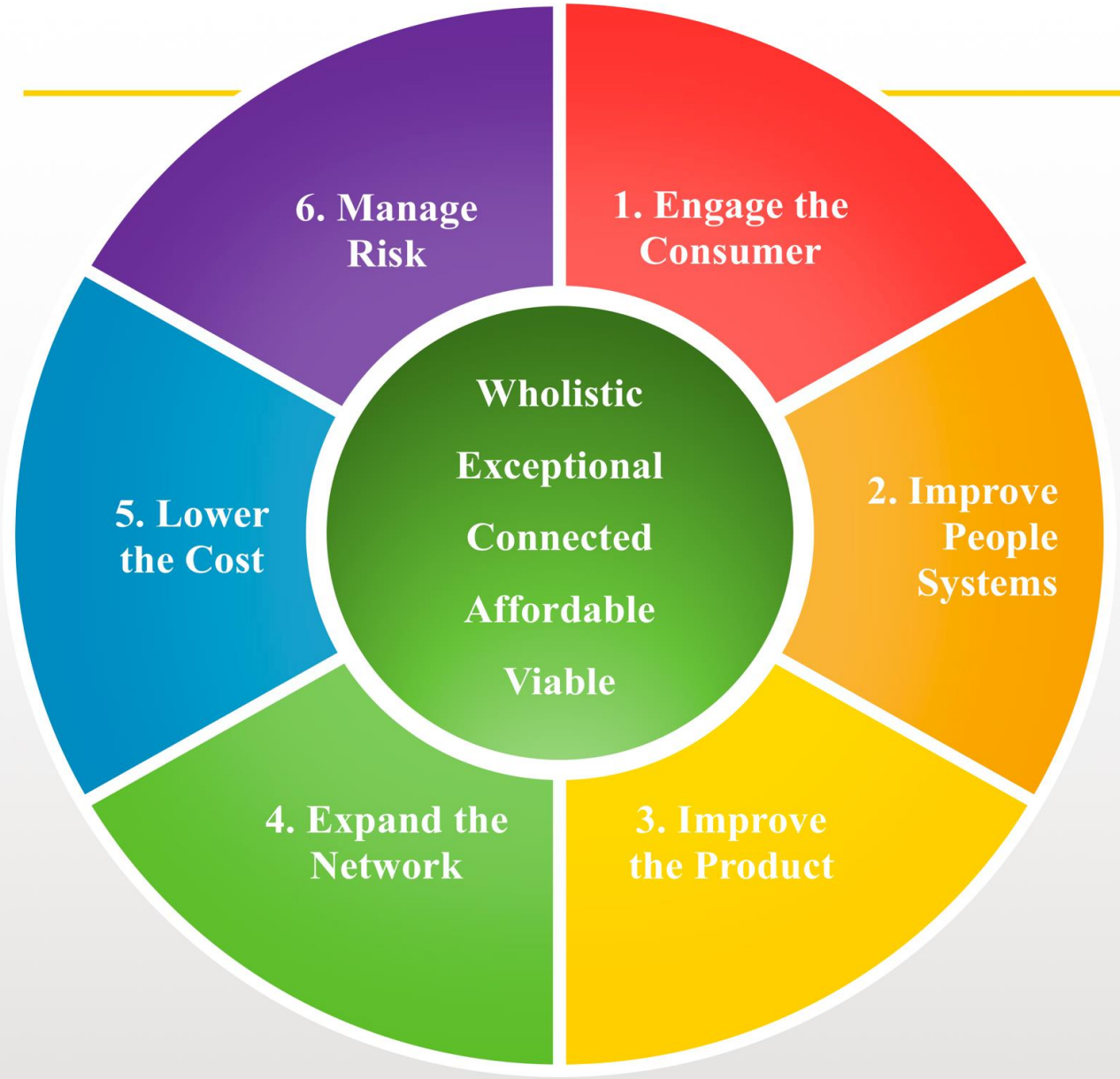
Leadership Message

Rob Herzog

Vice President Research Operations

Leadership Message

Strategic Imperatives



WORLD | ASIA | CHINA

Made-to-Order Medicine: China, U.S. Race to Decode Your Genes

Beijing's giant data-collection effort will help it set the stage for targeted medical treatments

Leadership Message

August 2017

FLORIDA HOSPITAL RESEARCH INSTITUTE BRANDING

Arden Piazza
Marketing

FLORIDA HOSPITAL

NEXT STEPS

- Website
- Photo Shoot
- ‘Why Participate’ Video
- Sales Collateral

About Us

Center for Thrombosis Research

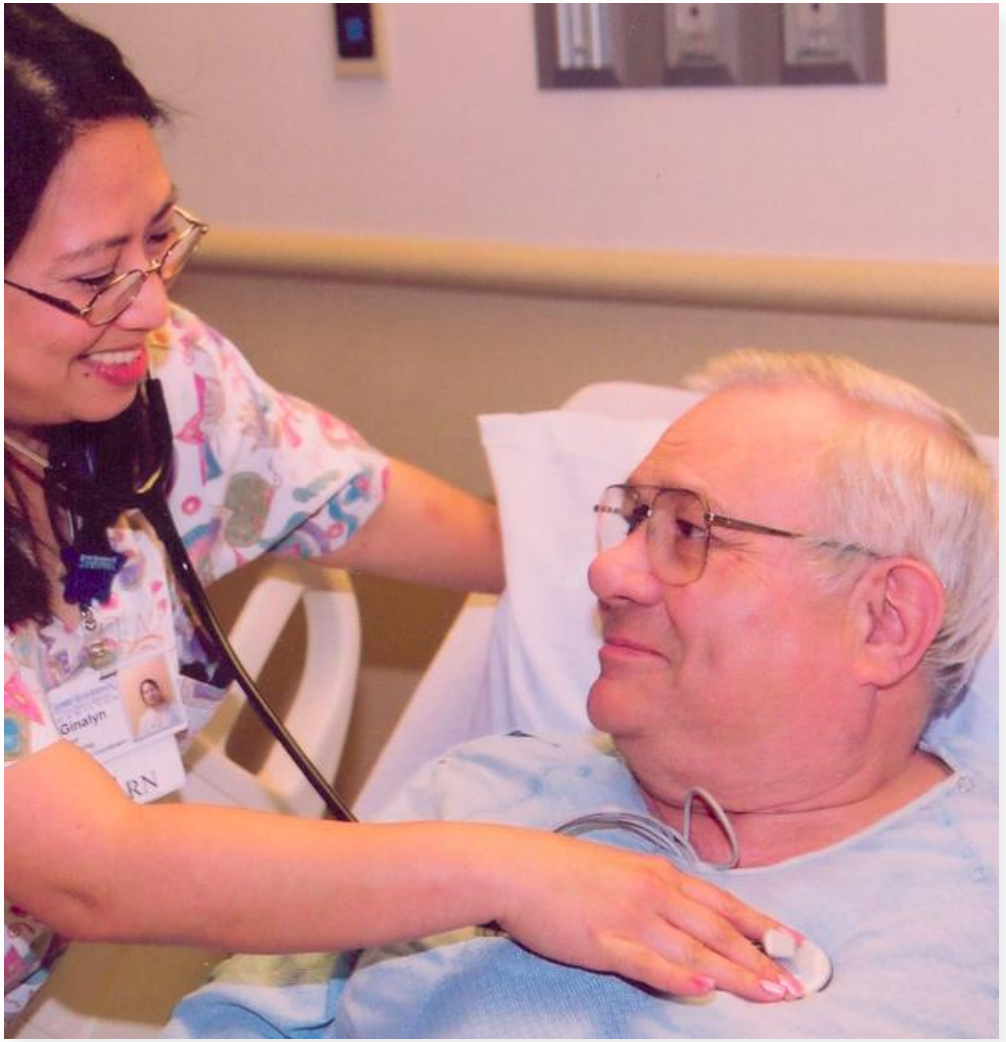
John Francis, Ph.D.

Mission

To provide high quality clinical laboratory testing for the patients and physicians of Florida Hospital and beyond; and to undertake research that is clinically focused, ethically appropriate and fiscally responsible

Why Focus on Thrombosis?

- Biggest single cause of death in the western world (MI, stroke, pulmonary embolism)
- Involved in many other diseases – cancer, heart disease, lupus, infertility, inflammation, obesity and pregnancy loss
- Need for new anticoagulant drugs and risk assessment
- Often **preventable**



About Us

- Integrated clinical and research laboratories
- Busiest specialty coagulation lab in southeastern US – 50,000 tests annually
- Variety of investigator-initiated clinical and translational research
- Strong contract research base

Contract Research

Clinical Laboratory

- Reagent & Equipment evaluation - FDA 510(k)
- Post-marketing studies
- Clinical trials core lab services

Research Laboratory

- Effects of drugs on platelet function
- Therapeutic antibody safety testing (laboratory and animal models)
- Method and protocol development

Main Areas of Current Research

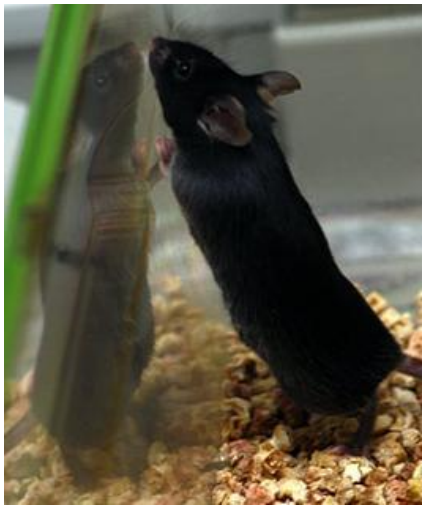
- Platelet activation by IgG antibodies in autoimmune diseases and immunotherapy
- Role of the IgG receptor in inflammation and thrombosis in autoimmune diseases
- Role of platelets in the regulation of adaptive immunity
- Platelet IgG receptor as a therapeutic target

Platelet Activation by Therapeutic and Autoimmune IgG Antibodies

- Some therapeutic monoclonal antibodies are associated with thrombosis
- Mechanism of thrombosis was unknown
- We showed that – in the test tube – some antibodies can activate blood platelets via their IgG receptors
- This side effect was not apparent in pre-clinical studies
- Mice do NOT have the platelet IgG receptor (FcγRIIa)
- Solution – use a mouse which carries the human IgG receptor gene (transgenic mouse)

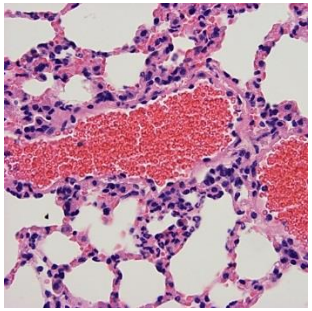
‘Thrombotic’ Therapeutic Antibodies in Mice Transgenic for the IgG Receptor

Wild type mice

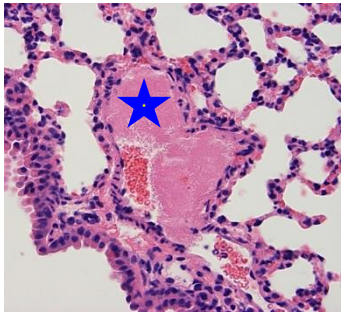


Anti-CD40L
Anti-VEGF
(Avastin)

Transgenic mice



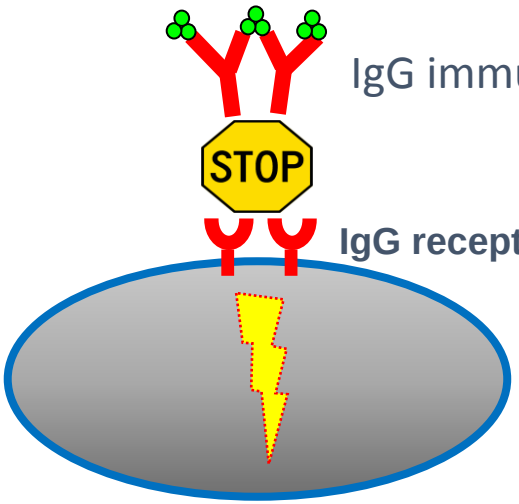
No thrombosis (open vessels)



Thrombosis (occluded vessels)

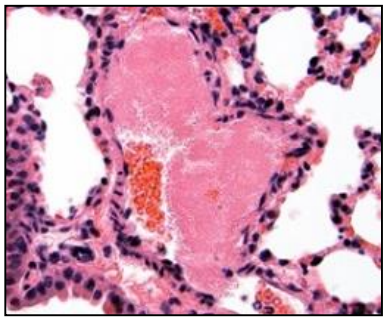
Multiple new studies, research contracts, publications

Development of Novel Therapy Based on Platelet IgG Receptor Blockade



IgG immune complex

IgG receptor



Thrombus formation

Anti-Platelet Drugs

Aspirin
Integrillin
Plavix

Anticoagulant Drugs

Heparin
Coumadin
Bivalirudin

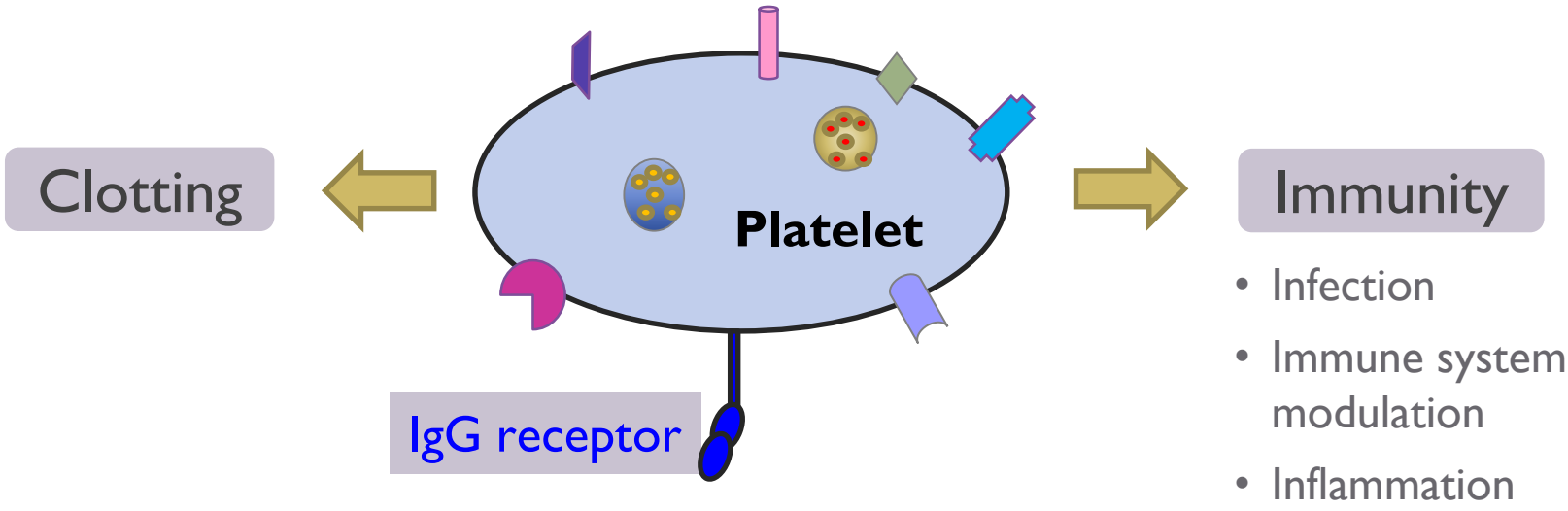
Activated platelet

Clotting Activation

Summary of Results

- We have engineered monoclonal antibodies that:
  - Potently block the IgG receptor (CD32a)
  - Safe – no adverse reactions in transgenic mice
  - Efficacious – more potently protect against thrombosis than any anti-platelet or anticoagulant agent tested
  - Broad clinical potential – may have utility in a variety of pathological conditions (e.g., HIT, SLE, ITP, arthritis)
  - US Patent awarded 2016
  - Now focusing on demonstrating clinical utility

Immune Thrombocytopenia (ITP): A model to study interplay between coagulation and inflammation in autoimmune disease



- Establish mouse model that better reflects human ITP
- Study role of antibody receptors in ITP
- Test our anti-CD32a antibodies as possible therapy

Summary of Results

ITP-inducing antibodies

All mouse Fcγ

- Low platelet counts
- **No** platelet activation
- **No** inflammation

Human FcγRIIA

All human Fcγ

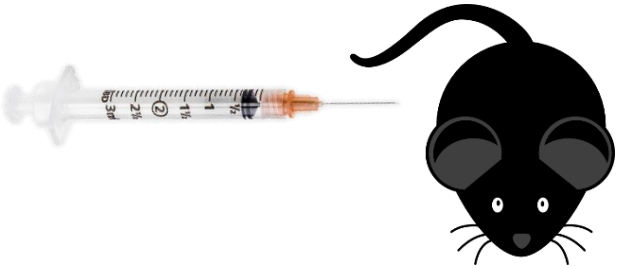
- Low platelet counts
- **Platelet activation**
- **Inflammation**

Our model of ITP appears to better reflect the human disease

Role of Human Fcγ Receptors in a Mouse Model of Lupus

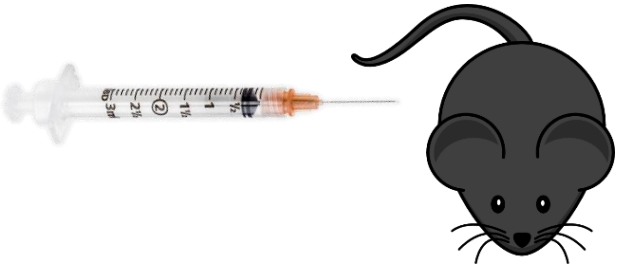
- Develop a model of Lupus in FcγR (transgenic) mice
- Determine the role of FcγR and platelets in the development of Lupus
- Explore FcγRs as therapeutic targets

Summary of Results



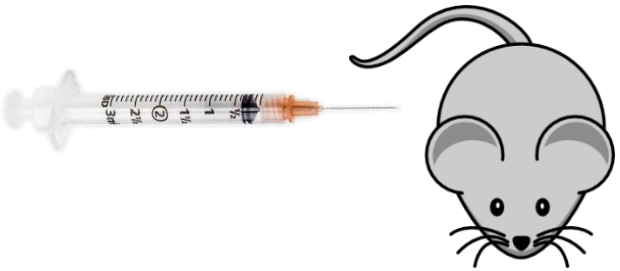
ALL MOUSE

- Animals are mostly **asymptomatic**
- Development of autoantibodies
- Normal spleen
- Glomerulonephritis 3 to 6 months



PARTLY HUMAN

- Animals are mostly **asymptomatic**
- Development of autoantibodies
- Splenomegaly
- Glomerulonephritis (?)



ALL HUMAN

- **Symptomatic - 10 days**
- Development of autoantibodies
- Splenomegaly
- Widespread lung vasculitis

Mechanism of Thrombosis in Patients with Antiphospholipid Syndrome

- To test the hypothesis that platelet activation in APS is at least partially dependent on the IgG receptor
- To correlate IgG receptor-dependent platelet activation with clinical thrombosis
- To examine new opportunities for thrombosis risk assessment and therapy

Summary of Results

Anti-phospholipid antibodies strongly activated platelets via their IgG receptors in the test tube

TRANSGENIC MOUSE

Thrombosis

NORMAL MOUSE

No symptoms

Platelets and Regulation of Immunity: Role of G6f in Platelet Function

- Platelets contain many proteins that have non-clotting functions

- Newly identified platelet protein, G6f:
  - ✓Possible novel role in platelet clotting function
  - ✓Possible role in immune modulation via platelets
  - ✓Potential anti-platelet and/or anti-inflammatory targets

Improving the Diagnosis & Management of Heparin-Induced Thrombocytopenia (HIT) with a new "Immuno-Functional" Assay

Problem	Objective
HIT tests currently 'batched' daily with a turnaround time of 8-30 hours	"On-demand" during open hours – reduce time-to-result
Current test has too many "weak positive" results with uncertain clinical significance	Eliminate false positive results
Test results are being 'confirmed' by sendout SRA test (~90% are negative)	Reduce SRA tests by ~80%
Many patients receive anticoagulant therapy while waiting for SRA result	Eliminate unnecessary (and expensive) anticoagulant therapy

21 patients recruited to date

Summary

- Clear and broad clinical significance for all projects
- Current focus on role of platelets in inflammation and immunity, drug safety, and development of novel diagnostics and therapies
- Significant impact on immunotherapy development
- Steady clinical and contract revenue streams
- Strong academic performance over 20 years (~120 papers, 450+ presentations)

Research Services Updates

- OSP – Regina Tan
  - Clinical Trial Amendments – Michelle Kilponen
  - Grant Submissions – Leerin Shields
  - CTMS Implementation – Regina Tan
  - OSP Website – Regina Tan
- ORI – Christina Jackson
  - Introduction of new ORI Team Member
  - Research Billing Compliance
  - Research Oversight Committee
  - ClinicalTrials.gov
  - Research Investigator Forum
- IRB – Janice Turchin
  - Common Rule Update
- RAS – Michelle Dolske
  - Research Classes

Office of Sponsored Programs

- Clinical Trial Amendments
- Grant Submissions
- CTMS Implementation
- OSP Intranet Website

OSP: Clinical Trial Amendments

Clinical Trial Amendments

- In an effort to ensure that the **administrative**, **financial**, **contractual**, and **compliance** requirements are evaluated and updated as necessary for any changes or amendments to an existing and approved study, the Office of Sponsored Programs will incorporate a **BUDGET AMENDMENT REVIEW** in its current process.

Effective Date: November 1, 2017

OSP: Clinical Trial Amendments

DEPARTMENT RESPONSIBILITIES	OSP RESPONSIBILITIES	
PRIOR to accepting budget changes from the Sponsor: 1. Submit new amendment request by uploading the following documents in the appropriate system[1]. ▪ Revised Protocol ▪ Revised Consent ▪ Revised Contract and Sponsor's budget ▪ New/Updated Physician Payment Letters 2. Submit previously approved internal budget with required changes and notify OSP of the request with a **detailed** summary of changes via email[2]. 3. Inform OSP if changes affect physician payments. 3. Upon notification of internal budget amendment approval, Department either accepts or negotiates Sponsor's budget. 4. Email[2] FINAL Sponsor Budget Amendment to OSP. 5. Notify applicable parties of any changed related to clinical billing (e.g. PFS, FHMG, Fri, etc.) 6. Notify Research Finance of any applicable changes to sponsor invoicing or revenue accruals.	OSP Clinical Trial[3] Team	1. Review the new amendment request. 2. If available, update billing grids or coverage analyses, as necessary. 3. Approve amendment to Internal budget. 4. If applicable, create new or revise existing Schedule As for execution. Send to Department once fully executed. 5. If applicable, execute contract amendment. 6. Upload revised documents in the appropriate system[1].
	OSP CTMS Builder	1. Review the new amendment request. 2. Update CTMS Study Build as necessary. This includes, but not limited to: ▪ Creating new protocol version ▪ Add Visits and/or Elements ▪ Update to physician payments within the system ▪ Adding new consent version

1 If CTMS has **not** been implemented in your department, upload new amendment request documents in IRBNet; otherwise, upload new amendment request documents in Clinical Conductor.

[1] If CTMS has **not** been implemented in your department, notification should be sent to FH.OSP@FLHosp.org; otherwise, notification should be sent to FH.OSP@FLHosp.org and to the primary and backup CTMS Study Builders assigned to your department. OSP is currently optimizing the notification features within Clinical Conductor. Until this function is optimized and workflow is finalized, an email notification is necessary.

[3] If Study is funded under a Grant, amendment requests will be processed by the Grants Team.

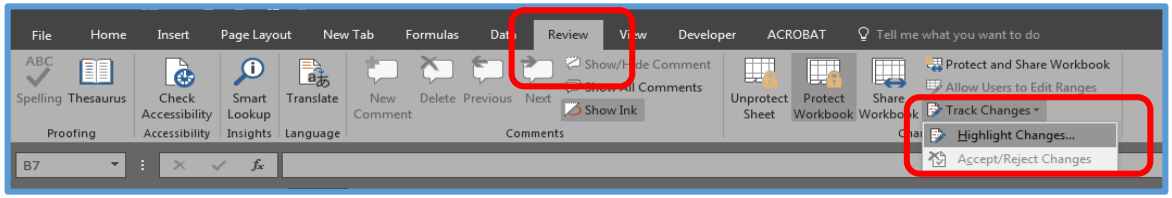
Version 09.25.17

OSP: Clinical Trial Amendments

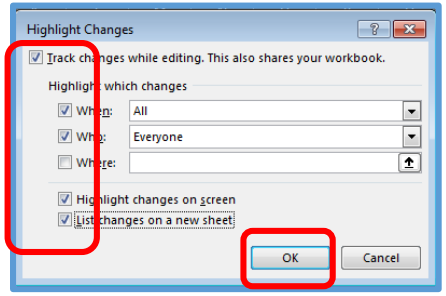
TO UPDATE THE OSP APPROVED INTERNAL BUDGET

****Please remember to use the **most current OSP-approved internal budget**. Please contact OSP if you need a copy of the unredacted version.*

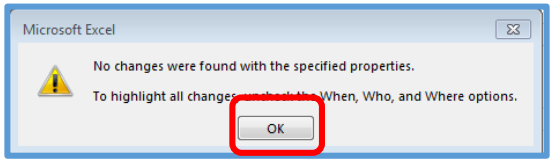
1. In the Review Tab, click Track Changes → Highlight Changes.



2. The Highlight Changes box will pop-up. Check the boxes as shown below. Click OK



3. Click OK.

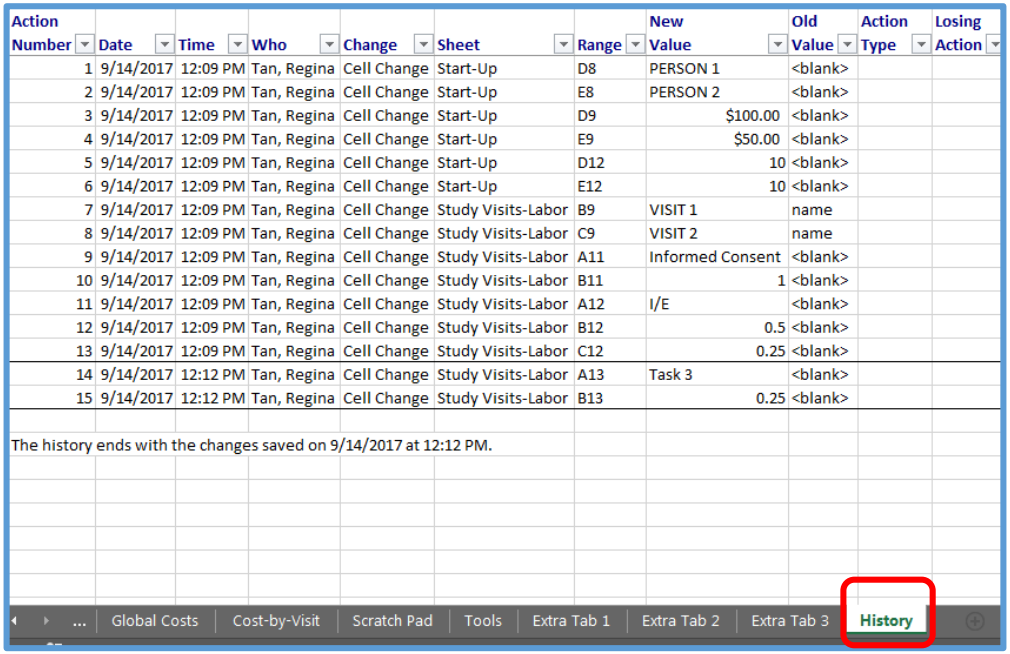


OSP: Clinical Trial Amendments

TO UPDATE THE OSP APPROVED INTERNAL BUDGET

****Please remember to use the **most current OSP-approved internal budget**. Please contact OSP if you need a copy of the unredacted version.*

4. Make the necessary changes. Save.
5. Go back to Review Tab → Track Changes → Highlight Changes. Check box for List changes on a new sheet. Click OK. A History Tab should be generated to list ALL changes made.



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2	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Start-Up	E8	PERSON 2	<blank>		
3	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Start-Up	D9	$100.00	<blank>		
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5	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Start-Up	D12	10	<blank>		
6	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Start-Up	E12	10	<blank>		
7	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Study Visits-Labor	B9	VISIT 1	name		
8	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Study Visits-Labor	C9	VISIT 2	name		
9	9/14/2017	12:09 PM	Tan, Regina	Cell Change	Study Visits-Labor	A11	Informed Consent	<blank>		
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The history ends with the changes saved on 9/14/2017 at 12:12 PM.

... | Global Costs | Cost-by-Visit | Scratch Pad | Tools | Extra Tab 1 | Extra Tab 2 | Extra Tab 3 | History

OSP: Clinical Trial Amendments

- **Question 1:** Why is this additional budget amendment review being implemented?

- **Answer 1:** Similar to new budget review, the additional budget amendment review process I being implemented in order to ensure that the administrative, financial, contractual, and compliance requirements are addressed.

OSP: Clinical Trial Amendments

- **Question 2:** What will be the turnaround of budget amendment review?

- **Answer 2:** On average, a new/full budget is reviewed and sent back to the department contact in less than five business days. OSP will only review changes to the previously approved budget. As such, this will be an abbreviated review and on average, should be reviewed and sent back to the department contact within two business days.

OSP: Clinical Trial Amendments

- **Question 3:** How will this additional budget amendment review affect my study execution timeline?

- **Answer 3:** As a reminder, studies requiring budget amendments are current and active studies that have already received institutional clearances. The additional budget amendment review should have very little to no effect on your study execution timeline. Changes to the budget typically issue out from sponsor-initiated protocol amendments.

OSP: Clinical Trial Amendments

- **Question 4:** I already submitted the request in IRBNet/Clinical Conductor. Why do I need to send another email to notify OSP?

- **Answer 4:** An email notification to OSP is necessary to submit the modification to the internal budget. This document is not uploaded in IRBNet due to the confidential information (e.g. salary rates) contained in this document. The internal budget may be uploaded in Clinical Conductor Enterprise (CCE) as an unshared study document. However, the notification features of Clinical Conductor is still being optimized.

OSP: Grant Submissions

Grant Submissions

1. Grant.gov WORKSPACE and NIH ASSIST
2. New FORMS-E application packages
3. NIH Clinical Trial application

OSP: Grant Submissions

Grants.gov WORKSPACE and NIH Assist

- Grants.gov is retiring its legacy PDF application package on December 31, 2017
  - Applicants will no longer be able to download the older, single PDF application package
  - For any funding opportunities where applicants have downloaded the legacy PDF application package, they will be able to continue to submit that package until March 31, 2018
- eSubmission Options
  - Grant.gov workspace
  - NIH Assist
- Five business day internal deadline
  - With the new eSubmission system requirements, your cooperation and adherence to the internal deadline is important to ensure successful submission

OSP: Grant Submissions

New FORMS-E application package

- Applicants must use FORMS-E application packages for due dates on or after January 25, 2018
- **Focus of changes:**
  - Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms.
  - Expansion and use of discrete form fields for clinical trial information to:
    - Provide the level of information needed for peer review
    - Lead applicants through clinical trial information collection requirements
    - Present key information to reviewers and agency staff in a consistent format, and…
    - Align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
  - Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

OSP: Grant Submissions

NIH Clinical Trial Applications

- Per NOT-OD-16-147, NIH will require that all applications with receipt dates on or after September 27, 2017 with plans to conduct clinical trials must be submitted in response to a clinical trial-specific Funding Opportunity Announcement
  - NIH will no longer accept clinical trial applications through “parent” FOAs or through other FOAs that are not specifically designed to accept clinical trials

OSP: CTMS

CTMS implementation

- CTMS LIVE Departments:
  - Cardiovascular Research
  - Neuroscience Research
  - Children's and Women's Research **(September 26, 2017)**
- OSP will work with FHRI Leadership to determine the next department(s) for implementation

OSP: Website

https://drupal02.floridahospital.org/researchadmin/

- OSP is in the process of updating our website to better serve those who visit
- If you are unable to locate the information you need, please contact FH.OSP@flhosp.org

Institutional Review Board (IRB) Update

Janice Turchin

- Revised Common Rule

Revised Common Rule Discussion

What can you expect?

What we're working on.

Keep in mind:

FDA Regulations still apply

Revised Common Rule Discussion

- Changes to informed consent/process.
- Changes in yearly reporting.
- Changes in levels of review.
- Single IRB Review

Keep in mind:

FDA Regulations still apply

Revised Common Rule Discussion

Changes to informed consent/process.

- §__.116(a)(4) requires that "The prospective subject or the legally authorized representative **must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."**
- §__.116(a)(5)(i) requires "Informed consent must begin with a concise and focused presentation of the **key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.**

Keep in mind:

FDA Regulations still apply

Revised Common Rule Discussion

Changes in yearly reporting

- For Example: Expedited / Exempt
- Plans for abbreviated Progress Report

Keep in mind:

FDA Regulations still apply

Revised Common Rule Discussion

Changes in levels of review.

For example, Expedited today may be Exempt in 2018

- secondary research use of identifiable biospecimens/data
  - will require “limited review”
- certain benign interventions
  - will require “limited review”

Keep in mind:

FDA Regulations still apply

Revised Common Rule Discussion

Single IRB Review – Effective 2020

The "Why"

- This provision is consistent with:
  - NIH single IRB policy effective 1/2018
  - 21st Century Cures Act effort to reduce duplication with a deadline for harmonization of 12/2019

Keep in mind:

FDA Regulations still apply

Office of Research Integrity (ORI) Update

Christina Jackson

- Introduction of new ORI Team Member
  - Vanessa Lowe
- Research Billing Compliance
- Research Oversight Committee
- ClinicalTrials.gov new PRS Administrator
  - Shelley Watson
- Research Investigator Forum
  - “Save the Date”

ORI – Research Billing Compliance

- New email address for FHMG research account notifications:
  - FHMG.Clinical.Trials@flhosp.org
- Communicate info quickly via Subject Line in email
  - “Research-Routine Care Only”
  - “Release Bill”
- ORI Website
  - Notification and Reconciliation Process Document
  - FHMG physician list
  - FAQs
- ORI Mailbox
  - FH.ORI@flhosp.org

ORI – Research Oversight Committee

- Purpose: To provide separation between research operations and research compliance
- ROC reports to Corporate Compliance
- Includes a minimum of 10 voting members, up to 12
  - We currently have 10 voting members
- Representation includes:
  - Medical Staff, FH Corporate Responsibility (FH and FHMG), IRB, FH Legal, FH Finance, Clinical Ops and/or Nursing, Biostats
- First meeting in January, 2017
  - 2017: Jan, Feb, Apr, Aug, and plan to met Oct and Nov
- Committee Charter is now approved and published in SharePoint

ORI – ClinicalTrials.gov

Key Clinical Trial Reporting Requirements

Reporting Requirement	ICMJE Policy (Effective 2005)	FDAAA Final Rule Issued in 2016	Final NIH Policy Issued in 2016
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1	All
Intervention Type	All	Drug, Biologic, & Device Products regulated by the FDA	All (includes behavioral interventions)
Funding Source	Any	Any	
Enforcement	Refusal to Publish	Criminal proceedings and Civil penalties (up to $10,000/day); Loss of HHS funding	Loss of NIH funding

ORI – Research Investigator Forum

- SAVE THE DATE!
- First week of December (holding 2 potential dates)
  - Awaiting confirmation from the guest speaker
- Thank you for your Survey Monkey responses
- 90 minute forum planned
  - Short address from research leadership
  - Keynote speaker
  - Two breakout sessions offered
  - Location: Werner Auditorium

Research Advancement & Support (RAS) Update

Michelle Dolske

- Classes scheduled through end of year!
- Rolled out all our new workshops
- Email FH.RAS@flhosp.org to sign up
- Hurricane Reschedules:
  - Workshop 3b now on October 4th
  - Workshop 3a now on October 24th

Better Together

SOAR

Becca Essner, Research Analytics

Portfolio Management

- FHRI is undertaking an analysis of research portfolios in each research unit
- Portfolio Management is a process of looking at active and proposed studies to determine their
  - Scientific Merit
  - Academic Impact
  - Business Impact
  - Clinical Impact

Scientific, Operational, and Administrative Review: SOAR

- Two step process – can occur concurrently
- Scientific Review
  - Looks at Clinical Impact and Academic Strength
  - Completed by appropriate Clinical and Scientific Leaders
- Operational Review
  - Looks at Finance & Feasibility and Strategic Alignment
  - Completed by Operational Leaders of research units and FHRI

Scientific, Operational, and Administrative Review: SOAR

- Members of the review teams will be determined by research unit leadership and their senior directors
- Some smaller or similar research units may share reviewers
  - Shares burden of review
  - Corrects for internal departmental pressure to participate in some studies
- Review questions can be pushed to reviewers using OpenClinica
  - Convenience of asynchronous review – no meetings to attend
  - SOPs for consistency
  - Positive messaging about process from senior research leadership

Open Mic

What will SOAR accomplish?

What are we missing?

Impact Story

How We Make a Difference

Lorraine Hickson, MRA, CCRP

Bryan Allison, MBA

J. Scott Magnuson, M.D.

Celebration Health

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Closing Remarks

Rob Herzog

Thank You for Attending!

Our next Research Matters meeting will be in November or December…

Details will be released soon!