Agenda

- Introduction - Meredith Fitz-Gerald
- Research Administration Updates - Jonathan Miller
- IRB Updates - Vanessa Champigny
- OSP Updates - Renee Clements
- CTAO Updates - Mark Marchant
- CBR Updates - Dawn Matthews
- OnCore Updates - John Sandefur
- Power Trials Updates - Alicia Martin-Gunter
Office of the Vice President for Research

• UAB Grand Challenge
  Projects that unite unique UAB around a single issue of high importance.
  https://www.uab.edu/plan/grand-challenge

• Kamilah Frison, Business Officer
  • Helping with Research Cores

• AAALAC site visit - Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
  • Commended how knowledgeable lab personnel were about animal care issues.
Occupational Health and Safety

• Recent organizational changes
  • Emergency Management and Physical Security joining UAB police
  • OH&S facilities functions reporting to Jolene King, Asst VP for Facilities Administration
  • OH&S research safety functions, including safety committees, continue to report to Lauretta Gerrity, Senior Associate VP for Research Administration
Occupational Health & Safety and IRAP

- Working to get the following groups into IRAP:
  - Institutional Biosafety Committee
  - Chemical Safety and Environmental Management Committee
  - Radioisotope and Radiation Safety Committee
- Radiation Safety IRAP progress
  - Many of their records already loaded
  - eForm in final preparation – vetted by campus users, state radiation safety group, and the committee
  - Streamlining processes and elimination paper forms
  - Expected launch - end of May 2018
Other reporting changes

• Effective Fall 2017, the following units report to Jonathan Miller:
  • IRAP
  • IRB
  • IACUC
  • CIRB
  • MTO
IRAP Resources

• Investigator handbooks for individual modules
• IRAP website – www.uab.edu/irap
• Individual help available by contacting IRAP@uab.edu or 975-IRAP
• Live Help Sessions EVERY Tuesday afternoon
UAB IRB

IRB Topics

• Single IRB
• IRAP
• IRB Training
UAB Single IRB

Single IRB/Central IRB

The model when one IRB performs regulatory review for multiple participating sites

Single IRB Guidance on Website

- Single IRB scenarios
- Single IRB Policy
- Submission instructions
- Fees
- Reliance Agreement Options
- Review the information *before* you call us!
UAB Single IRB

Reliance Agreement/Authorization Agreement

• Agreement that defines responsibilities and extends authority of reviewing IRB to relying institution

Changes in Online Reliance Platforms

• IRB Choice – no new studies may be added

• TIN – using IRB Reliance Exchange (IREx) as central IRB
UAB Single IRB – UAB as a Relying Site

IRAP Submissions

- New IRB Form! Coming soon!
- Institution Review Form Relying on an Outside IRB
- To be used for **WIRB and other External IRB Studies**

Institution Review Form Relying on Outside IRB

<table>
<thead>
<tr>
<th>1. UAB Principal Investigator (PI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (with degree)</td>
</tr>
<tr>
<td>Department/Division</td>
</tr>
<tr>
<td>Phone</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI Contact (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
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<td>Phone</td>
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</table>

<table>
<thead>
<tr>
<th>UAB Billing Contact* (if applicable)</th>
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</thead>
<tbody>
<tr>
<td>Name</td>
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<td>Phone</td>
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</tbody>
</table>

<table>
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<tr>
<th>2. UAB IRB Protocol Identification</th>
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</thead>
<tbody>
<tr>
<td>Protocol Title</td>
</tr>
<tr>
<td>Study Sponsor(s)</td>
</tr>
</tbody>
</table>
UAB IRB Website

Guidance: IRAP

Office of the IRB

The UAB Institutional Review Board for Human Use (IRB) is established under federal regulations for the protection of human subjects. Its purpose is to help protect the welfare of human participants in research conducted under the auspices of the University of Alabama at Birmingham.

The guiding ethical principles of the IRB—freedom and justice—are embodied in the Belmont Report, Guidelines for the Protection of Human Subjects, and the Declaration of Helsinki. The Board has authority to permit, disapprove, or require changes in research activity to be conducted under their sponsorship.

University policy requires that all research involving human subjects be reviewed and approved by the UAB IRB before the research begins. This requirement applies to all human subjects research conducted by faculty, staff, and students, on- and off-campus, regardless of funding.

Research involving human subjects includes the collection of data about or from human subjects and the use of existing data or specimens. Any changes to an IRB-approved project must be reviewed and approved by the IRB before they can be implemented. Continuing review is also required at regular intervals for protocols reviewed by the convened IRB and through expedited procedures.

The UAB IRB requires Principal Investigators and all other research team members to complete and submit an initial protocol and all amendments to the IRB for approval.

IRB News and Announcements

Change in State Law Regarding Age of Consent

Post by Office of the Institutional Review Board for Human Use 10/05/15

IRB Form Changes - June 2015

Post by Office of the Institutional Review Board for Human Use 9/25/15
UAB IRB Website

Guidance: IRAP – Naming Conventions

- How to find IRAP Protocol Correspondence (Including IRB Approval and Review Attachments)
- Quick Step By Step Instructions for How to Create a New Submission in IRAP
- Quick Step By Step Instructions for How to Create a Continuing Review or Amendment Submission in IRAP
- Quick Step by Step Instruction for How to Create a Response in IRAP
- Access to IRAP for IRB submissions
- IRAP FAQs
- IRAP Naming Conventions
UAB IRB Website

Guidance: IRAP – Naming Conventions

• Helps IRB staff and Board Members identify documents.
• Faster review process!
UAB IRB

IRAP Submissions – Naming Conventions
• Name and Category ONLY
UAB IRB Training

IRB Continuing/Refresher Training

- All IRB (and GCP) Training valid for 3 years
- New Course Summer 2018
- CITI
Contact Information

Office of the IRB
AB470
934-3789
irb@uab.edu
OSP UPDATES

Renee Clements, Associate Director

April 10, 2018
Agenda

1. Revised Extramural Checklist
2. New DUA Checklist
3. Clinicaltrials.gov information
# Revised Extramural Checklist

## UAB Extramural Support Checklist

Complete all applicable fields based on your submission type (e.g., proposal or contract).

All submissions must be submitted electronically in accordance with the [OSP Review Plan](#). For additional information, please see references at [UAB Extramural Support Checklist Instructions and Glossary](#) and [Required Documents](#).

### 1. Sponsor Portal Information

<table>
<thead>
<tr>
<th>Sponsor Portal</th>
<th>Sponsor Portal Application #</th>
<th>OSP Review</th>
<th>Complete</th>
<th>Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD/PI UAB PI</td>
<td>Last Name:</td>
<td>First Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BlazerID:</td>
<td>Phone:</td>
<td>Email:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mail Address:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitting Unit</td>
<td>School:</td>
<td>Dept:</td>
<td>Div:</td>
<td></td>
</tr>
</tbody>
</table>

The submitting unit should normally be the primary appointment of the Principal Investigator, not a Center.

- Graduate Student Fellowship: [ ] No [ ] Yes
- Trainee / Assignee: Last Name: [ ] No [ ] Yes
- BlazerID: Phone: Email: [ ] No [ ] Yes

### 2. Funding Source/Sponsor:

If pass through award, indicate Originating Sponsor:

### 3. CFDA #: (If applicable):

### 4. Submission Type:

- [ ] Original/New *
- [ ] Fee for Service *
- [ ] Transfer In *
- [ ] Study Startup Agreement
- [ ] Resubmission *
- [ ] Competing Continuation/Renewal *
- [ ] Change in PI *
- [ ] Amendment/Modification
- [ ] Supplement/Revision
- [ ] Transfer Out

- The Responsible Personnel List (RPL) is required (1) for all new applications (submission types of Original/New; Competing Continuation/Renewal; Transfer In; Change in PI; Resubmission; or Fee for Service) and (2) at any time there is a change in Responsible personnel on a sponsored project. Note that for program projects/center grants (P series grants), a separate RPL is required for each subproject. The RPL should not be submitted for the parent or overall project of a program project.

- Previous OSP#: Start Date: Change Date:

### 5. Sponsor Deadline Date:

### 6. Is this project being conducted: [ ] On-Campus [ ] Off-Campus

If more than 50% of UAB's portion of the project is performed off-campus, the [off-campus F&A rate](#) will apply to the entire project.

---

**UAB**

The University of Alabama at Birmingham

Knowledge that will change your world
# Revised Extramural Checklist

## Complete all applicable questions below regardless of sponsor type or activity description:

- **Is this project a clinical trial?** 
  - No
  - Yes

## Sponsor / Contract Research Organization (CRO)

- **CRO Name:**
- **Sponsor/CRO Full Name:**
- **Contact Info:**
  - Phone:
  - Email:
- **Sponsor/CRO Reference # for project:**

## Source of Clinical Protocol/SOW/Research Plan:

- **Sponsor Provided/Written Protocol**
- **Non-UAB Investigator Initiated**
- **UAB Investigator Initiated**

- **Will the federally funded CRU be utilized?**
  - No
  - Yes
- **Funding Source’s Protocol #:**

### Phase:
- I
- II
- II/III
- III
- III/IV
- IV
- Post IV
- No Phase

### IND #:

### IDE #:

## Requested Project Period Dates

- **From:**
- **To:**

## Requested Funding

### Direct:

### F&A:

### Total:

### F&A Rate: %

---

## Will F&A costs be allocated to or shared with a unit other than the unit of the PI/PD’s primary appointment?

- No
- Yes

*If yes, complete and attach the [UAB Facilities and Administrative Cost (IDC) Revenue Redistribution Agreement.]*
### Revised Extramural Checklist

<table>
<thead>
<tr>
<th>30</th>
<th>Intellectual Property/Declaration – Check the appropriate box.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I plan to participate in this project regardless of the intellectual property terms in the agreement. I understand and agree that if the sponsor requires ownership of, or a royalty-free license to, inventions developed by me and/or other UAB employees during this project, (i) UAB will not receive any financial consideration arising from the sponsor’s commercial exploitation of the UAB-developed invention(s), and (ii) as a result, neither I nor any other UAB employee who has made an inventive contribution to the invention(s) will be entitled to receive any of the financial consideration that might otherwise be allocated to us in accordance with the UAB patent policy.</td>
</tr>
<tr>
<td></td>
<td>I will not participate in this project if UAB is unable to ensure that ownership rights to all inventions developed by me and/or all other UAB employees during this project remain with UAB/UABRF, or if UAB is unable to retain its right to receive financial consideration arising from commercial exploitation of such inventions.</td>
</tr>
</tbody>
</table>
# DUA Checklist

The UAB DUA Checklist is to be used when submitting DUA documents/requests. Please submit the completed form along with any required attachments to the Office of Sponsored Programs (OSP).

<table>
<thead>
<tr>
<th>General Information</th>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider/Recipient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provider/Recipient Contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Project Title</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Are you Providing and/or Receiving?
   - [ ] Providing
   - [ ] Receiving
   - [ ] Both Providing and Receiving

2. Does the Data contain information collected from human research subjects?
   - [ ] Yes
   - [ ] No

3. Does the Data contain any identifiers, individually identifiable health information or protected health information (PHI)? See: [Data Use Agreements Webpage](#)
   - [ ] Yes
   - [ ] No

4. If the Recipient, how will you fund the research to be conducted with the Data?

5. If the Provider, how was the research funded that generated the Data?
Clinicaltrials.gov

- Federal regulation requires clinical trials be registered on clinicaltrials.gov
- OSP Webpage Updated
Contact Information

OSP – 934.5266 or osp@uab.edu
Renee Clements – 996.7054 or rclement@uab.edu
Updates on Clinical Trials Initiatives

Mark Marchant, MPH, MBA, CCRP
Director, CTAO
• Electronic Subject Payment System
• Utilizes ClinCards
• Replaces Checks, Visa Debit Cards, Petty Cash
• Web Portal for Subject Entry and Visit Keeping
• Cards have no value until study visits kept in system
• Reporting capabilities
• Phased Roll-out
  • Test Sites: Lung Health Center & Psychiatry (October 2017)
  • Wave 1:
    • Q1 2018
    • Anesthesiology; Cell, Developmental & Integrative Biology; Dermatology; Emergency Medicine; Genetics; OB/GYN; Ophthalmology; Oral & Maxillofacial Surgery; Pathology; Pediatrics
  • Wave 2:
    • Q2 2018
    • School of Public Health; Medical Education
• **Cost**
  • Cards: $3.50 paid by University
  • Loads: $1.15 paid by Study (effective June 1\(^{st}\))

• **Reminders:**
  • Consent Language: Review current language to ensure silent on payment type
  • Budget: Include load fee
QUESTIONS

???
CBR UPDATES

Dawn Matthews, MPA, CCRC, CPC, CNM
Manager, Clinical Billing Review
CBR UPDATES

- CBR is in the beginning stages of updating their processes internally to better assist with submission processing.
- CBR will be looking for another analyst as one of our analysts will be leaving to pursue other endeavors outside of UAB.
- Just as a reminder - If you are in Wave 1 or 2 of OnCore, you will need to send your OnCore Calendar Services (OCS) submission prior to CBR review so the study build is in OnCore for CBR use in their review.
CBR UPDATES

??Questions??
OnCore Initiative

John Sandefur
Enterprise Project Manager and OnCore Initiative Team Leader
OnCore Implementation

- Wave 2
  - Neurology, Neurosurgery, Otolaryngology, Urology, Radiology, Psychiatry, Surgery
  - Validation week begins 4/16
  - Go-live begins 4/23
- Wave 3
  - Exercise Medicine, Orthopedic Surgery, Dermatology, Anesthesiology, Emergency Medicine, Genetics, OB/GYN:URO/GYN, Ophthalmology, Oral and Maxillofacial Surgery, Pathology, Pediatrics, Physical Medicine and Rehabilitation, Psychology, Physical Therapy, Public Health/Health Behavior, Nutrition
  - Go-live during September 2018
  - SiteMinder retirement
OnCore Financials Project

- Factors to consider – moving away from a SiteMinder-centric world
  - New universal OnCore chargemaster
    - Simplified to allow pricing lookup by users
    - Consolidated and coordinated with the billing offices
  - New OnCore target version(s) require significant upgrades to infrastructure and offer expanded financial features
  - Identification and introduction of best practices for budgeting and invoicing
  - Development of OnCore budget templates
  - Development of new training materials to reflect the above items
  - Revision of clinical trials billing notice (CTBN) code and processes in coordination with the billing offices
- Timeframe and duration
  - Target to begin in May
  - Duration 5-7 months
PowerTrials: Quick Overview and Updates

CCTS Lunch & Learn

April 10, 2018
**Project Overview**

1. **OnCore**
   - Research study built in OnCore
   - Responsible: OnCore

2. **Cerner IMPACT PowerTrials**

   - PowerPlan built with the orderables required by the study
   - Responsible: HSIS

   **PowerChart**
   - 1. Banner Bar
   - 2. Research Summary
   - Patient placed “on study” in banner bar, linked to research summary
   - Responsible: Clinical Trials Admin Office (CTAO)/HSIS

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**UAB MEDICINE**

Knowledge that will change your world
Sample Research Summary

**Title of Protocol:** Phase 2 Randomized, Double-Blinked, Controlled Study of Tucatinib vs Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma

**Study Agents (Drug or Device):**
1. Tucatinib
2. Capecitabine (Xeloda)
3. Trastuzumab (Herceptin)

**Purpose/Objective of Study:**
The purpose of the study is to assess the survival and clinical benefit of tucatinib versus placebo when combined with capecitabine and trastuzumab in patients with advanced HER2+ breast cancer.

**Mechanism of Drug Action/Device Description:**
Tucatinib is a highly selective oral reversible HER2 tyrosine kinase inhibitor. It has >1000 fold increase in potency for HER2 inhibition compared to EGFR and blocks HER2 signaling while avoiding EGFR-related side effects.

Capecitabine is an oral prodrug of fluorouracil that interferes with DNA and RNA synthesis.

Trastuzumab is an anti-HER2 monoclonal antibody that binds to the HER2 extracellular domain and blocks HER2 cleavage, stimulating antibody-dependent, cell-mediated cytotoxicity, and inhibits HER2-mediating mitogenic signaling. Trastuzumab is administered intravenously.

**Toxicity/Side Effects:**
- Tucatinib: diarrhea, rash, extremity pain, nausea, fatigue, cough, hepatotoxicity, heart failure
- Capecitabine: diarrhea, cardiotoxicity, hand-foot syndrome, pancreatitis, hyperbilirubinemia
- Trastuzumab: infusion reactions, infections, dyspnea, myalgias, congestive heart failure

**Caution:**
Do not place patient on Coumadin (other anticoagulants are ok).

CYP3A4 or CYP2C8 Inducers or Inhibitors are NOT permitted on study (e.g. gemfibrozil, clarithromycin, azoles, barbiturates). Please ask your study coordinator before starting any new medications.

**Key Contacts:**
- **Principal Investigator:** Dr. Erica Stinger-Reaser
  - Phone: 4-2092, Pager: 4079
- **Study Coordinator:** Felicia Witherspoon
  - Phone: 4-4317, Pager: 3119

*Emails: esmasor@uabmc.edu, fwithers@uab.edu*
### Sample PowerPlan

#### PowerOrders

<table>
<thead>
<tr>
<th>Component</th>
<th>Status</th>
<th>Dose</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC WITH DIFF</td>
<td>Routine collect, Blood, Q1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prothrombin Time (PT)</td>
<td>Routine collect, Blood, E000000005/E000000005/E000000005/E000000005</td>
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<td>PTT</td>
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<td>Phosphorous Serum</td>
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<td>Magnesium Serum</td>
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<tr>
<td>Comprehensive Metabolic Panel 2 (CMP)</td>
<td>Routine collect, Blood, Q1</td>
<td></td>
<td></td>
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<tr>
<td>HBV Quant</td>
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<tr>
<td>Hepatitis C Antibody</td>
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<tr>
<td>HCV QNT (HCV RNA Quantitative)</td>
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<td>Urine Pregnancy Test</td>
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<td>Thyroid Stimulating Hormone</td>
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<tr>
<td>Thyroxine Free</td>
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<tr>
<td>CA 125</td>
<td>Routine collect, Blood, Q1</td>
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</tr>
</tbody>
</table>

#### Radiology

- CT Rch Chest with contrast METRIC
  - bill to insurance, JRB/E000000005, Q1
- CT Rch Body with contrast METRIC
  - bill to insurance, JRB/E000000005, Q1
- MR Rch Body with contrast METRIC
  - E000000005 – Nonstandard imaging protocol, Q1

#### Research - I300000905 - UAB1790, Cycle 1 Day 1 (Planned)

- CBC WITH DIFF
- Phosphorous Serum
- Comprehensive Metabolic Panel 2 (CMP)
- Urine Pregnancy Test

#### Research - I300000905 - UAB1790, Screening (Planned)

- Routine collect, Blood, E000000005/E000000005/E000000005/E000000005


Last updated on: 3/28/2018 8:43 by: Christopher, Holli W
The HSIS PowerTrials team builds the PowerPlan based off the OnCore Protocol Calendar.

- PowerPlans currently only include Lab and Rad orderables.
- Billing modifiers are built into the order to automate billing (SOC vs Study).

Build in Test environment first.

Build in the Production environment after successful testing in Test environment.
Validation of PowerPlan built in Test environment.

- Check that all orderables required by Protocol are included.
- Check that the billing modifier is correct.

Testing the PowerPlan in the General Services Building (GSB).

Validation of the PowerPlan built in the Production Environment
After the patient has consented for the study, the Research Coordinator will Add the PowerPlan to the patient’s encounter when a patient has consented for the study, using the UAB Protocol #, Study Name, or IRB #.
All of the study required cycles that contain Lab and Rad orders will display on the patient’s chart.

The Research Coordinator will ‘Initiate’ the Cycle that applies when the patient comes in for the required visit.

Q1: billed to the patient’s insurance as Standard of Care

IRB number: billed to the Clinical Trial
PowerTrials Updates

- New PowerTrials website!
  - Updates!
  - Resources!
    - IMPACT Research Coordinator Resource Manual: Research PowerPlan Ordering
    - PowerTrials PowerPlan Presentation
    - PowerTrials Quick Tips and Tricks
    - PowerTrials Process
  - FAQs!

- http://www.uab.edu/medicine/ctao/investigators/powertrials
PowerTrials Future State

- Adding additional orderables (ECG, PFTs, Dexascans, Research Pharmacy, etc.)!

- Launch PowerTrials to the DOM Wave 1A and Wave 1B departments!
Things to Remember

- Until 100% implementation is completed, some orders will continue to go through the original process (green sheet, order through Impact, etc.)

- Your licensure will determine whether or not you have the privileges to place orders and/or PowerTrials PowerPlans.
Questions

- Questions?

- For further questions or concerns:

  Alicia Gunter
  PowerTrials Administrator (HSIS)
  (205) 996 - 8763 office
  abmartin@uabmc.edu
Questions??

Next CCTS Lunch and Learn:
August 14th, 2018