



CRA Orientation Program:

Selected Topics on
Coordinating Clinical Research
at Upstate

SUNY Upstate Medical University
2/26/2009

Topic:



General Information

Research Administration Overview:

- Sponsored Programs
- Clinical Trials
- Research Development
- Research Compliance

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Sponsored Programs Office:

- Federal, State and Non-Profit Grant Review and Submission



Clinical Trials Office:

- Pharmaceutical/Device Company and PI Initiated (funded) Contract Review and Submission.



Research Development:

Assists faculty and staff to identify extramural sponsors for their research and related programs

- Administers the Intramural Research Grant Program



Research Compliance:

- Institutional Review Board (IRB)
- Research Misconduct
- Quality Assessment & Improvement Program (QAIP)
- Institutional Biosafety Committee (IBC)
- Radiation Safety Committee (RSC)
- Committee for the Humane Use of Animals (CHUA)



CITI: Collaborative Institutional Training Initiative

- All faculty, staff and students, who participate in the conduct of research involving human subjects, are required to successfully complete the web based education program, CITI.



CITI

- Certification of completion for the initial CITI training program is valid for three years. Re-certification is required every three years thereafter.
- http://www.upstate.edu/researchadmin/irb/citi_reg.php

CRA Professional Organizations

- SoCRA: Society of Clinical Research Associates
<http://www.socra.org/>

- ACRP: Association of Clinical Research Professionals
<http://www.acrpnet.org/>



Professional Organizations Provide:

- Certification Programs
- Educational Programs & Workshops
- Annual Conferences
- Professional Journals:
 - "SoCRA Source"
 - "The Monitor"

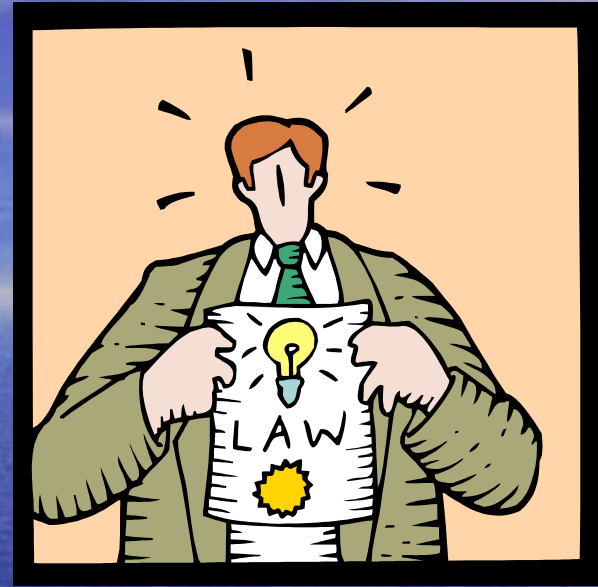
CRA Educational Opportunities:

- **'Hot Topics'** Presentations: useful info, CME credit, opportunity to visit with other CRAs, and lunch (~ monthly)
- **'Research Forum'**: Quarterly newsletter for the Office of Research Administration
- **Health Sciences Library**

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Topic:



Agencies,
Policies,
Regulations

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DHHS: 45 CFR 46 (the Common Rule):

- IRB membership and functions
- Informed Consent
- Additional protections for vulnerable populations:
 - Fetuses, pregnant women, in-vitro...
 - Prisoners
 - Children

FDA Regulations:

21 CFR 50: Protection of Human Subjects

21 CFR 54: PI Financial Disclosure

21 CFR 56: Institutional Review Boards

21 CFR 312: Invest. New Drug Application

21 CFR 812: Invest. Device Exemptions

FDA Form 1571: Investigational New Drug (IND) Application

FDA's primary objectives:

- Assure the safety and rights of subjects (in all phases of investigation)
- Help assure that quality of the scientific evaluation is adequate in evaluating the drug's effectiveness and safety (Phases 2 and 3)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0014
 Expiration Date: May 31, 2006
 See OMB Statement on Reverse

INVESTIGATIONAL NEW DRUG APPLICATION (IND)
 (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. NAME OF SPONSOR	2. MAILING ADDRESS
3. ADDRESS (Include Street, City, State and Zip Code)	4. TELEPHONE NUMBER (Include Area Code)
5. NAME(S) OF DRUG (Include available number, Trade Name(s), Chemical Name(s))	6. IND NUMBER (If previously assigned)
7. INDICATIONS/Condition(s) to be studied	
8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CONDUCTED: <input type="checkbox"/> PHASE 1 <input type="checkbox"/> PHASE 2 <input type="checkbox"/> PHASE 3 <input type="checkbox"/> OTHER _____ (Specify)	
9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), DRUG MASTER FILES (21 CFR Part 314.80) AND PRODUCT LICENSE APPLICATIONS (21 CFR Part 601) REFERRED TO IN THIS APPLICATION.	

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.

9. IND NUMBER

11. THIS SUBMISSION CONTAINS THE FOLLOWING: (Check all that apply)

<input type="checkbox"/> INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)	<input type="checkbox"/> RESPONSE TO CLINICAL HOLD
---	--

PROTOCOL AMENDMENT(S):	INFORMATION AMENDMENT(S):	IND SAFETY REPORT(S):
<input type="checkbox"/> NEW PROTOCOL	<input type="checkbox"/> CLINICAL-MICROBIOLOGY	<input type="checkbox"/> INITIAL WRITTEN REPORT
<input type="checkbox"/> CHANGE IN PROTOCOL	<input type="checkbox"/> PHARMACOKINETICS ONLY	<input type="checkbox"/> FOLLOW UP TO A WRITTEN REPORT
<input type="checkbox"/> NEW INVESTIGATOR	<input type="checkbox"/> CLINICAL	
<input type="checkbox"/> REQUEST FOR SUPPLEMENTAL INFORMATION	<input type="checkbox"/> ANNUAL REPORT	<input type="checkbox"/> GENERAL CONCILS/CONURCL
<input type="checkbox"/> REQUEST FOR RESTATEMENT OF IND THAT IS WITHDRAWN, INADVERTENTLY TERMINATED OR DISCONTINUED	<input type="checkbox"/> OTHER _____ (Specify)	

CHECK ONLY IF APPLICABLE

INDICATIONS AND NEW DRUG DISCONTINUED WITH APPLICATION FOR ANY CHECKED BELOW, REFERENCE TO THE SITE OF CLINICAL INVESTIGATION

TREATMENT OF 21 CFR 312.60 PREVIOUS PROTOCOL 21 CFR 312.61 CHANGE TO 21 CFR 312.62

FOR FDA USE ONLY

CONSUMER RECEIPT STAMP	IND RECEIPT STAMP	DIVISION ASSIGNMENT:
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FDA Form 1572:

“Statement of Investigator”

- Summarizes what the FDA requires for an acceptable clinical study
- Statement of qualifications (CV)
- Investigator’s signed agreement to conduct study according to the current protocol and in compliance with federal regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0510-0047
Expiration Date: January 31, 2006
See OMB Statement of Reviews.

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator Form FDA 1572 (21 CFR 312.55)(j).

1. NAME AND ADDRESS OF INVESTIGATOR

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED:

CURRICULUM VITAE

OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(ES).

6. NAMES OF THE SUBINVESTIGATORS (e.g., research nurses, assistants, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE ICD FOR THE STUDY(ES) TO BE CONDUCTED BY THE INVESTIGATOR.

FDA Forms: **MedWatch**



- MedWatch allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page ___ of ___

FDA Form 3026 (Rev. 04/2011) Expires 12/31/16
See Date Expiration on Reverse

FDA USE ONLY	
Tracking response to	

A. PATIENT INFORMATION			
1. Patient Identifier In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight a. _____ lb b. _____ kg

D. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	
Check all that apply:	
<input type="checkbox"/> Adverse Event	<input type="checkbox"/> Product Problem (e.g., defective medication)
<input type="checkbox"/> Product Use Error	<input type="checkbox"/> Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)	
<input type="checkbox"/> Death	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-Threatening	<input type="checkbox"/> Dangerous Anomaly/Defect
<input type="checkbox"/> Hospitalization (inpatient or prolonged)	<input type="checkbox"/> Other Serious Adverse Medical Event
<input type="checkbox"/> Recurred Involvement to Patient (Permanent impairment/damage) (Yes/No)	

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy) 05/04/2016
-------------------------------	---

5. Describe Event, Problem, or Product Use Error

6. Relevant Test/Laboratory Data, including dates

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, medication problems, etc.)

D. SUSPECT PRODUCT(S)		
1. Name, Strength, Manufacturer (from product label)		
#1		
#2		

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if known; provide start, end, or other relevant)	6. Event Abated After Use Suspended or Dose Reduced?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncert/Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncert/Apply

4. Diagnosis or Reason for Use (if known)	5. Event Reappeared After Reintroduction?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncert/Apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncert/Apply

6. Lot #	7. Expiration Date	8. NDD # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE		
1. Brand Name		
2. Common Device Name		
3. Manufacturer Name, City and State		
4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	
6. If Implanted, Give Date (mm/dd/yyyy)	7. If Implanted, Give Date (mm/dd/yyyy)	

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input type="checkbox"/> No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (include location of use)

G. REPORTER (See confidentiality section on back)
1. Name and Address
Phone # _____ E-mail _____

PLEASE TYPE OR USE BLACK INK

OHRP: Office for Human Research Protections

- Part of DHHS
- provides oversight and guidance for human subject research
- develops educational programs
- FWA is the formal agreement with OHRP to comply with the regulations pertaining to human subject protections

HIPAA Regulations: The “Privacy Rule”

- Part of the Health Insurance Portability and Accountability Act of 1996
- Protects the use and disclosure of protected health information (PHI)



HIPAA: Notice of Privacy Practices

- Upstate's Notice of Privacy Practices (NOPP) must be provided to research subjects (if not waived)
- NOPP is notice of how the institution may use or disclose an individual's PHI, the individual's rights and the institution's legal duties

HIPAA

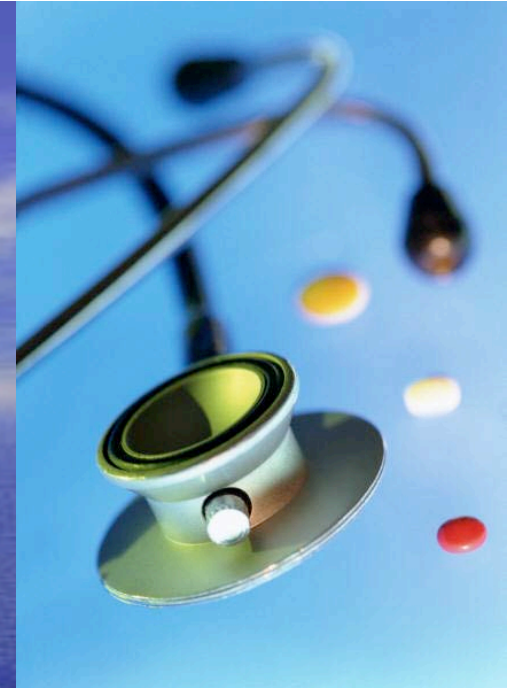
- Upstate's Notice of Privacy Practices can be printed from the IRB and other Upstate websites, or hardcopies can be obtained through Central Stores
- May be different from medical office NOPP, so make sure the Upstate NOPP is given to research subjects
- **Document** that NOPP was given

ICH Guidelines for Good Clinical Practice (GCP):

- An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
- Compliance provides public assurance that
 1. the rights, safety, and wellbeing of trial subjects are protected
 2. the clinical trial data are credible.

ICH GCP Guidelines:

- Informed Consent Process
- Accurate collection of data
- Maintaining of audit trails
- Reporting adverse events
- Record retention
- <http://www.fda.gov/cder/guidance/959fnl.pdf>



Upstate IRB Guidelines and Policies:

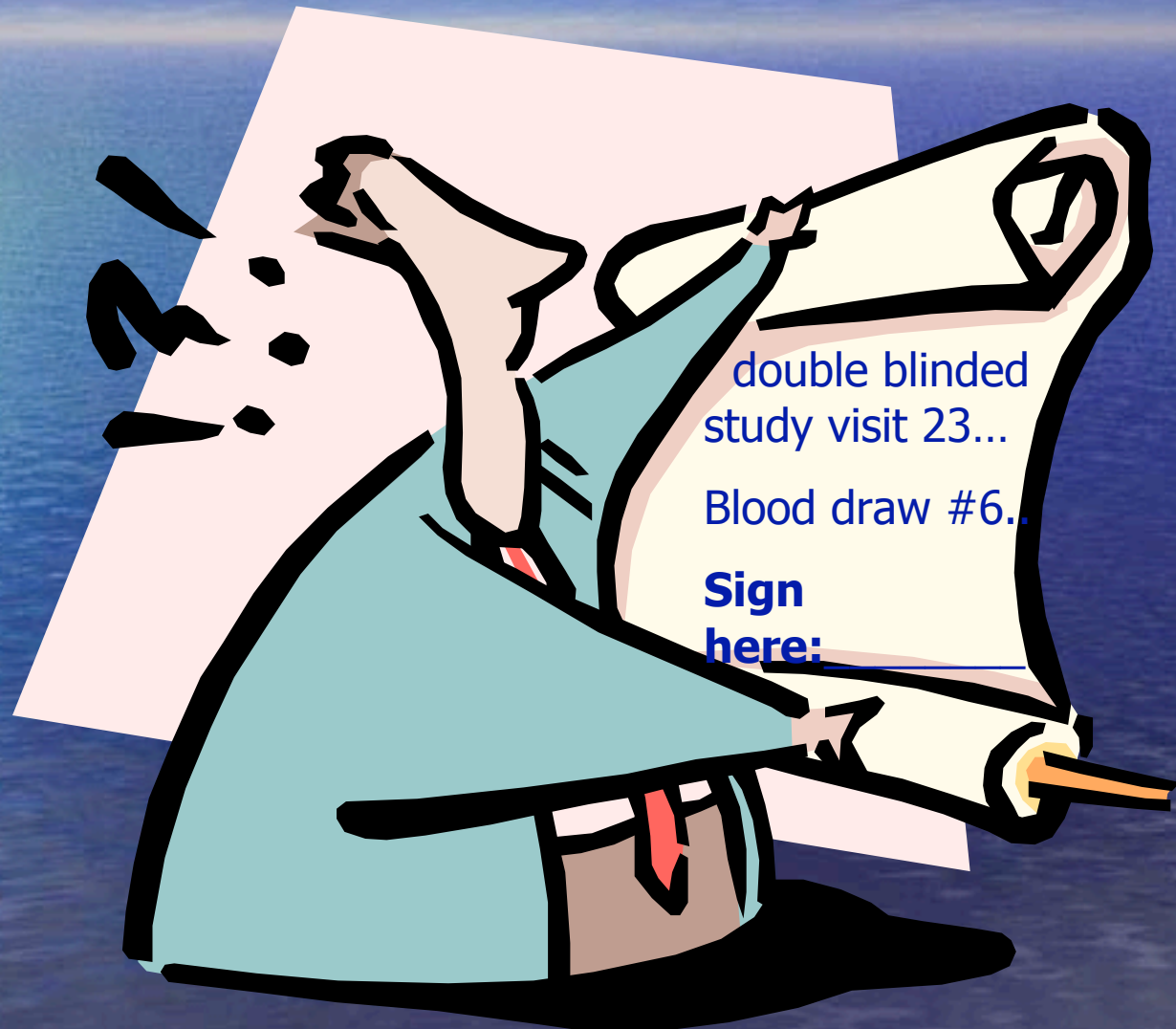
http://www.upstate.edu/researchadmin/irb/policies_guidelines.php

Topic:

Informed Consent



Which of the following subjects do you want in your study?



Subject #1



“Unless you’ve studied medicine, you don’t know what you’re signing. It was Greek to me. No one ever really explained anything to me. They handed me the papers and gave me a lot of time to look them over. I just asked a few questions, then went ahead and signed it. That was probably a stupid thing to do.”

Subject #2



“They wanted to make sure I knew exactly what the terms were. They explained everything very well and said what the risks were and side effects might have been. And they were forever reminding me that if I had any problems to call immediately. They also made it clear that I could ask questions or stop at any time.”

Informed Consent:

Informed consent is a

process by which a subject voluntarily confirms a willingness to participate in a particular trial, after having been informed of all aspects of the trial



Informed Consent Key Words:

Process:

- Ongoing interactive dialogue
- Begins before enrollment
- Continues until participation is complete

Informed Consent Key Words:

Voluntary:

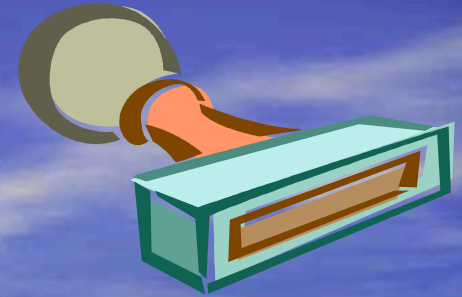
- without undue influence
- without improper reward
- without threats or coercion
- without manipulation
- without use of authority

Informed Consent Key Words:

Informed:

- Information sufficient in amount to make a knowledgeable decision
- At the correct educational level
- In language that is understandable to the subject

Consent Form IRB Stamp:



- Consent forms **must have an IRB stamp at the bottom of each page.**
- This stamp signifies IRB approval
- The stamp contains the expiration date of consent form, and may contain a revision date

Is a Witness Signature a Regulatory Requirement?

- Answer: No

Witness signatures are included if the sponsor or IRB requires it

- Reasons to include a witness signature:
 - High risk studies
 - Studies involving vulnerable populations
 - Investigator protection
- **But...if a witness line is there, use it**



“Optional” or “Choice” Boxes:

“specimen banking”
or “future contact”



Tip: Unless completed you do not have written permission to conduct options. Consider moving box to signature page.

Remember:



- Make sure that all lines of the signed consent document are completed, and that each signature is personally dated
- Make sure that every enrolled subject receives a signed copy of their **ENTIRE** consent form, document that you did **SO.**

Remember:



- Never use an unstamped consent document
- Always use the most current approved version of the consent document

Remember:



- Keep all pages of original signed consent documents for every subject you have enrolled (even screen-fails)
- Never make handwritten changes to any consent document



Consent Must Be:



- obtained prior to any study procedure, including screening
- obtained by a study team member listed on the IRB application who has the authority (granted by the PI) to obtain consent

Topic:

Documentation



A Word to the Wise:



- Organize
- Organize
- Organize

Study Documentation:



- Note-to-File
- Source Documents: “raw data”
 - hospital and clinic charts
 - laboratory and radiology reports
 - EKGs
- Laboratory Documentation:
 - University Hospital Pathology Manual
 - CV of Lab Administrator
 - lab certification
- Subject Enrollment Log

**SUNY Upstate Medical University
Subject Enrollment Log**

IRB#

Principal Investigator:

Study Title:

subjects approved by IRB ____

Subject name or number	Date enrolled (signed consent)	Person Obtaining Consent	Subject Given Signed Consent Copy	Subject Met Eligibility Criteria?
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

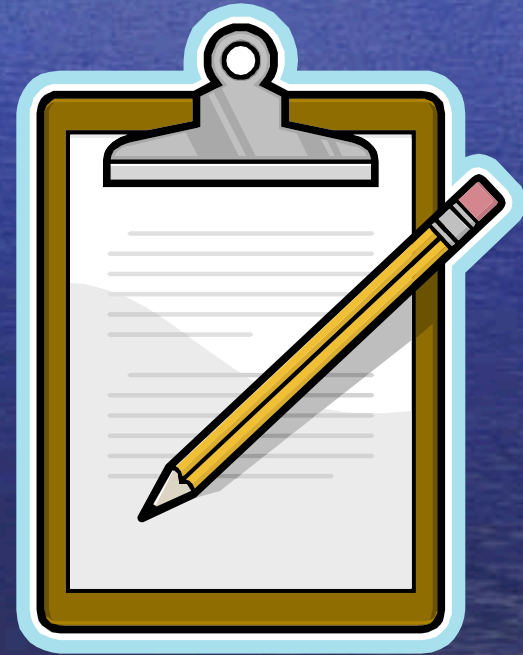
Topic:

Monitoring Visits & Audits

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3 types:

- QAIP Site Visits
- Sponsor Visits
- FDA Audits



QAIP: Quality Assessment & Improvement Program

- established in the fall of 2005
- a post (IRB) approval internal monitoring program
- provides subjects with an extra level of protection by reviewing the conduct of the study in real time
- Over 90 site visits conducted so far

Quality Assessment & Improvement Program:

- conducts routine study site visits
- provides on-site education to PI/staff
- suggests best practice procedures
- investigates problems or complaints
- provides the Vice President for Research and the IRB with info on compliance
- can act as a liaison between the investigator and the IRB

Steps of QAIP Site Visit:

- Interview
- Records Review
- Wrap-up Meeting

Sponsor/CRO Monitoring Visits:

- For studies that make a high contribution to sponsor's development programs
- For studies where it appears there may be compliance problems
- For studies where the sponsor knows or suspects there will be an FDA audit
- **Periodic routine oversight**

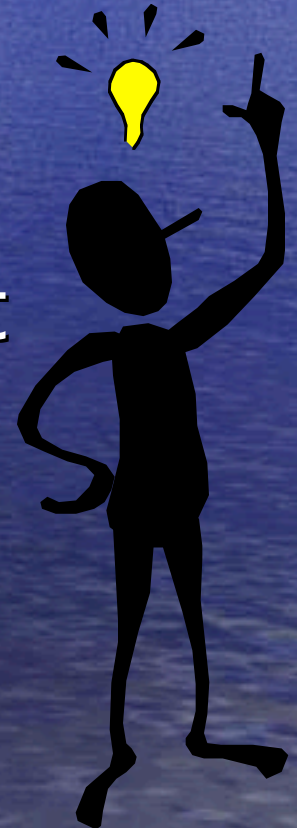
FDA Audits: 3 types

- Bioequivalence study inspection: (When one study is the sole basis for a drug's approval)
- Study-related: (studies that are important to a New Drug Application)
- Investigator-related: (a large number or pivotal study, work outside PI specialty, findings inconsistent with other sites, sponsor or IRB concerns, subject complaint, etc.)

(from The CRC's Guide to Coordinating Clinical Research)

A few Last Thoughts:

- The safety and well-being of your study subjects always comes first
- Establish a good, collegial working relationship with your investigator
- Know your protocols and case report forms thoroughly
- Keep organized
- Read the regulations



- Think of your sponsor monitors as the other half of the team
- Don't be afraid to admit you don't know something—find out
- Don't be afraid to admit mistakes
- Remember that you are making a difference in people's lives
- Be nice
- Smile



Contact Info: QAIP

- **Robin Cerro, NP, MSN**

Quality Assessment & Improvement
Program (QAIP) Coordinator

315-464-4317

cerror@upstate.edu

Contact Info: IRB Office

- **Marti Benedict, RN, BSN**

IRB/IBC Administrator & Chief Compliance Officer for Research

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IRB Coordinator

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2/26/2009

The IRB and IBC

Institutional **R**evision **B**oard &
Institutional **B**ioSafety **C**ommittee

What is an IRB?

- An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

What is Research?

Federal Regulations define research as:

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”

What is a Human Subject?

Human Subjects are defined as living individuals about whom an investigator conducting research obtains:

- data through intervention or interaction or,
- identifiable private information.

IRB PURVIEW

- The IRB reviews ALL research involving human subjects

This includes:

- human tissue
 - medical records
 - surveys of human subjects
- Applies to human subject research conducted by our faculty & staff - *on or off* campus.

IRB Meetings

- A majority of the IRB members must be present to convene a meeting
 - including *at least one* non-scientist member
- A majority (of the members present) vote is required to pass any motion.
- The Upstate IRB meets monthly

IRB REVIEW

- A comprehensive review includes:
 - Scientific Review
 - Ethical Review
 - Compliance with Regulations
- Research may need additional reviews (e.g., UH, SU, VAMC, etc.)
- No one can reverse a disapproval by the IRB

Scientific Review- An IRB Obligation

- The principle of beneficence (Belmont Report) requires that the study design can answer the research question
- Without an adequate research design and implementation, the study is useless, and does not therefore justify the use of human subjects, regardless of the level of risks involved.

How the IRB Review Works

Study Design
Risk Assessment
Benefit Assessment
Study Team (COIs)

Subject Selection:
Who & Where

Informed Consent Process
Voluntary Participation
Privacy & Confidentiality
Recruitment (how & when)

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Requirement for IRB's to Monitor Approved Research

- Continuing IRB review of all approved studies is required
 - at intervals appropriate to the degree of risk,
 - **but not less than once per year.**
- The IRB determines the approval period at initial review.
- The IRB has the authority to observe or have a third party observe the consent process and the research.

Common Rule

1. Choose an Entree



EXEMPT



EXPEDITED



FULL BOARD

2. Choice must be based on criteria outlined in the common rule (45CFR 46). IRB Review is based on the ethical principles (respect, beneficence, justice)

April 14, 2003
Marti Benedict

SUNY Upstate Medical University
2/26/2009

Privacy Rule

3. Pick an appropriate wine to complement your entree



AUTHORIZATION



WAIVER



DE-IDENTIFICATION



LIMITED DATA SET

The Mission of the IRB

TO PROTECT THE RIGHTS AND WELFARE
OF RESEARCH SUBJECTS

“If we knew what it was we were doing, it would
not be called research, would it ?”

Albert Einstein

Institutional Biosafety Committee

- The National Institutes of Health has official authority over IBCs
- The IBC reviews research which involves
 - recombinant DNA
 - infectious agents
 - bio-hazardous agents

What is the purpose of an IBC?

- The IBC reviews recombinant DNA research projects for compliance with the NIH Guidelines.

this includes:

- **Containment levels**
- **Facilities**
- **Institutional procedures and practices**
- **Training and expertise of personnel**

Why is an IBC needed?

- To protect the public
- To protect the environment
- To protect the investigator
- To protect the staff

Human blood, fresh tissue, & body fluids

- Because all human blood, fresh tissue, or body fluids must be regarded as possibly infected with blood borne pathogens, the Upstate IBC will:
 - review procedures for safe handling
 - inspect Upstate research facilities where human blood, fresh human tissue, or body fluids are used, or research facilities used by Upstate research personnel, to ensure maximum safety.

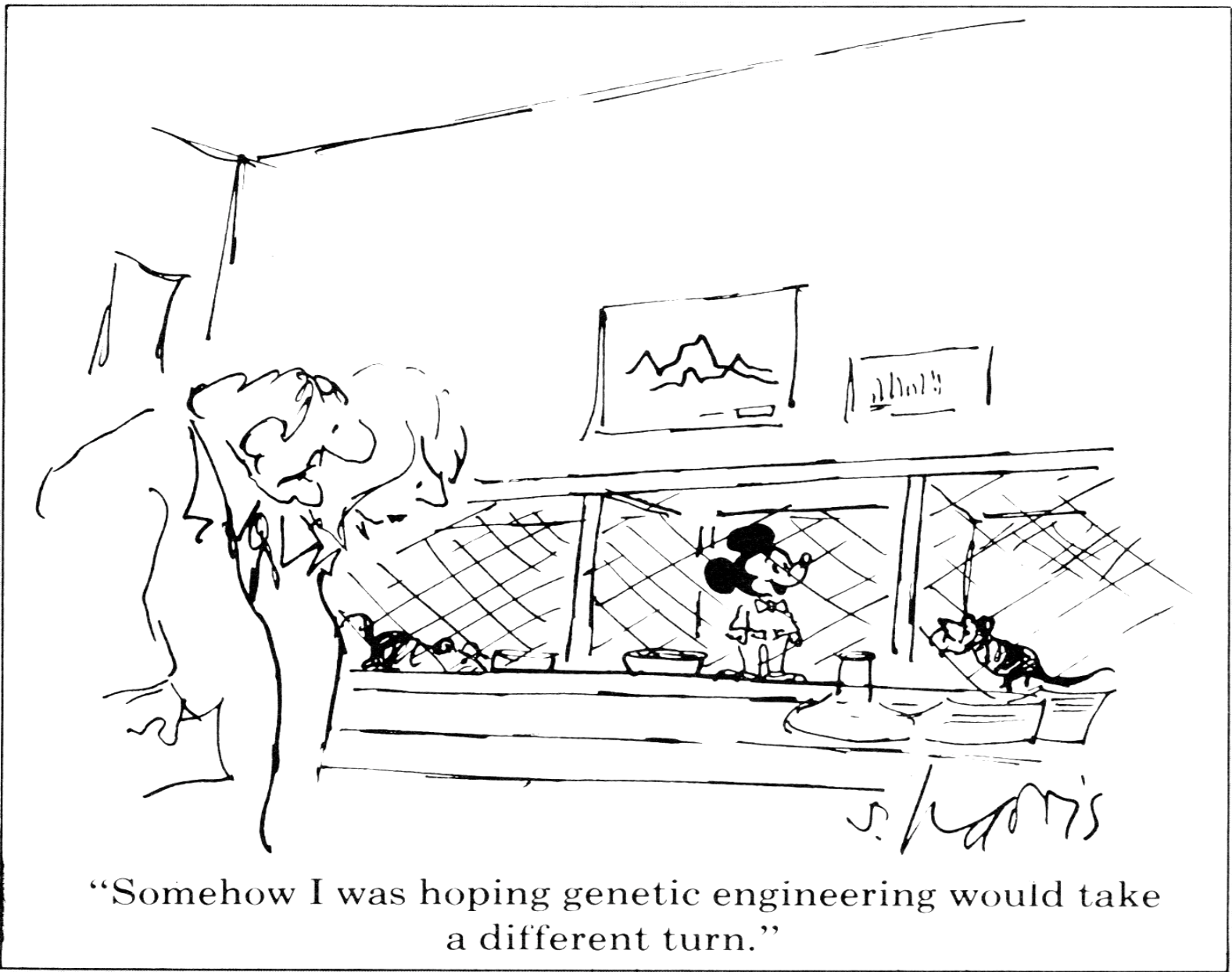
IBC Review Procedures for Clinical Research vs. Basic Science Research

- Different application forms, policies and requirements
- Clinical research generally does not require review at a convened IBC meeting
- Site visits are always required for research using human blood, fresh tissue, or body fluids

Training Requirements

- All employees working with potentially infected substances must complete the training offered by the Department of Environmental Health & Safety, and extended training offered by their laboratory supervisor

Sidney Harris © 1977. (This cartoon originally appeared in American Scientist.)



2/26/2009

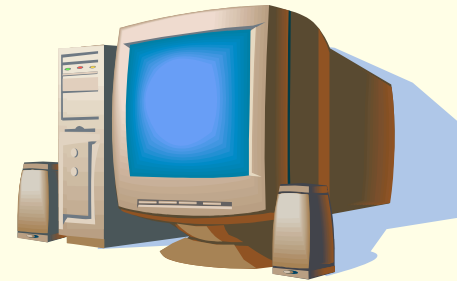
Access to Patient Information and Electronic Data

Cindy Nappa

Institutional Privacy Administrator

Access to CAIS for Research Purposes *

- Privacy & Security Rule require 'role-based access' (RBA) controls
- Implementation is a balance between technology capabilities and policy/procedure
- No perfect RBA model as long as human behavior is part of the equation.
- Must only access records of research subjects



Access to Electronic PHI for Research

If not in direct patient care role:



- Study must entail recurring data needs
- Justification that it is not practicable to obtain PHI from other sources
- Access not granted for reviews preparatory to research
- Must be listed as a study team member on the approved IRB application

Process for Obtaining Access to E-PHI

Completion of the following:



- Research Request for Access Form → Completed by PI and Requestor; serves as attestation that pre-requirements have been met and conditions of access
- Review and Approval by the Privacy Officer → forwarded to the Security Coordinator
- Access set-up under 'Research View' → search by medical record number or two identifiers
- Cyclic/Response Auditing → determine accounts accessed and utilization of access



Clinical Trials

Budgets and Agreements
Role of the Research Foundation of
SUNY

SUNY Upstate Medical University
2/26/2009



Role of the Research Foundation

- A 1977 Agreement between SUNY and the RF provides the RF with sole authority to administer sponsored program activities.
- The RF is a private, nonprofit, 501(c)(3) educational corporation. It is not a state agency.
- Signatory on all contracts, agreements, amendments. (PI's are not authorized to sign)



CTO Services

- **Central contact point for SUNY Upstate researchers, coordinators and sponsors**
- **Match study opportunities with our researchers**
- **Coordinate and track clinical trial pre-award contract process**
- **Assist w/ Budget review and negotiation**
- **Maintain CTO website:
<http://www.upstate.edu/researchadmin/clintrials>**



Budgets

- **CTO Fact Sheet**
- **1x Fees**
- **Indirect Cost Rate**
- **Patient Costs (Professional & Technical Components)**



Clinical Trial Agreements

- **CTO receives the ‘Draft’ agreement/budget.**
- **CTO routes draft to RF ... constant contact while under legal review.**
- **RF review ... involves language content only, ie.. Indemnification, publication,etc.**

CTA - continued

- **When budget and agreement are finalized by all parties. CTO receives either hard copy/electronic copy for PI signature. (Coordinate w/ CRA to obtain signatures)**
- **Fully executed received, IRB approval obtained, CFS received - RF account established.**



Clinical Trials Office

Jennifer A. Rudes, Clinical Trials Officer
Kathleen E. Pazaras, Administrative Assistant
1212 Weiskotten Hall, Syracuse, NY 13210
315-464-5476 / FAX 315-464-5386
RudesJ@upstate.edu

- **Just give us a call – or come on in!**
- **Open Monday – Friday, 8:30 a.m. to 4:30 p.m.**

CLINICAL RESEARCH BILLING

Gerri Paparella
Research Billing Coordinator
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SUNY Upstate Medical University
2/26/2009

Discussion Areas

- Budgeting
- Billing Process



Budgeting



- Carefully review study protocol
- Identify all clinical services
- Differentiate between “routine services” (SOC) and “research services”
- Obtain pricing information for services to be paid from research grant
- Negotiate a realistic amount from sponsor

Budgeting for Clinical Services Tips

- Know where each service will be provided e.g., CRU, UH clinic, MSG private office
- Know specific CPT code for services
- Obtain professional and technical fee for services
- Factor an increase in costs for multi-year study

Obtaining Fee Information

- Hospital Services – (e.g. technical component for clinic visit or radiology, use of OR, lab services etc.) contact Anne Hoston in Financial Services- email cdmcoord@upstate.edu, phone 464-8384
- Professional Services- (e.g. UH clinic visit, radiology, ECG interpretation) contact the appropriate MSG

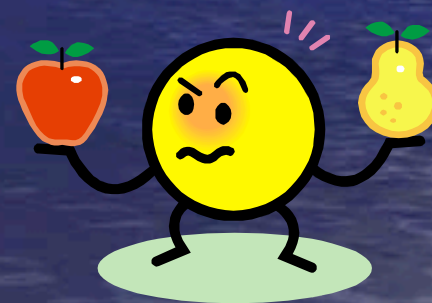
Five Budget Mistakes:

- Accepting the sponsor's proposed budget without quantify your costs
- Ignoring details of the protocol
- Not seeing case report forms before finalizing budget
- Not obtaining accurate fees (professional AND technical)
- Accepting any loss

Routine Medical Service
(Standard of Care) Billable to
Insurance

Vs

Research Service Billable to
Research Grant



Why is it important to delineate payment responsibility?

Billing insurance for payment of services that meets the guidelines established by Medicare, Medicaid or any other payer as "research" is fraudulent billing. Submitting a false claim to Medicare may result in substantial civil and possibly criminal law penalties, sanctions and exclusion from future participation.



Research Billing Process

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Why We have a Process

To address concerns of the government and to provide safeguards that medical services provided to subjects enrolled in research studies are billed to and paid by the appropriate entity

BILLING PROCESS

- Complete CFS (submit to CTO) or "Research Billing Form" (submit to PFS)
- Upon IRB approval & issuance of project/award number notify IMT
- Obtain CAIS access (CRA View). Complete Request for Access to Electronic Individually Identifiable Health Information (IIHI) for Research Purposes.
- As subjects are enrolled in the study flag each subject in CAIS
- At each study visit confirm subject is registered as "RESEARCH"
- Obtain access to HBI for "Weekly Research Billing Report"
- On weekly basis obtain/review "Research Billing Report"

(Process continued)

- For each subject on report indicate whether charges are “routine” (SOC) or “research”
- Submit your charge determination via email to Patient Access Services (within 7 days)
- You will be billed for hospital services per your determination
- Review hospital bill, if this corresponds to your review determination, complete Research Foundation P.O and submit to Research Accounts Payable for payment to the hospital
- If hospital bill is incorrect or if you have questions about the bill you received contact PFS (Bobbi McBride 464-8092).
- When study subject disenrolls or participation is terminated remove research flag in CAIS
- When study is finished but before research account is closed notify IMT & PFS

Research Billing Contacts

- Question about the price of a hospital service(s)- Ann Hoston
- Question about charges listed on “Weekly Research Billing Report”- Jackie Wheeler
- Question about a hospital bill you received – Bobbi McBride or Gerri Paparella
- Question about the research billing process-Gerri Paparella
- Question about the price of a professional service- Applicable Medical Service Group



OTHER QUESTIONS ???

Not Sure Who To Call !

Contact the Research Billing Coordinator @ 464-4824 or
email rschcood@upstate.edu

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Meet the Staff- Questions & Discussion

