

RESEARCH PROTOCOL REVIEW:

Guidelines and Policies for Investigators

Indiana University East
Institutional Review Board

PREFACE

Indiana University and Indiana University East have always exercised great care in their protection of subjects, investigators and the environment when conducting research. This concern predates today's extensive federal regulations. The information presented in this Guide is a summary of procedures that are necessary to demonstrate the University's assurance to the federal government that our research procedures are consistent with the highest ethical standards. The complete text of this assurance is available on the WWW at <http://www.iupui.edu/%7Eeresgrad/spon/assurance.htm> All faculty are urged to acquaint themselves with the responsibilities agreed to in this assurance, regardless of whether or not they are currently engaged in research with human subjects.

Documents providing both historic perspective and current operational policy for the University and the campus research risk review boards have been carefully referenced. For additional information and assistance, investigators are encouraged to contact members of the IUE IRB or the staff of Research and Sponsored Programs.

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RESEARCH PROTOCOL REVIEW
GUIDELINES AND POLICIES FOR INVESTIGATORS
INDIANA UNIVERSITY EAST

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GUIDELINES AND POLICIES FOR INVESTIGATORS
INDIANA UNIVERSITY EAST

INTRODUCTION

In recent years, federal government and other agencies have significantly increased their regulation of sponsored research programs. The following guidelines are provided to inform investigators about some of the regulations and policies with which they must comply. These documents provide a brief summary of some of the important guidelines governing the conduct of research involving humans, animals, or recombinant DNA. These policies apply to all research regardless of whether or not it is funded by the University or with external funds. It is critical that all faculty members who plan to conduct research be familiar with these requirements since failure to adhere could have serious consequences for both the individual investigator as well as the institution. The required documentation and further guidance in any of these areas can be obtained by contacting Academic Affairs at 973-8239, Whitewater Hall, Room 262.

All research conducted at Indiana University East (IUE) involving humans, animals, or recombinant DNA must be reviewed and approved by the respective campus research risk review boards. These boards review research plans and monitor ongoing research to insure full compliance with federal regulations and University policies. Protocol submission and requests for approval of research to each of these boards involves *separate procedures*. Transmittal of a proposal for external funding does not constitute a request for protocol review. Therefore, it is important that the investigator initiate each procedure well in advance of any deadlines to allow adequate time for the review and approval process.

All research documentation is subject to federal audit. Since these requirements and, consequently, the application forms, undergo constant revision, it is important to make sure that all research submissions are completed on the current forms.

Most research conducted on behalf of IUE must be under the direct supervision of a faculty member who is responsible for insuring that the research is conducted in accordance with all applicable institutional policies, governmental regulations, funding agency requirements, and contractual commitments. Refer to Appendix A for eligibility criteria for research submissions.

Academic Affairs maintains a library of resource materials available to faculty. These materials include videotapes, manuals, and publications on a variety of topics pertaining to research.

I. RESEARCH INVOLVING HUMAN SUBJECTS

A. RESEARCH REQUIRING REVIEW

The University maintains an assurance with the Department of Health and Human Services (DHHS) which requires that *all* research projects involving human subjects conducted by an employee of Indiana University be reviewed and approved by an Institutional Review Board (IRB) *prior* to initiating any research. Research is defined by DHHS as "a systematic investigation to develop or contribute to generalizable knowledge" (45 CFR 46). Such studies may involve various invasive or noninvasive procedures, removal of body tissues or fluids, administration of drugs, exposure to various forms of radiation, alteration of diet or environment, simple observation, administration of questionnaires, or review of records. If an investigator is uncertain about whether research requires IRB review, the chair of the IRB should be contacted for clarification.

Following are different types of research that are subject to committee review:

1. Exempt or Expedited Research Reviews

Research activities involving minimal risk will be reviewed by a subcommittee of the IRB when they qualify for exempt or expedited review (these forms are included in IRB Instruction Packets). These activities include research such as review of existing records, collection of pathological or diagnostic specimens, survey or interview procedures, educational tests, observation of public behavior, recording of data from subjects, etc. It is important to review these checklists for specific qualification requirements. The preliminary determination that a research project is eligible for exempt or expedited review is made by the principal investigator (PI); however, if upon review by the IRB it is determined that the research does not qualify as exempt or expedited research, it must then be submitted as full review in accordance with the requirements and deadlines listed in the instruction packet.

2. Full Review

The IRB Instruction Packet outlines specific documentation necessary for this review. The IRB meets on a regular basis to review all documents related to research projects.

3. Classroom Research

Classroom research that is conducted only as a course assignment may or may not be subject to IRB review (see Appendix B). Any classroom research that may place the subjects at risk is still subject to IRB review.

4. Program Evaluation

Routine evaluation of University programs, including teaching, usually is not considered research and, therefore, would not be subject to IRB review. However, if the results of the evaluation are published or presented for use outside of the University setting, the program is subject to IRB review.

5. One-Time Emergency Use

A situation, which in the judgment of a physician, calls for the emergency use of an investigational drug or biologic may be exempt from IRB review provided that it is a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. The FDA has clarified this further stating that the one-time use means "**one single use (one regimen) in one patient at the institution.**" This single emergency use of an IND is exempt from prospective IRB approval provided that

the use is reported in writing to the IRB within five (5) working days. The IRB office should be contacted at 274-8289 *prior* to considering the use to determine whether that particular agent has been previously used at this institution. **Any subsequent use of the investigational product at the institution is subject to IRB review (see Appendix C).** It should be noted that, according to OPRR regulations, whenever emergency care is initiated without prior IRB review and approval, the patient may not be considered to be a research subject, nor may the outcome of the care be included in any report of research activity. Prospective research approvals allow subjects to be enrolled in studies without unnecessary delays at the time when treatment is most critical.

B. PROTOCOL REVIEW PROCESS

1. Instructions and Forms for Completing Research Submissions

The person responsible for overseeing a research project (principal investigator or PI) involving human subjects must insure appropriate committee review before undertaking any project activities. The research submission and all related documents, e.g., amendments, continuing reviews, etc., must be signed by the principal investigator. Forms for submission and instructions for their completion can be obtained from the Academic Affairs office. Research applications and any related documents are to be forwarded to this office where they will be directed to the IRB committee for review.

To facilitate approval of the research submission, it is necessary for all relevant information to be completed as outlined in the instruction packet. The protocol must include a clear and concise explanation of the proposed research. Particular attention should be paid to the informed consent statement. The informed consent statement must be written in simple, clear language (8th grade level) that is intelligible to the average layman with no prior scientific knowledge, i.e., all technical and medical terminology should be defined.

2. Deadlines

The deadlines for submitting full review research protocols are indicated in the instruction packet. These deadlines are strictly adhered to. Early submissions will increase opportunity for discussion and resolution of issues in advance of investigator's deadline. Incomplete submissions will not be accepted for review, and proposals submitted after the deadline will not be reviewed until the following meeting. Therefore, investigators may minimize the time it takes to receive final approval by carefully preparing the protocol so that it meets the guidelines of the IRB on its first submission.

3. Committee Reviews

When human subjects are involved in a research project in any way, a "protocol" (research study or submission) must be submitted to the IRB. All such research projects must be approved by the IUE Institutional Review Board (IRB) or appropriate subcommittee prior to initiation of the research.

4. Committee Actions

The review committee may take one of four actions in regard to proposed protocols and consent forms:

- a) **Final Approval** - The PI may commence the research only after receiving written approval indicated by a signed copy of the "Documentation of Review and Approval" with a cover letter outlining the additional responsibilities for conducting research at IUE.
- b) **Provisional Approval** - The PI must respond in writing to provisions requested by the board **and** receive final approval prior to initiating the research.
- c) **Tabled** - Deferred for reconsideration at a subsequent meeting after PI has responded to modifications requested by the board.
- d) **Denied** - The PI will be notified in writing of reasons for disapproval.

Upon completion of the review, the investigator will receive a written response from the IRB shortly after the meeting. Any questions raised by the committee must be responded to in writing within sixty (60) days (provisionally approved or tabled studies). No work may be initiated until written final approval is received from the IRB.

5. Requirements of Funding Agencies

A number of funding agencies, including the National Institutes of Health (NIH), require IRB certification to be submitted with the proposal before they will review grant applications involving human subjects. Since revision of submitted protocols is frequently required prior to approval, it is essential that protocols for review by the IRB be submitted in a timely fashion, preferably at least six weeks in advance of the grant application deadline.

C. RESPONSIBILITIES OF THE INVESTIGATOR

1. Amendments and Continuing Reviews

It is the responsibility of the principal investigator to report *any* proposed changes whatsoever to the research study via an amendment form. In addition, the status of the study must be filed with the IRB on at least an annual basis, depending upon the degree of risk, via a continuing review form. The IRB will generate the continuing review forms for completion. However, this form must also be completed if an approved study will not be initiated or is discontinued for any reason in the interim. This is particularly true when an investigator leaves the University. Other specific requirements are outlined in the instruction packet.

2. File Maintenance

It is important for the investigator to keep a copy of every document related to the research study that is submitted to the IRB. For audit purposes, these documents must be kept for at least **three** (3) years after terminating the study.

3. Advertisements

If the proposed research is regulated under Food and Drug Administration (FDA) requirements, i.e., investigational drugs or devices will be used, the written advertisements used to recruit research subjects must be included along with the mode of communication at the time of study submission. If advertising will be used at a later time and is not submitted with a new study, an amendment form must be completed. These advertisements must be reviewed and approved by the IRB prior to their use.

4. Reporting of Adverse Reactions

Any adverse experience associated with the use of experimental drugs or devices that is both serious and unexpected must be reported to the IRB within three (3) working days after the incident. Specific reporting requirements can be found in Appendix D. Most sponsors of drug or device research also require prompt reporting to the clinical monitor. At the discretion of the IRB, the study may be suspended until it is assured that continuing the research will not jeopardize future subjects.

5. Updated Investigational Brochures, Progress Reports and Final Reports

Three copies of sponsor updates or reports on progress must be provided to the committee with the investigator's written assessment of the report, summarizing any changes and their significance to the study.

D. RESEARCH CONDUCTED AT OTHER CAMPUSES OR INSTITUTIONS

1. Proposal Routing and Protocol Review Procedures

Research studies are normally reviewed on a campus specific basis, with the exception of the School of Medicine. Campus specific is defined as the campus where the faculty applicant is located. All School of Medicine protocols, including the Regional Centers for Medical Education, will be reviewed by the Indiana University Purdue University Indianapolis (IUPUI) IRBs (see Appendix E). Other variables may occasionally require different review procedures be used than those indicated on this chart. That decision will be made by the research administration offices representing the campuses involved.

2. Cooperating Departments or Institutions

If it is anticipated that another department may be involved in the research, include a co-investigator from each cooperating department or a letter of cooperation indicating the department's willingness to be involved in the study. If the study will be conducted with another institution, include a letter of cooperation from that institution.

3. Multicenter Studies

A multicenter protocol in the format agreed upon by the multicenter group may be accepted by the IRB. However, the informed consent statement must conform to the format required by the IUE IRB.

E. MISCELLANEOUS

1. Studies Involving Special Populations

Federal regulations require additional protection for special subject populations involved in research including minors, prisoners, mentally disabled, pregnant women, fetuses, abortuses, and economically or educationally disadvantaged. These requirements are discussed in 45 CFR 46 and may be obtained at <http://grants.nih.gov/grants/oprr/humansubjects/45cfr46.htm>.

2. Investigational Drug and Device Studies

Research involving investigational drugs or devices involves special responsibilities on the part of investigators. These responsibilities are outlined in Appendix F.

3. Hazardous Chemicals

If the research involves infectious wastes or hazardous chemicals, contact Charles Brown, Physical Facilities at 973-8218.

4. Radiation and/or Radioactivity

If the research involves the use of radiation and/or radioactivity in addition to what is already used for standard clinical treatment *or* the subject would receive radiation exposure only due to participation in the research, appropriate approval must also be obtained. Further information, contact Charles Brown, Physical Facilities, at 973-8218.

INDIANA UNIVERSITY EAST
INSTITUTIONAL REVIEW BOARD
GUIDELINES FOR RESEARCH RISK PROTOCOL REVIEW

In addition to the protection of subjects and others associated with research, two primary factors that must be considered when research risk review boards assume responsibility for reviewing research protocols are the liability involved by conducting the research and the service provided by the review to the mission of our campus.

The institutional assurance with the Office for Protection from Research Risks and applicable federal regulations require that all research involving human subjects, animals, or recombinant DNA, be reviewed by the appropriate review committee. This applies to all research, whether funded or not. When research involves IU facilities and subjects, but is not conducted by IU employees, it will be subject to review.

Consideration for eligibility will include the following criteria:

- 1) In all cases, persons submitting protocols must be either:
 - ? IU employees (anyone receiving compensation for performing responsibilities on behalf of the University); includes adjunct faculty who receive compensation.
 - ? Persons conducting research as a part of their University responsibility, e.g., VA paid employees with non-paid IU appointments.

Other eligibility considerations (not included above) are as follows:

- 1) Students whose research is submitted to the Board by a faculty member serving as project director.
- 2) The eligibility of emeritus faculty and faculty on sabbatical will be considered on a case-by-case basis. Among the factors to be considered are location and nature of the research, relation of research to the faculty member's regular University assignment, etc.
- 3) Adjunct faculty (not compensated) are eligible when the research is a function of the adjunct relationship and for which the school assumes responsibility.
- 4) Other special status appointments, e.g., non-paid visiting and non-paid clinical appointees, alone should not be construed as entitlement to a committee review.
- 5) When an IU employee is doing research on behalf of another organization, e.g., in a consultant relationship with compensation provided by the other institution or in a student status at another institution (i.e., not IU), the responsibility for the review is with the other organization.
- 6) **FOR THE SCHOOL OF MEDICINE ONLY:** The principal investigator responsible for a research project must have a faculty status (IU faculty appointment). This includes clinical and scientist ranks, visiting professors and visiting scientists; however, it does not include post docs, residents, interns, grad students, research associates and assistants and students. (Those ineligible may request review if the protocol is submitted by a faculty member.)
- 7) Research may be conducted under collaborative arrangements. The research may require an inter-institutional agreement.
- 8) Research conducted by other organizations may be arranged by Research & Sponsored Programs when the review is provided as a contracted service.

INDIANA UNIVERSITY EAST
INSTITUTIONAL REVIEW BOARD

STUDENT RESEARCH INVOLVING HUMAN SUBJECTS

As defined in CFR Title 45, Part 46 (Department of Health and Human Services policy for Protection of Human Research Subjects), "research" is "a systematic investigation designed to develop or contribute to generalizable knowledge." Since classwork assignments are usually not intended to, or likely to lead to generalizable results, the IRB does not normally include these projects under its operational definition of research. Rather, they are viewed as practicum resources of teaching. Student research which may place subjects at risk, whether conducted as a course assignment or not, or which is undertaken with the intent of adding to generalizable knowledge, is subject to IRB review.

Student projects which meet the following criteria, will not require review by the IRB:

1. Research practica (usually in the form of course-related research projects and/or directed studies), the objective of which is to provide research experience for the student, and
2. Which do not involve physically or psychologically invasive, intrusive, stressful procedures or, in the judgment of the instructor, have the potential for placing subjects at more than minimal risk.*

Classroom and independent study projects, theses, dissertations, or any research that may place the subjects at risk are still subject to IRB review. In clinical courses, subjects will be considered to be at risk if the procedures used and/or the questions asked do not fall under what is construed as being ordinary practice. Consideration should be given to the research setting when assessing risk. For example, hospitalized patients may be at greater risk than the non-hospitalized population.

Special populations including pregnant women, fetuses, prisoners, or human in vitro fertilization are considered vulnerable research subjects and, therefore, would be subject to IRB review. The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with minors except for research involving observations of public behavior when the investigators do not participate in the activities being observed.

The following procedures are to be followed for all student research projects:

1. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project may fall in the category of research as explained above, thus requiring IRB review.
2. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge or that it may involve risk, the project must be reported on the appropriate forms provided by the IRB for its review and approval prior to initiating the research. These forms may be obtained from Research & Sponsored Programs. A faculty member must be listed as the principal investigator responsible for overseeing that any student research submitted to the IRB complies with federal regulations and University policies.

*Minimal Risk is defined by DHHS policy for the Protection of Human Research Subjects--45 CFR 46 subpart A--as "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

STUDENT RESEARCH INVOLVING HUMAN SUBJECTS

3. If there is any doubt as to whether the project should be reviewed by the IRB, Research & Sponsored Programs is to be contacted for assistance. If the Research & Sponsored Programs staff or the IRB believes that a particular project is subject to regular IRB review, the proposed project must receive IRB review.
4. In the event IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Consequently, the researchers should adhere to ethical standards and use informed consent when appropriate.
5. If it is anticipated that the study will either be funded (regardless of source) and/or published or presented, IRB approval **must** be obtained.

GUIDELINES FOR EMERGENCY USE OF A TEST ARTICLE

- 1) Emergency use is defined as the use of a test article (e.g., investigational drug) on a human subject in a life threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain Institutional Review Board (IRB) approval.
- 2) Emergency use of an investigational test article will ordinarily be allowed only once by an investigator; subsequent use will require full IRB review. Ad hoc review of investigational drug protocols will not be allowed.
- 3) If a test article is used in an emergency situation, the investigator is responsible for providing the following information within five (5) working days to the Board:
 - a. The name of the drug (trade name, generic name, and chemical name if available)
 - b. IND number
 - c. Name of sponsor
 - d. Indications for use including justification of the emergency situation
 - e. A copy of the informed consent which was used.
- 4) The investigator is required to obtain informed consent from the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
 - a. The subject is confronted by a life-threatening situation necessitating the use of a test article.
 - b. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the subject.
 - c. Time is not sufficient to obtain consent of the subject's legal representative.
 - d. No alternative method of approved or generally recognized therapy is available that provides equal or greater likelihood of saving the life of the subject.
- 5) If in the investigator's opinion immediate use of the test article is required to preserve the life of the subject and if time is not sufficient to obtain the independent determination required, the determination shall be made by the clinical investigator. The use of the article must be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation within five (5) working days. The clinical investigator shall notify the IRB within five (5) working days after the use of the test article.

**INVESTIGATOR REQUIREMENTS FOR REPORTING ADVERSE REACTIONS
to the
INSTITUTIONAL REVIEW BOARD (IRB)**

IMPORTANT:

?? REPORTING REQUIREMENTS FOR ADVERSE REACTIONS SHOULD INCLUDE ONLY THOSE REACTIONS ASSOCIATED WITH THE USE OF THE DRUG OR DEVICE WHICH ARE BOTH **SERIOUS AND UNEXPECTED**.

?? IN ADDITION TO THE FORMS REQUIRED FOR FDA OR STUDY SPONSOR FORMS FOR ADVERSE REACTIONS, YOU MUST ALSO SUBMIT THE FOLLOWING:

1. A cover letter containing the following:
 - a. Study number and title to which the adverse reaction relates.
 - b. Your assessment of the report outlining specific changes and the significance/relevance to the study, e.g., changes in risk/benefit ratio.
 - c. If the report is from the drug sponsor, have you observed similar adverse effects in your study?
 - d. Do you believe the informed consent statement should reflect changes in the potential risk involved? If other research studies involve the use of this drug, amend the informed consent statements of those studies, with the modifications highlighted to reflect the potential risk.
 - e. Has this adverse reaction been reported previously? If so, do you consider the frequency unusually high?
 - f. Identification of the principal investigator and the principal investigator's signature.
2. If the adverse reaction results in a revision of the informed consent statement, a study amendment form and two copies of the revised consent form must also be submitted.

?? FOR REASONS OF PATIENT CONFIDENTIALITY DO *NOT* INCLUDE PATIENT NAMES IN YOUR ADVERSE REACTION REPORT. YOU MAY INSTEAD SUBSTITUTE A CODE.

?? THIS REPORTING REQUIREMENTS OF OTHERS (e.g., sponsors, FDA, hospital) IS NOT SATISFIED OR PRECLUDED BY THE REPORT.

?? NEWLY DISCOVERED INFORMATION AND UNANTICIPATED RISKS MAY REQUIRE THE IRB TO REVIEW YOUR PROTOCOL MORE THAN ONCE A YEAR.

Reporting (Terms are defined on the reverse side):

1. Any adverse experience *associated with the use of the drug* that is both *serious and unexpected* must be reported to the IRB within 3 working days after the incident.
2. Events that do not fall into the 3-day category should be noted in the continuing review.

INVESTIGATOR REQUIREMENTS FOR REPORTING ADVERSE REACTIONS

Please contact Academic Affairs at 973-8239 if you have any questions.

DEFINITIONS: The following terms are defined in Food and Drug Administration, HHS 21 CFR 312.32:

- "*Associated with the use of the drug*" means that there is a reasonable possibility that the experience may have been caused by the drug.
- "*Serious adverse experience*" means any experience that suggests a significant hazard, contraindication, side effect, or precaution. With respect to human clinical experience, a serious adverse drug experience includes any experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose. With respect to results obtained from tests in laboratory animals, a serious adverse drug experience includes any experience suggesting a significant risk for human subjects, including any finding of mutagenicity, teratogenicity, or carcinogenicity.
- "*Unexpected adverse experience*" means any adverse experience that is not identified in nature, severity, or frequency in the current investigator brochure; or, if an investigator brochure is not required, that is not identified in nature, severity, or frequency in the risk information described in the general investigational plan or elsewhere in the current application, as amended.
- "*Life-threatening*" means that the patient was, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more serious form might have caused death.
- As outlined in 21 CFR 812.3(s)(s) "*Unanticipated adverse device effect*" means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigation plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

INDIANA UNIVERSITY
 PROTOCOL REVIEW PROCEDURES

HUMAN SUBJECTS

<u>Campus or Unit</u>	<u>Proposal Transmittal</u>	<u>Initial Protocol Review</u>	<u>Certification of Status</u>	<u>Continuing Reviews, Amendments, and All Similar Documentation</u>	
			<u>At Proposal Submission (Pending/Approved)</u>	<u>Follow-up, Approvals and Renewals</u>	
All IUB*	IUB	IUB	IUB	IUB	IUB
Medical Sciences/IUB	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
All IUPUI	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Regional Centers for Medical Education**	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Columbus Center	IUPUI	IUPUI	IUPUI	IUPUI	IUPUI
Purdue University Pharmacy at IUPUI	Purdue	IUPUI	Purdue	Purdue	IUPUI
Regional Campuses	IUB	Regional Campuses	IUB	Regional Campuses	Regional Campuses
Central System	IUB	IUB	IUB	IUB	IUB

NOTE: This chart applies to all research or training protocols involving human subjects, for funded or non-funded projects. Active committees are found only on campuses where needs exist.

PROTOCOLS INVOLVING HUMAN SUBJECTS WILL BE REVIEWED ON A CAMPUS SPECIFIC BASIS WITH THE EXCEPTION OF THE SCHOOL OF MEDICINE. All School of Medicine protocols, including the Regional Centers for Medical Education, will be reviewed by the IUPUI IRB. Campus specific is defined as the campus where the faculty applicant is located. Other variables may require that a decision to modify a normal procedure be made by the campus research administration offices representing the campuses involved.

* Except for Medical Sciences

** Lafayette and Muncie Centers are not processed through IU

INVESTIGATOR COMMITMENTS IN DRUG AND DEVICE STUDIES

Principal investigators are reminded of the following commitments which they agree to in carrying out research studies with drugs and/or devices.

1. The agreement to conduct the study(ies) in accordance with the relevant, current protocol(s), only making changes in a protocol after notifying the sponsor (if study is from a sponsor) and receiving the written approval of the IRB. Justification for exception to this commitment must involve protection of the safety, rights, or welfare of study participants
2. The agreement to personally conduct or supervise the described investigation(s).
3. The agreement to inform any patient or subject, or any person used as controls, that the drugs or devices are being used for investigational purposes and assure that the requirements relating to the obtaining of informed consent and IRB approval, as required by federal regulations, are followed.
4. The agreement to report adverse experiences that occur in the course of the investigation(s) to the sponsor and the IRB in accordance with current federal regulations.
5. The agreement to read and understand all of the information on the drug and/or device provided by the sponsor.
6. The agreement to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.
7. The agreement to maintain adequate and accurate records in accordance with current federal regulations and in a manner which will facilitate reconstruction of study events by the IRB should the necessity for an in-depth review arise. This agreement implies that such records will be made available for inspection both under current federal law and by the IRB
8. The agreement to notify the sponsor if the IRB finds that a device presents a significant risk to the subjects.
9. The agreement to insure that initiation of the study(ies) and all changes to the study(ies) will have prior IRB approval and the agreement to report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. The only changes which can be made without prior IRB approval are those found necessary to eliminate apparent immediate hazards to human subjects.

Note: The above commitments, although not taken from a specific federal or state regulation, are based upon section (9) of Statement of Investigators (Title 21, Code of Federal Regulations (CFR) Part 312) and convey the IRBs general overview of principal investigator responsibilities. These general guidelines are not meant to supersede any specific state or federal regulation.

REFERENCES

These documents may be reviewed in the office of Academic Affairs.

HUMAN SUBJECTS RESEARCH

1. Indiana University Assurance of Compliance with Department of Health and Human Services (DHHS) Regulations on the Protection of Human Subjects.
2. "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.
3. DHHS, "Protection of Human Subjects," 45 Code of Federal Regulations (CFR) 46, Revised June 18, 1991.
4. Food and Drug Administration (FDA), "Protection of Human Subjects," Title 21 CFR Part 50, January 27, 1981.
5. FDA, "Institutional Review Boards," Title 21 CFR Part 56, January 27, 1981.
6. FDA, "Investigational New Drug Application," Title 21 CFR Part 312, March 19, 1987.
7. FDA, "Investigational Device Exemptions," Title 21 CFR Part 812, January 18, 1980.