Investigational New Drug (IND)/Investigational Device Exemption (IDE) Orientation

Responsibilities of IND/IDE Sponsor-Investigators

Sponsor-Investigator Outreach Group

AGENDA

1. DEFINITIONS AND APPLICABLE REGULATIONS
2. INVESTIGATIONAL NEW DRUG (IND) PROCESS
3. INVESTIGATIONAL DEVICE EXEMPTION (IDE) PROCESS
4. SPONSOR AND INVESTIGATOR RESPONSIBILITIES
5. RESOURCES AVAILABLE
6. CLOSING THOUGHTS AND Q & A
Definitions – Related to Drugs

- **Investigational New Drug** is a new drug or biologic used in a *clinical investigation*.

- **Drug**: articles used to treat, mitigate, cure, diagnose, or prevent a disease in man or other animals; and articles intended to affect the structure or any function of the body;

- **IND application**: An Investigational New Drug (IND) Application is a request for authorization to administer an investigational drug or biologic to humans or to administer a marketed (approved) drug for a new indication, dosage and/or patient population. An IND contains documentation submitted to the Food and Drug Administration (FDA) to allow for the conduct of a clinical study using an investigational drug.
Definitions related to Device

- **Investigational Device**: An investigational device is a medical device that is the *subject of a clinical study* designed to evaluate the effectiveness and/or safety of the device.

- **Device**: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, which is recognized in the National Formulary, or U.S. Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of a disease in man or other animals; and articles intended to affect the structure or any function of the body; (not through chemical means)

- **IDE application**: An Investigational Device Exemption (IDE) contains documentation submitted to the FDA to allow for the conduct of a clinical study using a significant risk device that is new or not approved for the proposed indication. An IDE covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, and reports.

Definitions (continued)

- **Sponsor** is an individual, company, academic institution, or other organization that takes responsibility for and initiates a clinical investigation. The sponsor is **not** the “funding organization” by FDA definitions.

- **Investigator** is an individual under whose immediate direction a drug/device is administered or dispensed.

- **Sponsor-Investigator** is an individual who both initiates and conducts an investigation. The requirements/responsibilities under this part include both those applicable to an investigator and a sponsor. This means s/he must register the trial with ClinicalTrials.gov. Sponsor-Investigators must also conclude or close investigations.
Responsibilities of IND/IDE Sponsor-Investigators

APPLICABLE REGULATIONS

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives
the FDA authority to regulate drugs and devices

Drugs/Biologics

➢ Code of Federal Regulations (CFR)

21 CFR Part 312: Investigational New Drugs

Devices

➢ Code of Federal Regulations (CFR)

21 CFR Part 812: Investigational Device Exemptions

Regulations (continued)

21 CFR § 11    Electronic Records; Electronic Signatures
21 CFR § 50    FDA (21 CFR) Protection of Human Subjects
21 CFR § 54    Financial Disclosure by Clinical Investigators
21 CFR § 56    Institutional Review Boards
21 CFR § 58    Good Laboratory Practices
21 CFR § 211, § 810    Good Manufacturing Practices
21 CFR § 820    Quality System Regulation
21 CFR § 1271    Good Tissue Practices
Responsibilities of IND/IDE Sponsor-Investigators

Regulations (continued)

Investigational Application

21 CFR § 312  IND Drugs and Biologics
21 CFR § 812  IDE Devices
21 CFR § 809  IVD In Vitro Diagnostics

Marketing Application

21 CFR § 601  BLA Biologics
21 CFR § 314  NDA Drugs
21 CFR § 814  PMA Devices

If a Federally Funded Study…

45 CFR Part 46 (DHHS) Protection of Human Subjects
Responsibilities of IND/IDE Sponsor-Investigators

Good Clinical Practice (GCP)

[link to www.fda.gov/oc/gcp/]

GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

Not Law, but FDA has embraced GCP, in general, but will enforce if protocol states that GCP will be followed.

(follow them…)

NOTE: GCP, GLP, GMP and GTP are not generic “good practice” but very specific standards of conduct.

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IND Applicability

• IND means an investigational new drug application; synonymous with Notice of Claimed Investigational Exemption for a New Drug;
• Investigational new drug means a new drug or biological drug that is used in a clinical investigation. It also includes a biological product that is used in vitro for diagnostic purposes.

• NOTE: IND application refers to route and dose as well as new indication or new population!

When is an IND Needed?

➢ Sponsor/Investigator intends to conduct a clinical study with an investigational drug

➢ Sponsor/Investigator intends to conduct a study with an approved drug, but…
  • in a new indication/population
  • dosage form OR
  • dosage range that is not covered in the current package insert (off label)
**When is an IND NOT Needed?**

**IND Exemption Criteria**

- Lawfully marketed in the US and:
  - Not intended to support a new indication;
  - Not intended to support a change in advertising;
  - Does not involve a factor that increases risk of use;
  - Conducted in compliance with IRB and Informed Consent requirements
  - Complies with the requirements for promotion and charging of investigational drugs.

Responsibilities of IND/IDE Sponsor-Investigators

For investigation-initiated Clinical Investigations

Does Your Study Implicate an IND Substantially to the FDA?

Note: The following worksheet is intended to help determine whether an IND is required prior to initiating your Investigator Initiated Clinical Trial.

Does your study meet ALL of the following criteria for IND exemption?

1. The investigation is not intended to be reported to the FDA as a well-controlled study to support a new indication for use.

2. The drug being used in your investigation is already marketed as a prescription drug product.

3. The investigation is not intended to support a significant change in the labeling of the drug product.

4. The investigation does not involve a route of administration that significantly increases the bioavailability of the drug product.

5. The investigation does not involve a dosage level that significantly increases the toxicity or decreases the effectiveness of the drug product.

Investigational Drug and/or Biological Name and Manufacturer:

IND Exemption Criteria | TRUE | FALSE
--- | --- | ---
1. | X | 
2. | X | 
3. | X | 
4. | X | 
5. | X | 

http://www.michr.umich.edu/services/regulatorysupport/miap

Guidance for Industry

IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer

January 2004

IND Application Path
(from FDA website)

**Responsibilities of IND/IDE Sponsor-Investigators**

**FDA Form 1571 (CFR 21 § 312.23(a)(1)(i-ix))**

- Contractual agreement between sponsor and FDA
- Contains name of person responsible for conduct and progress of the study (Item 14)
- Contains name of person responsible for the review and evaluation of information relevant to the safety of the drug (Item 15)
- Sponsor or sponsor’s authorized representative agrees to conduct investigation in accordance with all applicable regulatory requirements (Item 16)
FDA Form 1572 (CFR 21 § 312.53(c)(1)(i-viii))

- Contractual agreement between investigator and FDA
- Sponsor or sponsor’s authorized representative agrees to conduct investigation in accordance with all applicable regulatory requirements
- Contains name of person responsible for conduct and progress of the study, labs etc. in(Items 1-4)
- Contains name of IRB responsible for the review and approval of studies (Item 15)
- Lists staff who will assist the investigator (Item 6)
- Has CV of investigator and protocol outline attached
IND Maintenance (IND Amendments)

IND Amendment (Documents submitted to an active IND)

The 4 major types are...

- Protocol Amendments (21 CFR § 312.30)
- Information Amendments (21 CFR § 312.31)
- IND Safety Reports (21 CFR § 312.32)
- IND Annual Reports (21 CFR § 312.33)

Paper or electronic submissions are now possible.
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Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors

Significant Risk and Nonsignificant Risk Medical Device Studies

January 2006

Responsibilities of IND/IDE Sponsor-Investigators

Who Decides Whether a Device is SR or NSR?

- **Sponsor/Investigator**
  - Make the initial risk determination
  - Presents the IRB with this information

- **IRBs**
  - Required to determine whether the device study involves a SR or NSR device. For an investigational device that is considered to be non-significant risk, the IRB can approve the “IDE”.

- **FDA**
  - Available to help
  - Final arbiter

What is the sponsor’s responsibility to the IRB for NSR device studies?

- Provide reviewing IRB(s) with an explanation of why the device is not a SR
  - Description of device
  - Reports of prior investigations
  - Proposed investigational plan
  - Subject selection criteria

- Inform IRB if FDA determined the study to be NSR
Responsibilities of IND/IDE Sponsor-Investigators

 Significant Risk device is an investigational device that:

(1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

(2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;

(3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

(4) otherwise presents a potential for serious risk to a subject.

http://www.michr.umich.edu/services/regulatorysupport/miap
Examples of Significant Risk Cardiovascular devices

- Annuloplasty Rings
- Aortic and Mitral Valvuloplasty Catheters
- Arterial Embolization Devices
- Atherectomy and Thrombectomy Catheters
- Cardiac Assist Devices: artificial hearts, ventricular assist devices, intra-aortic balloon pumps, cardiomyoplasty devices
- Cardiac Bypass Devices: oxygenators, cardiopulmonary blood pumps, axial flow pumps, closed chest devices (except Class I cardiovascular surgical instruments), heat exchangers, catheters/cannulae, tubing, arterial filters, reservoirs
- Cardiac Mapping and Ablation Catheters
- Cardiac Pacemaker/Pulse Generators: antitachycardia, esophageal, external transcutaneous, implantable
- Cardiopulmonary Resuscitation (CPR) Devices
- Cardiovascular Intravascular (vena cava) Filters
- Coronary Artery Retroperfusion Systems
- Distal Embolic Protection Devices
- Extracorporeal Counterpulsation Devices
- Extracorporeal Membrane Oxygenators (ECMO)
- Implantable Cardioverters/Defibrillators
- Intravascular Brachytherapy Devices
- Intravascular Stents
- Laser Angioplasty Catheters
- Organ Storage/Transport Units
- Pacing Leads
- Percutaneous Conduction Tissue Ablation Electrodes
- Percutaneous Transluminal Angioplasty Catheters
- Replacement Heart Valves
- Transcatheter Cardiac Ocluders for atrial and ventricular septal defects, patent foramen ovale and patent ductus arteriosus
- Transmyocardial Revascularization, Percutaneous Myocardial Revascularization Devices
- Ultrasound Angioplasty Catheters
- Vascular and Arterial Graft Prostheses
- Vascular Hemostasis Devices

Non-significant Risk Devices

- Non-significant risk devices are devices that do not pose a potential for serious risk to the human subjects.
- A NSR device study requires only IRB approval prior to initiation of a clinical study. Sponsors of studies involving NSR devices are not required to submit an IDE application to FDA for approval. Submissions for NSR device investigations are made directly to the IRB of each participating institution.
- If the IRB disagrees and determines that the device poses a SR, the sponsor must report this finding to FDA within five working days [§ 812.150(b)(9)].
- FDA considers an investigation of a NSR device to have an approved IDE when IRB concurs with the NSR determination and approves the study.
Responsibilities of IND/IDE Sponsor-Investigators

IDE Exempt if:

- Used in accordance with indications/labeling
- Non-invasive diagnostic
- Consumer preference testing
- Solely for veterinary use
- Research on or with lab animals

What are the Requirements for NSR Device Studies?

- Abbreviated requirements per 21CFR 812.2(b)
  - Labeling
  - IRB approval
  - Informed consent
  - Monitoring
  - Record keeping
  - Reports
  - Prohibition against promotion.
- NSR studies are considered to have an approved IDE therefore no IDE to FDA
- Sponsors and IRBs do not have to advise FDA of NSR device studies
- IRBs must make a SR or NSR determination for every NSR study (21 CFR 812.66)
Responsibilities of IND/IDE Sponsor-Investigators

- Conduct study in compliance with GCP, protocol, & applicable IND/IDE regulations
- Ensuring informed consent of each subject is obtained (and retained)
- Personally conducting or supervising the investigation
- Protecting the rights, safety, and welfare of participants
- Ensure adequate medical care for the study participants
- Obtain necessary approvals from IRB
- Maintain and retain drug/device disposition and patient case history records
- Provide written reports to the IRB, as required
- Ensure changes are not implemented without prospective IRB/FDA approval
- Promptly report serious adverse events to the sponsor, IRB, and FDA
- Furnish Progress reports and Safety reports
- Ensure all study team members are informed about their obligations noted above
Responsibilities of IND/IDE Sponsor-Investigators

FDA RESPONSIBILITIES OF SPONSOR-INVESTIGATORS

IN ADDITION TO THE INVESTIGATOR RESPONSIBILITIES, SPONSOR-INVESTIGATORS ARE REQUIRED TO:

- Select qualified investigators at other institutions for multi-site trials
- Provide information to other investigators and study staff to ensure that the study is performed properly
- Ensure proper monitoring of the study
- Ensure the study is performed in accordance with the general investigational plan and protocol
- Submit necessary amendments/supplements to FDA
- Ensure that FDA and all participating investigators are promptly informed of significant new adverse effects or risks
- Maintain adequate records
- Maintain proper control of the study drug/device

Categories of Sponsor-Investigators at special risk for Compliance Problems

1. Very inexperienced investigators
2. Experienced clinical investigators who think they know the added responsibilities of sponsors
3. Very experienced investigators who have not adjusted to the modern era of FDA oversight
4. Sponsor-Investigator who have inherited an IND/IDE from someone else and so are not intimately familiar with the history of the trial
Labeling of Investigational Agents/Devices

21 CFR § 312.6 and § 812.5

- Immediate packaging of product
  - “CAUTION New Drug – Limited by Federal (or United States) law to investigational use”
  - “CAUTION Investigational device. Limited by Federal (or United States) law to investigational use.”

- The labels and labeling shall not
  - Bear false and misleading statements
  - Represent that the drug/device is safe and effective for purposes being investigated

Monitoring the Trial

- Clinical Trial Monitor examines quality of trial conduct:
  - Perform on-site (if indicated, also off-site) evaluations of trial-related activities
  - Identify deviations in protocol conduct
  - Review documents for Adverse Events
  - Drug accountability,
  - This includes monitoring of central support units like Research Pharmacy, (See form in Tab 4A of notebook) MCRU, MIAP etc.

- Extent and frequency of monitoring as appropriate:
  - Length, complexity, subject enrollment and other aspects of the trial; more than twice a year
Monitoring the Trial: DSMB

- Additional measure of human subject protection
- Evaluates accumulating data from a clinical trial
- Generally, established by the sponsor
  - Select members, should be independent
  - Charter generally written by sponsor, may have consultation by members
- Recommendations regarding the conduct and design of the trial (safety and efficacy)
- *Does not* visit sites or substitute for clinical trial monitors
- Send DSMB reports to the IRB for review

To Recap

- Monitoring is NOT
  - Your daily supervision
  - Weekly staff meeting
  - DSMB

- Monitoring is MORE LIKE an audit:
  - Think of when industry sponsors send monitors to your site to check over all of your records, etc.
Responsibilities of IND/IDE Sponsor-Investigators

Safety Reporting Via MedWatch

How to report

- **Patient/Subject**
- **Product info** (drug, biologic, device, etc.)
- **Description of Event or Problem**
- **Relevant tests/labs**
- **Reporter**

**Submission Timing**

<table>
<thead>
<tr>
<th>Submission</th>
<th>Timing</th>
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<tbody>
<tr>
<td>Amendment - New protocol</td>
<td>After IRB approval</td>
</tr>
<tr>
<td>Amendment - Changed protocol</td>
<td>At time of change</td>
</tr>
<tr>
<td>Amendment - New investigator</td>
<td>Within 30 days of being added</td>
</tr>
<tr>
<td>Amendment - Information</td>
<td>At time of occurrence</td>
</tr>
<tr>
<td><strong>IND safety report</strong></td>
<td>Within 15 calendar days of receiving notification</td>
</tr>
<tr>
<td><strong>Annual report</strong></td>
<td>Within 60 days of anniversary of IND</td>
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<tr>
<td>Withdrawal of IND</td>
<td>At time of withdrawal</td>
</tr>
<tr>
<td>Discontinuation of investigation</td>
<td>Within 5 working days of discontinuance</td>
</tr>
<tr>
<td>Financial disclosure report</td>
<td>At time of change</td>
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</table>
### FDA Submissions - Responsibilities To FDA for an IDE (812.150)

<table>
<thead>
<tr>
<th>Submission</th>
<th>Timing</th>
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<tbody>
<tr>
<td>Supplement - New protocol</td>
<td>After IRB approval</td>
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<tr>
<td>Supplement - Changed protocol</td>
<td>At time of change</td>
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<tr>
<td>Supplement - New investigator</td>
<td>Within 30 days of being added</td>
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<tr>
<td>Supplement - Information</td>
<td>At time of occurrence</td>
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<tr>
<td>Unanticipated Adverse Device Effects</td>
<td>Within 10 working days of receiving notification</td>
</tr>
<tr>
<td>Recalls and Device Disposition</td>
<td>Within 30 days</td>
</tr>
<tr>
<td>Progress/Annual report</td>
<td>At regular intervals (at least yearly)</td>
</tr>
<tr>
<td>Withdrawal of IRB or FDA approval</td>
<td>Within 5 working days of receipt of notice</td>
</tr>
<tr>
<td>Completion or Termination of investigation – Final Report</td>
<td>Within 30 days</td>
</tr>
</tbody>
</table>

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm
Responsibilities of IND/IDE Sponsor-Investigators

Most Common Violations Noted by the FDA, during inspections of clinical trials, in general*

- Failure to follow the protocol
  *example: Required testing is incomplete*
- Recordkeeping errors
- Informed consent problems/issues

* Includes industry and other sponsored trials as well as sponsor-investigator trials

Most Significant Violations noted by the FDA, during inspections of clinical trials, in general

- Enrollment of ineligible subjects
- Violation of protocol affecting safety
- Extensive data corrections and questionable changes
- Inadequate oversight of study personnel
  - Inappropriate delegation of authority
  - Poor oversight of sites
- No Informed consent
- Failure to communicate with IRB
General Overall Research-related Warning Letters

**Frequency of Issues in Past Warning Letters**

- Consent
- IRB
- Protocol
- Records
- AEs
- Device Accountability
- Investigator Compliance
- Monitoring

Notice frequency of consent, records and protocols! Caution: The responsibility for S-Is conducting multi-site studies is enormous.

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Findings From Recent Warning Letters To Sponsor-Investigators

<table>
<thead>
<tr>
<th>Sponsor Investigator Observations</th>
<th>IDE Study</th>
<th>IND Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaware he/she was Sponsor-Investigator</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to ensure proper monitoring</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Failure to obtain a signed investigator statement / Form FDA 1572</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Failure to give each investigator an investigator brochure</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to review and evaluate the evidence relating to the safety and effectiveness of the drug as its obtained from the investigator</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to submit an annual report of the investigation</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug/device</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Failure to maintain complete and accurate records showing any financial interests of investigators</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to maintain complete and accurate records showing any financial interests of investigators</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Failure to obtain sufficient accurate financial disclosure information from each participating investigator</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Failure to prepare and submit current investigator list to FDA at 6-month intervals</td>
<td>X</td>
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Responsibilities of IND/IDE Sponsor-Investigators

Resources Available at U of M to Assist With Your IND or IDE
MICHR IND/IDE Investigator Assistance Program (MIAP)

MIAP Established to Provide Comprehensive:

- Regulatory Expertise...
- Regulatory Support...
- Regulatory Education Services...

To Faculty Investigators and their Team Involved In FDA Regulated Clinical Research At The University of Michigan

MIAP SERVICES OVERVIEW

- Agent/Device development strategy consultation
- IND/IDE consultation including determination of need for IND or IDE
- Pre-IND FDA meeting requests and support
- Protocol development
- IND/IDE application preparation and submission
- Clinical hold response preparation/submission
- Communication with the FDA, IRB and other regulatory bodies

- IND/IDE “maintenance” support
  - Safety report submissions
  - Protocol amendments to the FDA
  - Annual reports to the FDA
- Clinical Trial Monitoring
  - Investigators meetings
  - Site initiation visits
  - Interim site monitoring visits
  - Study close out activities
MIAP is here to help with INDs and IDEs

**MIAP contacts:**

Kevin Weatherwax, CCRC, CCRA  
Manager, Project Management and Monitoring Core;  
MICHR IND/IDE Assistance Program (MIAP)  
Michigan Institute for Clinical and Health Research (MICHR)  
University of Michigan Health System  
NCRC Bldg # 400  
2800 Plymouth Road  
Ann Arbor, MI 48109-2800  
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Pager: 734-936-6266, #9912  
Fax: 734-998-7318  
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Responsibilities of IND/IDE Sponsor-Investigators

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Judy Birk, JD, IRBMED Director
Phone: 734-647-7615
Fax: 734-763-1234
Pager: jbirk@umich.edu

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Clinical Pharmacists:
Kim Redic, PharmD (manager)
Anna Christich, PharmD
Rivka Siden, PharmD
Amy Skyles, PharmD
Helen Tamer, PharmD
Susan Weadock, PharmD

Phone: 734-936-7469
Fax: 734-647-9302
Pharm-IDS-RPH@med.umich.edu

Drug shipment address:
University of Michigan Hospital
Department of Pharmacy Services-RP
UHB2D301, SPC 5008
1500 E. Medical Center Drive
Ann Arbor, MI 48109
Attention: Research Pharmacy

• Remember Monitoring form Tab 4A
Other Important Services

Biomedical Engineering Unit (BEU) provides critical services 24/7. It provides support for all patient care equipment including consultation (i.e., device selection, installation, applications and optimum service modes), periodic equipment inspections, in-service training, and corrective maintenance. It also provides preventative and corrective maintenance for clinical support equipment. For more information, contact Ron McCarty, Clinical Engineer, at 734-615-3502.

• UM Cancer Center Tissue Procurement Service (TPS) issues letters of approval necessary before obtaining IRB approval for research involving tissue. (www.pathology.med.umich.edu/giordanolab.tps.htm)

At this website you can review options for research involving tissue procurement, whether as frozen tissues, paraffin blocks or other tissue-based research.

Q & A

Thanks for your attention!