

INDIANA UNIVERSITY SOUTHEAST

RESEARCH POLICY MANUAL

Office of Academic Affairs

Fifth Edition

2005

## TABLE OF CONTENTS

	PAGE
I. Grant Support	3
A. Internal Support	3
1. Support from IUS	3
2. Support from Indiana University	4
3. Support for IUS Students	5
B. External Support	6
1. Application Procedures	6
2. Preparation of Proposals	6
3. Human and Animal Subjects	6
4. Hazardous Materials	6
C. Technology Transfer	6
II. Policies Governing Research, Grants, and Sabbaticals	7
A. Grant Policies and Administration—General	7
B. Specific Policies and Guidelines	7
1. Summer Faculty Fellowships	7
2. Grants-in-Aid	8
3. Second Meeting Travel Grants	9
4. Faculty Development Travel Grants	9
5. Quick Response Mini Grants	10
6. Improvement of Teaching Grants	10
7. Software	11
C. Sabbatical Leaves of Absence	11
1. Purpose	11
2. Terms of Leave	12
3. Eligibility	12
4. Scheduling	13
5. Application Procedure	13
D. External Grants	13
1. Timetable for Submission	14
2. Institutional Information	14
3. Budget Preparation	15
4. Facilities and Administrative Costs	16
5. Matching Funds	16
E. Protection of Research Subjects	17
1. Human Subjects Policy	17
2. Animal Subjects Policy	18
F. Research Misconduct and Fraud	20
G. Intellectual Property	21
H. Conflict of Interest	21
I. Affirmative Action and Equal Employment Opportunity	21
III. Appendices	22

## I. GRANT SUPPORT

### **A. Internal Support**

#### **1. Support from IUS**

IUS faculty members may apply for several types of support for research and creative activity. Funds for software and international projects are also available. Deadlines in addition to the ones listed below are sometimes announced. When deadlines fall on a weekend, applications are due the following Monday. See Part II for restrictions, conditions, and application procedures applicable to the programs listed below. Applications are available from the Office of Academic Affairs (LB-152, ext. 2210) and at *http://www.ius.edu/research/GuidesForms.cfm*.

Summer Faculty Fellowships for Research: The purpose of the fellowships is to provide support for full-time summer activities related to research or creative work. Half fellowships may be awarded in special circumstances, only. The amount of the award varies, but in no case may it exceed 20% of the individual's 10 month salary. Only tenured and tenure-track faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Deadline: October 15

Summer Faculty Fellowships for Teaching: The purpose of the fellowships is to provide support for full-time summer activities related to teaching enhancement or curriculum development. Half fellowships may be awarded in special circumstances, only. The amount of the award varies, but in no case may it exceed 20% of the individual's 10 month salary. All IUS faculty are eligible. Applications are reviewed by the Improvement of Learning Committee.

Deadline: October 15

Summer Faculty Fellowships for Faculty/Student Working Groups: The purpose of the fellowships is to provide support for faculty working with at least 2 students on individual or joint research projects or creative work. Provides a full summer faculty fellowship for the faculty member and a fellowship for each student participant. The amount of the award varies, but in no case may it exceed 20% of the faculty member's 10 month salary. Only tenured and tenure-track faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Deadline: March 15

Grant-in-Aid of Research: These grants provide support to cover expenses of research. The maximum is established each year by the Research and Grants Committee. The award has rarely exceeded \$1,000 for an individual applicant. All IUS faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Deadlines: October 15, November 15, February 15, and March 15.

Undergraduate Student Assistance Grants: These grants provide support to cover expenses of an undergraduate student research assistant. All IUS faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Deadlines: October 15, November 15, February 15, and March 15.

Second Meeting Travel Grants: These grants offer partial support for faculty members who have committed their annual meeting travel funds and have the opportunity to participate in some other significant way at a second professional meeting. All IUS faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Deadlines: October 15, November 15, February 15, and March 15.

Faculty Development Travel Grants: These grants offer partial support for travel to conferences and workshops whose relevance is inter-disciplinary or cross-disciplinary. They may not be used to supplement annual meeting travel funds. These funds are administered jointly by the Research and Grants and Improvement of Learning Committees. All IUS faculty are eligible. Applications are reviewed by a joint subcommittee of the Research & Grants and Improvement of Learning Committees.

Deadlines: October 15, November 15, February 15 and March 15.

Quick-Response Mini-Grants: These funds are available to pay minimal costs associated with research/creative work, the publication or presentation of such work or for the preparation of proposals for the funding of such work. Generally, the awards are approximately \$50. Mini-grants are administered by the Associate Vice Chancellor for Academic Affairs. All IUS faculty are eligible. Applications are reviewed by the Dean for Research.

Applications are accepted at any time.

Improvement of Teaching Grants: These grants support faculty efforts to promote the improvement of teaching at IUS. Examples of eligible projects include the design of individual study units and learning modules, original design and production of materials and seed money for development of larger projects. The Improvement of Learning Committee determines guidelines and policies for these grants and makes recommendations to the Associate Vice Chancellor for Academic Affairs regarding their award. All IUS faculty are eligible. Applications are reviewed by the Improvement of Learning Committee.

Deadlines: October 15, November 15, February 15 and March 15.

Software: The Integrated Technology Committee is authorized to fund requests for software (i.e. programs executable on computers and/or information in forms that permit access by such programs) for academic purposes. Software may also be included as a line item on budgets submitted for Grants-in-Aid of Research and Improvement of Teaching Grants. All IUS faculty are eligible.

Deadlines: The Integrated Technology Committee announces its deadlines each semester and makes its application available electronically. The established deadlines noted above apply to software included in other budgets.

Sabbatical Leaves of Absence: See p. 11. Only tenured faculty are eligible. Applications are reviewed by the Research & Grants Committee.

Office of International Programs/Chancellors Fund: The IUS International Programs Committee reviews applications to the OIP/Chancellors Fund. Faculty, adjuncts, and students may submit proposals that request support for international research, international travel, or support of instructional development with an international focus. Information and application forms are available under OIP/Chancellors Fund at <http://www.ius.edu/IntStudies/>

Deadlines: October 15 and February 15.

## **2. Support from Indiana University**

IUS faculty members also are eligible to apply for central funds from Indiana University and from centers and institutes that have system-wide missions. The following is a partial listing of programs that provide money for a variety of research and scholarly activities. Many, but not all, are designed to encourage collaboration among faculty members on different IU campuses. Information about and applications for these and other programs can be obtained from the IUS office of Academic Affairs, from the Office of the Vice President for Research (OVRP) in Bloomington, (812-855-8913) or from the sources listed below. OVRP also publishes guides to university funding periodically. More information may be obtained on the OVRP web page: <http://www.research.indiana.edu/>

Research and University Graduate School: Intercampus Research Fund; Intercampus Research Travel Grants; Intercampus Scholar Program; Research Project Initiation Expenses; Intercampus Graduate and Undergraduate Student Summer Research Assistant Grants. Descriptions, deadlines, and application forms can be found at <http://www.research.iu.edu/irc/irfopp.html>

Institute for Advanced Study: Internal Residential Scholars; Intercampus Visiting Scholars. Descriptions, deadlines, and application forms can be found at <http://www.indiana.edu/~ias/fellship.html>

Office of International Programs: International Interprograms Funds; International Opportunities for Libraries and Librarians; International Outreach Grants; Overseas Conference Fund; PCIP International Projects and Activities Fund; Short-Term Faculty Exchanges; International Enhancement Grants (specifically for regional campuses). Descriptions, deadlines, and application forms can be found under Funding Opportunities for Faculty and Librarians at <http://www.indiana.edu/~intlprog/>

Note: Many central IU applications require administrative endorsement. **All** should be routed through the Office of Academic Affairs.

### **3. Support for IUS Students**

IU Southeast provides several types of support for research, creative activity, and travel to student or professional conferences by IUS students. When deadlines fall on a weekend, applications are due the following Monday. Applications are available from the Office of Academic Affairs (LB-152, ext. 2210) and at <http://www.ius.edu/research/GuidesForms.cfm>.

Student Travel Awards. Provide partial travel funding for students who have the opportunity to participate in a student or professional meeting. Funds are limited and awarded competitively. Applications are reviewed by the Dean for Research.

Deadline: Applications are accepted at any time.

Student Research Fellowships. Three fellowships of \$1000 are awarded each semester to allow students to carry out major independent projects under the supervision of a faculty member. Students may also apply for \$500 in research supplies and equipment. Faculty mentors receive a \$500 stipend. Applications are reviewed by the Research & Grants Committee.

Deadlines: For fall and spring semesters, the deadline is the end of the first week of classes. For summer semester, the deadline is March 15.

Faculty/Student Working Group Fellowships. As part of the Faculty/Student Working Groups Fellowship described in section I.A.1, students participate as part of a faculty/student working group application. Student research fellows receive a \$1000 research fellowship. Applications are reviewed by the Research & Grants Committee.

Deadline: March 15.

Small Grants to Students. Limited funds are available for independent undergraduate research and creative work conducted by a student with faculty supervision. Applications are reviewed by the Dean for Research. Application format consists of a memo addressed to the Dean for Research detailing the project and the budgetary needs.

Deadline: Applications are accepted anytime.

## **B. External Contract and Grant Support**

External sources of funding include state and federal government agencies and private foundations. The Research at Indiana University web page (<http://www.research.indiana.edu>) provides the best starting point for information about external grant applications and sponsored research services at IU. Membership in Community of Science (COS: <http://www.cos.com/>) allows individuals to search a national database for funding sources.

### **1. Application Procedures**

Anyone contemplating applying for a funds from an external source should contact the Associate Vice Chancellor for Academic Affairs and Dean for Research. No application or preliminary proposal should be sent by an individual faculty or staff member directly to an agency or foundation. Such proposals must be sent by the Office of Academic Affairs to the Sponsored Research Services (SRS) office in Bloomington and must be accompanied by a **Route Sheet** which must be signed by the Principal Investigator, the School Dean, Academic and Administrative Affairs, and the Chancellor. Applications should be received in the Office of Academic Affairs 4 weeks before the deadline set by the funding source (see time table in section II.D.1). It is advisable to seek preliminary approval for budgets from SRS.

Certain fellowships and prizes awarded directly to individual scholars are not administered by the university and do not require university routing. Potential applicants should consult with the Associate Vice Chancellor for Academic Affairs and Dean for Research well before the due date to determine whether the opportunity they are seeking falls into this category.

All proposals submitted for **federal funding** require a **Conflicts of Interest Disclosure Form**. This form is required regardless of whether a potential conflict exists and may be obtained from the Office of Academic Affairs.

### **2. Preparation of Proposals**

Information to aid in the preparation of proposals is available from the Office of Academic Affairs. Proposal writers will need data about Facilities and Administrative (indirect) cost rates, fringe benefit rates, who to designate as the grantee, dates of agreement between IU or IUS and federal agencies regarding compliance with federal laws, etc. Rates change from year to year and sometimes month to month. Potential applicants should always check for the most current information before preparing applications.

### **3. Human and Animal Subjects**

All proposals involving the use of live subjects require additional paperwork prior to submission. Information on Institutional Review Board and Institutional Animal Care and Use procedures may be found in the section on Policies below; sample forms appear in the Appendix.

### **4. Hazardous Materials**

Researchers using hazardous materials of any type should be thoroughly familiar with the Indiana University Document *Chemical Hygiene and Safety Plan for Laboratory and Storerooms* which details the regulations for the use and disposal of such materials.

## **C. Technology Transfer**

The IU Research and Technology Corporation (IURTC) located on the Indianapolis campus is responsible for the development and implementation of technology transfer policies and procedures for all of Indiana University and for the benefit of the public domain. Serving as a centralized contact, IURTC's objectives are to stimulate the transfer or commercialization of intellectual property; facilitate development of industrial collaboration; and provide education, resources and assistance to the faculty, students, and staff related to the identity and protection of intellectual property and license portfolios. IURTC provides training and information, develops relationships with industry, negotiates license terms, and assists in the management and protection of intellectual property. The office can be reached by phone: 317-278-1901 or on the web at <http://iurtc.iu.edu>. Information regarding Indiana University's Intellectual Property Policy may be found in section II.G.

## II. POLICIES GOVERNING RESEARCH, GRANTS, AND SABBATICALS

### A. Policies and Administration - General

The policies pertaining to internal grants, fellowships, and sabbatical leaves derive from IU and IUS administrative policies and from decisions of the IUS Research and Grants Committee which is responsible for making recommendations to the Associate Vice Chancellor for Academic Affairs regarding these awards. The committee exercises broad discretion within the bounds of these policies. For example, it decides the number and maximum amounts of grants, when application deadlines will be, and what kinds of support will be given priority.

The policies pertaining to extramural grants and contracts derive from IU and IUS administrative policies and practices and from the policies of individual funding sources. Because of the complexity of these policies, it is essential that prospective grant applicants discuss their projects and budgets with the Associate Vice Chancellor for Academic Affairs and Dean for Research before and during the preparation of a proposal.

The Associate Vice Chancellor for Academic Affairs and Dean for Research is responsible for insuring that applications for research support, whether internal or external, adhere to the relevant administrative policies. For internal awards, he/she is responsible for setting up accounts, transferring funds, monitoring accounts, and insuring that mandated progress reports are filed. For external awards, these post-award functions are carried out by SRS. The Associate Vice Chancellor serves ex officio as a voting member of the Research and Grants Committee.

Applicants are encouraged to submit all applications for internal funding electronically in either Word or WordPerfect format.

### B. Specific Policies and Guidelines

#### 1. Summer Faculty Fellowships:

These fellowships provide support for full-time scholarly activity during the summer months.

A) In reviewing applications, the IUS Research and Grants Committee will base its recommendations on the following criteria:

1. Applicant's competence for the project (i.e., background, training, preparation, and previous research or creative work in the area);
2. Presumed contribution to knowledge (can be established by summarizing key works in the area);
3. Method and plan of work;
4. Evaluations of the project by knowledgeable reviewers; and/or
5. Documented accomplishments on previous research projects;
6. Overall clarity and quality of the proposal;
7. When the applicant last received similar support (i.e., preference is given to junior faculty and to those who have not been supported recently);
8. Whether the project is likely to lead to external support.

B) Instructions for Applying:

1. Applications are available from the Office of Academic Affairs and via the web at <http://www.ius.edu/research/GuidesForms.cfm>. References should be sent directly to the Associate Vice-Chancellor for Academic Affairs and will be held in confidence, i.e., their contents will not be shown to the applicant. Comments by referees must be germane to the project. A letter from the

applicant's Dean is required in all cases. Applicants without an established record of research are advised to obtain one or more additional references from person(s) knowledgeable in the field of the proposed project.

2. Previous financial support for this research area must be detailed; sources, dates and amounts of awards, and progress.
3. Applications, along with the Dean's letter, must be sent to the Associate Vice-Chancellor for Academic Affairs through the Dean by the announced deadlines.
4. A detailed plan of work including an explicit statement of the research hypothesis or question and a description of the research methods (or comparable information as appropriate to the applicant's discipline) is required.
5. A statement indicating whether the project can be carried out without additional funding is required.

C ). Restrictions and Conditions:

1. All laws, regulations and policies with regard to research using live human or animal subjects or hazardous materials will be followed.
2. A progress report will be required by October 1 following the fellowship.
3. Awards are not made to complete degree work, e.g., dissertations.
4. The I.R.S. may consider these fellowships as income. The University is required to make the standard deductions for income tax and F.I.C.A.
5. Individuals whose employment will not continue through the following academic year are ineligible for Summer Faculty Fellowships. Fellows terminating their employment for the following academic year after receiving fellowships will be required to repay the university.

**2. Grants-in-Aid**

These grants provide money to cover expenses of research or creative activity.

A) In reviewing applications, the IUS Research and Grants Committee will base its recommendation on the same criteria found under Summer Faculty Fellowships:

B) Instructions for Applying

- 1.-4. See instructions listed under Summer Faculty Fellowships.
5. A detailed budget is required:
  - a) Hourly wages should show both hourly rate and number of hours and include the current F.I.C.A rate for any hours worked by students who are not enrolled at least .5 FTE.
  - b) Travel should show both mileage and the coach class air fare. Whichever is least expensive is the maximum that will be awarded. Mileage should be calculated in accordance with current IU travel policy.
  - c) When the travel for which the funding is requested is exclusively for the purpose of gathering research data, the Committee will consider requests for travel *to* a foreign destination as well as travel within a foreign country.

d) When research in a foreign country is being undertaken in conjunction with a trip to an international conference, or for some other purpose, awards for travel will be limited to travel *within* the foreign country. Faculty members delivering papers to international conferences should apply to the Overseas Conference Fund for support.

e) University policy does not permit reimbursement for mileage in a foreign county. It does permit reimbursement for the costs of air, rail or coach tickets and/or the cost of car rental. Also, gasoline purchases are reimbursable.

f) Items labeled "miscellaneous" or "other expenses," unless clarified, will not be funded.

g) Per diem will not be awarded, although, if lodging and meals are itemized separately, lodging may be awarded in some circumstances.

h) Travel to Bloomington or other IU campuses ordinarily will not be awarded. Individuals whose projects involve travel to other IU campuses may be eligible for funding by OVRP.

i) A justification should be given for each budget item.

### C) Restrictions and Conditions:

1.-3. See Restrictions and Conditions under Summer Faculty Fellowships.

4. Requests for capital equipment are usually not funded; such purchases should be made from other sources of funding. At IU the current threshold for capital equipment is \$5000.

5. Travel for professional meetings is supported from other funds, as are teaching innovations.

6. Under most circumstances, a research account is opened and the budgeted funds deposited. The principal investigator serves as account manager and the Associate Vice Chancellor as account supervisor. The account manager is responsible for expenditures from the account in keeping with university fiscal policies. Transfer of funds within a budget must be approved by the Research and Grants Committee or the Associate Vice Chancellor for Academic Affairs.

7. The account manager is personally responsible for the balance if the account becomes overdrawn. Funds remaining after a project is completed should be returned to the Research and Grants Committee.

8. If a project supported by a Grant-in-Aid yields royalties or other income, the grantee is required to repay the University from such personal income when the amount is in excess of \$100 in any year. Thus, each year that the income exceeds \$100, the recipient is obligated to repay one-half of such excess until the grant is repaid.

### 3. Second Meeting Travel Grants

These awards provide partial support for travel to a second professional meeting in a given academic year.

A) In evaluating applications the members of the Research & Grants Committee will base its recommendation on the following criteria:

1. The nature of the applicant's participation in the second meeting,

2. The nature of the applicant's participation in the meeting for which regular travel funds were used;

3. The general level of the applicant's participation in scholarly associations;

4. When the applicant last received similar support, (i.e., preference is given to those who have not been supported recently.)

B) Instructions for Applying:

1. Applications are available from the Office of Academic Affairs or via the web at <http://www.ius.edu/research/GuidesForms.cfm>. Applications are to be submitted through that office.
2. Printed materials about the meeting, letters of acceptance and/or an invitations to participate should be included.

C) Restrictions and Conditions:

1. All Indiana University regulations governing travel apply.
2. The maximum grant from this source is \$400. There is no restriction on other sources of partial funding except that these funds may not be used to supplement those allocated for the faculty member's annual professional trip or first meeting.
3. Ordinarily awardees will charge expenses, up to the amount of the award, to their School's travel account. Schools will be reimbursed by the Office of Academic Affairs at the end of the fiscal year. Evidence that the awardee has attended both first and second meetings should be provided.
4. As a rule, no awards will be made retroactively.

**4. Faculty Development Travel Grants**

These awards provide partial support for travel to workshops, conferences, chautauquas, meetings and the like. The grants are administered jointly by the Research and Grants and Improvement of Learning Committees.

A) In evaluating applications the reviewers will base their recommendation on the following criteria:

1. The nature of the event and its participants;
2. The manner in which the IUS faculty member will participate;
3. The benefit to IUS or some unit of IUS broader than a single discipline which will presumably accrue as a result of the faculty member's participation.

B) Instructions for Applying:

1. Guidelines are available from the Office of Academic Affairs. Applications are to be submitted through that office.
2. Printed materials about the event and/or an invitation to participate and complete information about costs of attendance and other sources of partial support must be included.
3. A letter from a Dean or other appropriate administrator or colleague attesting to the contribution the applicant's attendance can make to IUS must be included.

C) Restrictions and Conditions:

1. All Indiana University regulations governing travel apply.

2. There is no restriction on other sources of partial funding except that these funds may not be used to supplement those allocated for the faculty member's annual professional trip.
3. Ordinarily awardees will charge expenses, up to the amount of the award, to their school's travel account. Schools will be reimbursed by the Office of Academic Affairs by the Office of Academic Affairs at the end of the fiscal year. Evidence that the awardee has made the trip should be provided.
4. As a rule, no awards will be made retroactively.
5. In accepting these funds the faculty member agrees to share the knowledge she/he has gained in an appropriate forum and in a timely fashion.

### **5. Quick Response Mini Grants**

These funds are available to pay minimal costs associated with research/creative work, with the publication or presentation of such work, or with the preparation of proposals for the funding of such work. Typical uses are copying, long distance phone calls, database searches, and manuscript submission fees.

Application is in the form of a memo submitted to the Associate Vice Chancellor for Academic Affairs providing a one-paragraph description of the project and a statement regarding the proposed use of the funds. Awards are generally not made in cash; where feasible items or services are charged to existing accounts and reimbursed by Academic Affairs.

### **6. Improvement of Teaching Grants**

These grants provide money to support innovative approaches to teaching, to enhance the uses of technology in the classroom, to obtain classroom resources that are not funded as equipment or have been placed on annual equipment requests and not funded, and to assist with registration fees for conferences directly designed to improve teaching through improved methods or increased knowledge of materials to be taught.

A) In reviewing applications, the IUS Improvement of Learning Committee will address itself to the following factors:

1. Contribution to improvement of teaching.
2. Benefits to be gained from the project.
3. Overall quality and clarity of the proposal.
4. Other funding sources applied for/received for the project.
5. Whether there are aspects of the project which are applicable to other disciplines.

B) Instructions for Applying

1. Applications are available from the Office of Academic Affairs.
2. Applications must be sent to the Associate Vice Chancellor for Academic Affairs through the Dean by the announced deadline.
3. Financial support for this and other projects must be detailed: sources, dates and amounts of awards.
4. A detailed budget is required:
  - a) Hourly wages should show both hourly rate and number of hours and include the current F.I.C.A. rate for any hours worked by students who are not enrolled at least .5 FTE.

- b) Travel should show both mileage and the coach class air fare. Whichever is least expensive is the maximum that will be awarded. Mileage should be calculated in accordance with current IU travel policy.
- c) Items labeled "miscellaneous" or "other expenses", unless clarified, will not be funded.
- d) Per diem will not be awarded, although, if lodging and meals are itemized separately, lodging may be awarded in some circumstances.
- e) Travel to Bloomington or other points within the IU system ordinarily will not be awarded. Individuals whose projects involve travel to other IU campuses may be eligible for funding from other sources.

## **7. Software**

Both individual and network software for research or teaching may be funded. Committees may exercise their best judgement and forward software requests from one to another.

- A) All requests to purchase software must be reviewed by the IUS Integrated Technology Committee before submission to any committee that provides funds. The purpose of this review is to avoid unnecessary duplication, to assure a good fit between software and hardware, and to identify the appropriate vendor.
- B) In reviewing proposals, priority will be given to purchases for which no additional hardware is required.

## **C. Sabbatical Leaves of Absence**

### **1. Purpose**

The purposes of the sabbatical leave program are to provide time to faculty for scholarly research and the travel required to do it and to allow faculty to keep abreast of developments in their field (IU Academic Handbook, June, 2001, p. 93). Faculty members who request sabbatical leaves are required to provide evidence that granting their requests will achieve these purposes. Also, requirements for eligibility and scheduling must be met.

The sabbatical leave is granted on the basis of an acceptable proposal from the faculty member, indicating the manner by which these general objectives are to be achieved. It is expected that the plan will be adhered to with reasonable diligence. The faculty member should advise the Vice Chancellor of Academic Affairs and the Research and Grants Committee about any change in sabbatical plans which might occur after a sabbatical proposal has been approved. If the changes result in a completely new project, then a new proposal should be submitted for review. If the sabbatical proposal is based on the assumption that the faculty member will take a one year sabbatical, and a year long leave does not materialize, then the Vice Chancellor of Academic Affairs and the Research and Grants Committee should be notified as to how the proposal will be affected by the shortened leave period. For example, if more than one project has been proposed and not all can be completed, then the faculty member should notify the Vice-Chancellor and the committee which of the projects will be pursued for a one semester leave.

Faculty who have been granted a one-year sabbatical leave must confirm to the Vice Chancellor of Academic Affairs by March 1 whether they intend to take a full year leave at half salary. If, for any reason, the sabbatical leave is shortened to one semester, the compensation for that semester will be half salary. Reinstatement to the faculty position for the balance of the year is contingent upon institutional needs and resources and upon the availability of a line position. This policy was established by the IU Board of Trustees.

Within three months after the termination of the leave, the faculty member will submit a report to the Vice Chancellor for Academic Affairs on a form designed for this purpose. It will be available to the Research and Grants Committee for use in evaluating future applications for such leaves. The Vice Chancellor for Academic Affairs may request the Research and Grants Committee to review a sabbatical report and to advise the Vice Chancellor whether the sabbatical leave time was used appropriately and in accordance with the approved sabbatical proposal.

Acceptable programs for the use of time may include:

- A) Research on significant problems.
- B) Important creative or descriptive work in any means of expression, for example, writing, painting, and so forth.
- C) Postdoctoral study along a specified line at another institution.
- D) Other projects satisfactory to the Research and Grants Committee.

**2. Terms of Leave**

Sabbatical leave will be for one semester at full salary or for one year at half salary. The sabbatical leave program requires that persons on sabbatical leave devote full time to the scholarly activity for which leave is granted and will receive no salary or stipend from other sources than the University except that (1) persons on leave for a year at half pay may engage in other scholarly activity consistent with that for which leave is granted and receive salary, stipend or honoraria from other sources in such amounts that total salary, stipend, and honoraria do not exceed approximately the annual income normally earned, and (2) persons on leave may receive grants from other sources for travel and research expenses incidental to their scholarly activity. Faculty members who receive sabbatical leave for a full year at half salary should discuss their retirement benefits with the Office of Human Resources.

Under special circumstances permission may be granted for a faculty member to augment a full-year, half-salary sabbatical stipend through part-time teaching at a host institution. The purpose of such an exception is to make it possible for a faculty member lacking outside support to pursue an opportunity for research or creative activity during a full-year rather than a half-year sabbatical leave. The faculty member must explain in writing how the prospects for a productive sabbatical leave will be enhanced, and must specify the nature and extent of the proposed teaching. The School Dean must then recommend the exception to the Vice Chancellor for Academic Affairs, who will make the final determination as to whether or not it can be allowed. Under no circumstances may total stipends, salaries, etc., exceed the normal salary the faculty member would have received had he or she been on normal appointment at IUS.

**3. Eligibility**

A faculty member is eligible to apply for one sabbatical leave during each period of seven years' full-time service (including time on sabbatical leave), following the completion of the first six years of full-time service as a faculty member at Indiana University Southeast. Years of service at another university will not count toward sabbatical eligibility. A faculty member may be granted one sabbatical leave in the seventh, eighth, ninth, tenth, eleventh, twelfth, or thirteenth year of service, and one in the fourteenth, fifteenth, sixteenth, seventeenth, eighteenth, nineteenth, or twentieth year of service. Ordinarily, however, a sabbatical leave will not be granted within less than four years following a preceding sabbatical leave. However, a sabbatical leave need not be taken in a single academic year but may be divided over several academic years. Leaves without pay do not count as part of the period by which eligibility for sabbatical leave is determined, except that recipients of nationally or internationally competitive fellowships may count up to one such year toward their next sabbatical leave. The sabbatical leave program applies only to persons who will return to their positions at Indiana University for at least one academic year following a period of sabbatical leave. For example, sabbatical leave will not be granted for the last year of a faculty member's service prior to retirement.

**4. Scheduling**

As far as possible, departmental schedules should be arranged so as to permit eligible members of the faculty to take leaves. In arranging schedules, an attempt should be made to minimize the cost of substitute instruction and the disruption of the departmental program. To facilitate this planning, faculty members who wish to apply for leave during any part of a given academic year must begin the process approximately 18 months in advance of their anticipated leave.

**5. Application Procedure**

In accordance with a resolution of the IUS Faculty Senate (March 23, 1989), the Research and Grants Committee has established the following application schedule:

A) Advisory notification. By March 15 of the year preceding formal application potential applicants notify their

deans of their intention to apply for a sabbatical leave via a memorandum. They should indicate whether they anticipate taking a full-year or one semester leave. This notification is non-binding and does not require any information about the applicant's plans. Deans should attempt to resolve serious scheduling problems that would leave a particular discipline understaffed. Deans then forward lists of those planning to apply to the Associate Vice Chancellor for Academic Affairs. The purpose of this step is to facilitate budget planning.

B) Application. By the first of October, those applying for sabbatical leaves at any time during the following academic year submit their applications to their deans. Forms for this purpose are available from the Office of Academic Affairs and via the web at <http://www.ius.edu/research/GuidesForms.cfm>. Three working days later, Division Deans will deliver these applications to the Associate Vice Chancellor for Academic Affairs with a statement indicating how each applicant's essential teaching assignments will be covered, an estimate of the cost of doing so, and an evaluation of the proposed sabbatical leave project. The Associate Vice Chancellor for Academic Affairs distributes the applications to the Research and Grants Committee. By October 21 the Research and Grants Committee will provide feedback to the applicants via the Associate Vice Chancellor of Academic Affairs.

C) Revised Application. By November 21 revised applications are submitted to division deans who forward them with details concerning schedule adjustments, additional staff, or other anticipated expenditures to the Associate Vice Chancellor for Academic Affairs, who submits final applications to the Research and Grants Committee for discussion and recommendation to the Vice Chancellor for Academic Affairs. Applicants shall be given the opportunity to make representation to the committee in support of their applications.

The Administration will notify the Research and Grants Committee and nominees of recommendations in a timely manner. A positive recommendation at the campus level provides sufficient certainty to permit the applicant to make definite plans for the sabbatical leave.

#### **D. External Contracts and Grants Policies**

Contracts and grants from extramural agencies are subject to the policies and restrictions of the funding agency as well as of the university. Any faculty or staff member who intends to apply for external monies should be sure he or she is thoroughly familiar with all applicable policies and restrictions. As noted above, prospective applicants should discuss their proposals with the Associate Vice Chancellor of Academic Affairs and Dean for Research well in advance of application deadlines. Doing so will insure adherence to university policies and will minimize delays in the administrative processing of applications. It is recommended that budget assistance be sought early in the process of proposal preparation.

##### **1. Timetable for Submission**

All proposals for external grants and contracts must be routed through the campus and the university. The following time table specifies the minimum amount of time required to assure that your proposal is postmarked or received on or before the due date. Please remember that at each step of the approval process the person whose signature you need has to have time to read the proposal and may have several to read at once. Note that one paper copy with a route sheet is required even if your proposal is submitted electronically.

A) As soon as you consider developing a proposal: Consult with the dean for research to be certain you have all the information you require and know the routing process. Clarify whether reviews for potential research risks or conflicts of interest are required. Clarify whether external letters of support are required and begin securing them. Check to see if there are any black-out dates when Academic Affairs or Sponsored Research Services cannot process proposals owing to holidays or vacation schedules and allow added time for these.

B) Five weeks prior to due date: Develop the budget, line up required matching funds (if any), and obtain pre-approval from Sponsored Research Services. Academic Affairs will assist you.

C) Four weeks prior to due date: The completed application, with the necessary number of copies (= the number requested by the agency plus 2) should be delivered to the Associate Vice Chancellor of Academic Affairs along with the IU Route Sheet available from the Office of Academic Affairs (see Appendix) and also via the web at [http://www.research.iu.edu/forms/route\\_reg.pdf](http://www.research.iu.edu/forms/route_reg.pdf). Make certain the dean or director is aware of the due date and of

any matters of concern such as required matching funds, reassigned time or letter of support. The Route Sheet must be signed by the Principal Investigator, School Dean, Offices of Academic and Administrative Affairs, and Chancellor. The whole package then goes to SRS in Bloomington, where the signature of the appropriate authorized official of the university is added. SRS is responsible for sending the completed package to the agency.

D) Three weeks prior to due date: Check with your dean or director to be certain the proposal with signed route sheet has been forwarded to Academic Affairs for additional signatures.

E) One week prior to due date: Check with Academic Affairs to be certain the route sheet has been signed, copies made and the package forwarded to Sponsored Research Services.

## 2. Institutional Information

Proposal coversheets usually require specific institutional data. The data given here are to be used on **all** proposals. The grantee institution for extramural funds is always **Indiana University**. The only official authorized to sign for the university is **George E. Walker**. In some cases it may be appropriate to indicate that the actual site of the project is IUS. Applicants should check with the Associate Vice Chancellor for Academic Affairs before preparing coversheet. Up-to-date information can be found at <http://www.research.iu.edu/spoadmin/proposal.html#assemble>

### INSTITUTIONAL DATA FOR PROPOSALS

Applicant Organization Indiana University

Mailing Address P.O. Box 1847  
Bloomington, IN 47402-1847

Authorizing Official Michael A. McRobbie  
Vice President for Research  
P.O. Box 1847  
Bloomington, IN 47402-1847  
(812) 855-0516 FAX (812) 855-9943  
rugs@indiana.edu

Financial Officer Steven A. Martin  
Assistant Vice President for Research  
P.O. Box 1847  
Bloomington, IN 47402-1847  
(812) 855-3963 FAX (812) 855-9943  
stemarti@indiana.edu  
*for NIH application use: spon2@iupui.edu*

IRS/Entity Number 35-6001673  
*for NIH applications use: 1-356001673 -A1*

NSF  
Awardee Organization Code 0018093000  
Performing Organization Code 0018176000

NIH Institutional Profile Number  
Southeast 577804  
System 577801

Indirect Cost Negotiation Agreement DHHS 5-14-04

DUNS Number	00-604-6700
CAGE Code	4E748
Indiana Not-for-Profit Tax Registration Certificate Number	003123294
Congressional District: Bloomington & Southeast	9 <sup>th</sup>
Human Subjects Assurance Number	FWA00003544 IRB00000224
Animal Welfare Assurance Number	A4097-01

### **3. Budget Preparation**

Applicants should seek the advice of the Associate Vice Chancellor for Academic Affairs and Dean for Research when preparing grant budgets. Unless the agency specifies lower limits, requests for funds for travel, lodging, etc., should adhere to the university's current allowances in those areas.

If permitted by agency guidelines, applicants may request salary support in contract or grant applications. The university policy is that total academic-year salary from all sources of university-administered funds may not exceed 100% of a faculty member's assigned salary for that year. For example, if a person receives a grant to pay 25% of his/her academic-year salary, the salary he/she receives from the general fund will be reduced by 25%.

Summer salary requests should be at a weekly rate of 2.5% of 10-month salary. Up to nine weeks at this rate may be requested without approval. Requests for more than nine weeks will be considered only in unusual circumstances and must be approved by the Vice Chancellor for Academic Affairs.

The University has established guidelines for the calculation of benefits for academic year and summer salaries for faculty members and others. These are available from the Associate Vice Chancellor for Academic Affairs or at <http://www.research.iu.edu/spoadmin/proposal.html#budget>.

### **4. Facilities and Administrative Costs**

Facilities and Administrative (F&A) costs are the costs to the University for conduct and support of a research project which cannot easily be separated or specifically identified with that project. They are sometimes known as overhead, indirect, or administrative costs. Examples are the costs of space, library facilities, utilities, and accounting services.

The University's policy is to seek full reimbursement for F&A costs unless the granting agency's policies prohibit or limit it. Any request for less than full reimbursement must be accompanied by an explanation and an official statement of the relevant policies of the grant agency.

Requests for F&A costs are determined by a percentage of the requested direct costs, except for costs of capital equipment. The percentage, or F&A cost rate, changes yearly. Applicants should discuss F&A cost requests with the Associate Vice Chancellor while preparing applications. Current IU F&A cost rates are available at <http://www.research.iu.edu/srs/iur.html>

Faculty and staff members receiving grants that include F&A costs should discuss the policy for sharing those funds with the Associate Vice Chancellor for Academic Affairs and Dean for Research.

### **5. Matching Funds**

Many grants require matching cash or in-kind contributions. The nature and sources of these must be discussed with the Associate Vice Chancellor for Academic Affairs and Dean for Research prior to budget preparation.

## E. Protection of Research Subjects

All research, regardless of funding source, involving humans or live animals that is conducted on the IUS campus or under IUS auspices will adhere to Indiana University Southeast and Indiana University policies on the protection of research subjects. The Institutional Review Board for the Protection of Human Subjects in Research (IRB) and the Institutional Animal Care and Use Committee (IACUC) are responsible for monitoring research to insure compliance with these policies.

### **1. Human Subjects Policy**

A) Education in Human Subjects Protection: Recent federal regulations mandate a program of education in human subjects protection. All persons (**including students**) conducting research and seeking approval of the IRB are required to demonstrate that they have received training regarding the rights of research subjects and the conduct of research with human subjects. An on-line course and test are available at <http://www.research.iu.edu/rschcomp/niheducation.html>. Individuals taking the test should request that results be reported to the IUS IRB. Alternative means of fulfilling this requirement are also available.

### B) Faculty/Staff Research

The Department of Health and Human Services (HHS) defines research as "a systematic investigation designed to develop or contribute to generalizable knowledge." Regardless of their source of funding, faculty or staff members who plan to conduct research using human subjects are required to obtain the informed consent of those subjects and to take steps to minimize their exposure to physical or psychological risk.\* Additional precautions are necessary for special populations of subjects.\*\* All protocols for research with human subjects must be submitted to the IRB for review. As detailed in the Code of Federal Regulations, 45 CFR 46, certain types of research may be ruled EXEMPT from formal review or eligible for EXPEDITED review, but all **must** be presented to the IRB in order for that determination to be made. Moreover, recent federal regulations mandate a program of education in human subjects protection, and inclusion of both genders and of minorities in all subject populations. The IRB is empowered to provide guidance in these matters. Further information is given in the instructions which accompany the IRB packet (see Appendix).

-----

\*Minimal Risk is defined by HHS 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."

\*\*Special populations including pregnant women, fetuses, abortuses, prisoners, mentally disabled, economically or educationally disadvantaged or minors are considered vulnerable research subjects

-----

### C) Scholarship of Teaching Learning Research (SoTL)

Due to the dual roles (instructor/researcher and student/research participant) typical in SoTL research special caution is needed to ensure that the student/research participants do not feel untoward pressure to participate. To ensure ethical treatment towards the student/research participant a third party is needed to collect and hold the informed consents until after the course grades have been sent to the registrar's office. For more information, visit the Academic Affairs web page <http://www.ius.edu/AcadAffairs/>.

### D) Undergraduate and Graduate Student Research

Many student projects that involve human subjects are not intended to or likely to lead to generalizable results. Such projects would not fall under the operational definition of research quoted above and would not be subject to IRB review. Student research which may place subjects at risk, however, whether conducted as course assignments or not, or which is undertaken with the intent of adding to generalizable knowledge as, for example, a master's thesis, is subject to IRB review. Unfunded student projects which meet all of 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 only objective of which is to provide research experience for the student or data for classroom use, and
2. Which do not involve physically or psychologically invasive, intrusive, or stressful procedures or, in the judgment of the instructor, have the potential for placing subjects at more than minimal risk, and
3. Which do not involve special populations.

*The following procedures are to be followed on all undergraduate and graduate student research projects:*

1. Instructors are responsible for screening individual research projects and making the initial determination as to whether a given project meets the above criteria.
2. If an instructor determines that a research project has as one of its purposes the production of generalizable knowledge or that it may use members of special populations as subjects or involve risk, the project must be reported on the appropriate form provided by the IRB for its review and approval prior to initiating the research. These forms can be obtained from the office of Academic Affairs.
3. If there is any doubt as to whether the project should be reviewed by the IRB, the Associate Vice Chancellor for Academic Affairs is to be contacted for assistance. If the Associate Vice Chancellor for Academic Affairs believes that a particular project is subject to regular IRB review, the proposed project must be reviewed.
4. In the event IRB review is not needed for a particular project, the student researcher and the instructor are still obligated to treat their subjects ethically. Students should always obtain evidence of informed consent.
5. If it is anticipated that the study will be funded (regardless of source) and/or that the results will be presented outside the classroom or published, IRB approval must be obtained.

IRB forms and instruction packets and copies of the IU Southeast Assurance of Compliance with Department of Health and Human Services Regulations on the Protection of Human Subjects and the Code of Federal Regulations, 45 CF6 46 are available from the Office of Academic Affairs.

E) IRB Notification. Applicants will be notified in writing of the IRB's actions, and if a project is disapproved, of the reasons for the action. Once an approved project is under way, an investigator must notify the IRB in writing of any changes in the protocol which may affect the subjects' rights or welfare. The IRB reserves the right to request clarification or to disapprove the changes. The investigator must also notify the IRB in writing if unanticipated problems involving risks to the subjects or others arise.

The IRB will maintain records of all its meetings and actions. Researchers should keep informed consent documents in their own files for a minimum of three years.

F) Reporting Requirements. Completion or termination of the data collection phase of an approved project should be reported promptly to the IRB. In the event that data collection has not been completed within one calendar year of approval, a progress report is required. Forms for reporting project status are available from Academic Affairs or via the web at <http://www.ius.edu/research/GuidesForms.cfm>.

G) Projects Begun Without Review. No internal or external funds will be released for projects involving human subjects until written approval from the IRB is documented. Whether funded or not, no IRB review will be made of projects already in progress. A researcher who has begun the collection of data from human subjects without prior IRB review will be notified of termination of the research project. The notification of termination will be kept on

file in case questions about the project arise. Failure to comply with termination will result in permanent revocation of research privileges.

## **2. Animal Subjects Policy**

I U Southeast recognizes the important contributions to knowledge that arise from research and instruction employing animals as subjects. It also recognizes its responsibilities to insure that such animals are treated humanely, that they are maintained under the best possible conditions of health and tranquility, and that the public is protected from possible health hazards. Therefore, IUS adheres to the principles and guidelines set forth in its Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals and is registered with the USDA as a research site. To ensure compliance with appropriate policies and regulations, IUS has established an Institutional Animal Care and Use Committee (IACUC) that includes a Doctor of Veterinary Medicine and a community representative. All research and teaching procedures involving live vertebrate animals must be reviewed by the IACUC. Forms on which to describe projects are available in the Office of Academic Affairs. The Assurance and other relevant federal and university documents are also available. The following standards of animal care apply in all cases.

1. Each animal colony must meet the requirements specified by federal or state laws. (The Guide for Laboratory Animal Facilities and Care, prepared by the Institute of Laboratory Animal Resources, and Public Law 89-544, as amended by 91-579, shall be used as the references in apply these standards.);
2. Physical facilities shall provide adequate light, heat, ventilation, potable water;
3. All animals shall be protected from extremes of temperature viz., from ambient temperatures less than 50 degrees or greater than 85 degrees);
4. Size of cage used shall permit each animal to move about freely and to assume natural postural positions;
5. Cages shall be sanitized before introducing new animals.
6. Feeders and watering devices shall be cleaned as often as necessary to prevent contamination;
7. Carnivores and primates shall be housed in such a manner as to preclude contamination from their excreta;
8. Animals shall be fed daily or have feed available at all times;
9. Feed and bedding shall be stored in such a manner to insure that it will be clean and free from vermin;
10. All cages and holding areas shall be cleaned as frequently as necessary to prevent accumulation of excreta or to otherwise prevent conditions which would be hazardous to the animals' health. Excreta shall be removed from dog, cat, and primate cages at least daily;
11. In those cases in which the experimental procedure will cause undue pain or discomfort to the animal, the pain or discomfort shall be minimized by the use of tranquilizers, anesthetics, or analgesics;
12. It is recognized that occasional exceptions in the conditions of feeding, housing, and care specified in these regulations may be required in order to carry out legitimate experimental designs and procedure. The experimenter must always be able to justify such modifications as essential to accomplishing the purposes of the experiment. However, such modification shall not be made at the expense of sound sanitary practices. If the necessary modifications involved substandard or unusual conditions or procedures, prior approval of the IRB must be secured.

Visitation of Animal Care Facilities. Access to laboratory animal care facilities is generally limited to university personnel and students who are currently engaged in university-sponsored research or instruction involving the use of animals. In the event that other persons desire to visit such facilities, the following guidelines apply:

1. Potential visitors shall send a written request to the Associate Vice Chancellor for Academic Affairs and Dean for Research, stating which facility they wish to visit, the species they wish to observe, and the purpose of the visit. They shall also identify the specific individuals who desire to participate in the visit.
2. The Associate Vice Chancellor, or his/her designate, after consulting with the IACUC veterinarian, may arrange a visit if it is determined to be appropriate by the Associate Vice Chancellor and veterinarian. The Associate Vice Chancellor or his/her designate shall have the authority to control access to a specific research animal care area where it is determined that such control is essential to protect a specific research design.
3. Visitors should be informed that IUS and its animal care facilities are in compliance with the Animal Welfare Act, the NIH Guide for Care and Use of Laboratory Animals, and the Principles for Use of Animals in the PHS Manual for Grants and Contracts.

Further Information. Print and video materials about research involving human subjects and research and teaching with live animals is available from the Office of Academic Affairs.

#### **F. Research Misconduct and Fraud**

The Public Health Service (PHS) requires that all PHS awardees have policies and procedures in place for dealing with allegations of scientific misconduct or fraud (42 CFR 50). Indiana University is concerned that members of the university community meet the highest standards of ethics in the conduct of research. The university has, therefore, established procedures for handling instances of suspected research ethics violations in all disciplines - scientific and nonscientific -- regardless of the source of support (<http://www.research.iu.edu/rschcomp/index.html#misconduct>).

The policy, administered by the Vice President for Research, defines the various ethical breaches. These include misconduct such as plagiarism, falsification of data, abuse of confidentiality, suppressing or distorting contradictory data, deceptive publication attribution, and gross negligence; violation of research regulations; undisclosed conflicts of interest; misuse, misappropriation or misrepresentation of research funds; and failure to report observed misconduct. The policy also provides procedures for handling allegations of research ethics violations, which include maintaining the confidentiality of investigations. Persons who report a suspected violation in good faith are protected, as are persons accused of violating the standards of research ethics where no serious violation is in fact found. Allegations of research ethics violations are investigated by a university committee appointed by the Vice President for Research.

The policy requires that data that are relevant for supporting and verifying the findings of research projects be retained by the investigator for at least three years after the expiration date of the project. It also requires that researcher maintain current records and logs with sufficient detail to ensure that the course of the research can be reconstructed precisely at a future date.

Some granting agencies, including all agencies associated with the PHS, require that investigations involving their awardees be reported to the agency. Institutions with scientific misconduct assurances on file with the PHS must make an annual submission to the Office of Research Integrity (ORI) comprising an aggregate report on allegations, inquiries, and investigations, along with an annual assurance update[42 CFR 50.103(b)]. The university's research risk compliance officer maintains a repository of data on allegations, inquiries, and investigations as mandated by ORI for its review of data for internal administrative purposes. It is important to take note of the possibility that this information would have to be released in response to a request under the Federal Freedom of Information Act on PHS-funded projects.

## **G. Intellectual Property**

As specified in the “Indiana University Intellectual Property Policy” and other documents, the university exercises intellectual property rights to all inventions, creations, innovations, discoveries, and improvements -- *other than* traditional works of scholarship and instructional materials -- that have been developed with significant University resources (see <http://www.research.iu.edu/respol/intprop.html>). Primary responsibility for identifying, protecting, and managing applicable intellectual property resides with the Technology Transfer Office, under policies developed and supervised by the Intellectual Property Policy Committee and the Vice President for Research. Questions about intellectual property should be referred to, and copies of all relevant documents may be obtained from, the Office of Academic Affairs.

## **H. Conflict of Interest**

Indiana University requires an annual report of possible conflicts of interest in order that significant outside financial interests should be disclosed and reviewed to ensure that they are not improperly influencing teaching, research, or service, regardless of the source of funding. Disclosures must be completed by (1) all full-time tenured or tenure-track faculty, (2) all visiting faculty, and (3) all other academic appointees who are currently principal investigators on research projects. The disclosure form and instructions may be obtained from Academic Affairs or at the following web site: [http://www.research.iu.edu/rschcomp/coi/coi\\_intro.html](http://www.research.iu.edu/rschcomp/coi/coi_intro.html).

## **I. Affirmative Action and Equal Employment Opportunity**

Indiana University pledges to continue its commitment to the achievement of equal opportunity within the university and throughout American society as a whole. In this regard, Indiana University will recruit, hire, promote, educate, and provide services to persons based upon their individual qualifications. Indiana University prohibits discrimination based on arbitrary considerations of such characteristics as age, color, disability, ethnicity, gender, marital status, national origin, race, religion, sexual orientation, or veteran status.

Indiana University will take affirmative action, positive and extraordinary, to overcome the discriminatory effects of traditional policies and procedures with regard to the disabled, minorities, women, and Vietnam-era veterans.

All AA/EEO policies of the University are applicable to research and creative endeavors regardless of funding source. Detailed information concerning these policies and assistance in related matters may be obtained from the Campus Affirmative Action Office, LB 026, ext. 2306

## APPENDICES

- A. Internal Grant Forms
- B. Route Sheet and Administrative Digest for Applications for External Funding
- C. Conflict of Interest Disclosure Form for Applications for Federal Funding
- D. IRB Forms for Human Subjects
- E. IACUC Forms for Research and Teaching with Live Animals

NOTE: These are sample forms. Original forms may be obtained from the Academic Affairs Office, LB152, ext. 2210 or on the web at <http://www.ius.edu/Research/GuidesForms.cfm>.

## IUS INTERNAL GRANT APPLICATION COVER SHEET

Type(s) of award(s) sought:

\_\_\_\_\_ Faculty Development Travel Grant                      \_\_\_\_\_ Student Assistant Grant  
\_\_\_\_\_ Grant-in-Aid of Research                      \_\_\_\_\_ Summer Faculty Fellowship  
\_\_\_\_\_ Improvement of Teaching Grant                      \_\_\_\_\_ Other \_\_\_\_\_

Applicant=s Name: \_\_\_\_\_

Title & Department: \_\_\_\_\_

Project Title: \_\_\_\_\_

Amount Requested: \_\_\_\_\_ (grant applications only)

Special Needs. Does this project involve:

\_\_\_\_\_ Human Subjects                      \_\_\_\_\_ Laboratory Animals                      \_\_\_\_\_ Biohazards

Terms & Conditions:

1. Substantial deviations from grant budgets are not to be made without prior authorization and funds not needed for the projects described should be promptly returned.
2. A progress report will be submitted by October 1 of each year until funds are expended or the project is completed.
3. Because some projects supported through Grants-in-Aid of Research or Teaching may yield royalties or other income to the grantees, each applicant agrees, as a condition of the award, to repay the University fund from such personal income when the amount is in excess of \$100 in any year. Thus, each year that the income exceeds \$100, the recipient is obligated to repay to the University fund one-half of such excess until the grant is repaid.
4. It is understood that letters of reference solicited in connection with this application are confidential, and the applicant waives any right to request access to such letters.
5. The conduct of projects and management of funds under this award will adhere to the policies described in the IUS Research Policy Manual/Faculty Manual, and Policies and Procedures Manual, and to all laws and policies with regard to research involving live human or animal subjects or hazardous materials.
6. IU Southeast support will be appropriately acknowledged in presentations and publications resulting from this award.

In signing this application, the applicant signifies having read and agreed to these conditions.

Signature \_\_\_\_\_ Date: \_\_\_\_\_  
revised 7/96

## SECOND MEETING TRAVEL AWARDS FORM

Second Meeting Travel Awards provide partial support for faculty members who have the opportunity to present research or creative work at more than one professional meeting in a given fiscal year (July 1 through June 30). Funds are limited and are awarded competitively. Preference is also given to individuals who have not received such support recently. Funds are rarely awarded retroactively. The deadline dates for applications are October 15th, November 15<sup>th</sup>, February 15th and March 15th.

Complete the following form and attach an abstract of your paper/presentation and a copy of the conference program (or other relevant documentation). **Incomplete applications will not be considered.**

1. Name & Title of Professor
2. Have you received Second Meeting Travel Funds in the last five years? \_\_\_Yes \_\_\_No  
If so, when?
3. How have your division travel funds been used this year?
4. Did you receive any other funding for travel this year? \_\_\_Yes \_\_\_No  
If so, list type and amount
5. Name, Location & dates of first conference
6. Approximate budget for the first conference
7. Nature of your participation in the first conference
8. Name, Location & dates of second conference
9. Approximate budget for the second conference
10. Nature of your participation in the second conference

11. Process used to determine participation? (Check one)

invited  peer reviewed  volunteered

12. Is this the first presentation of this research or creative work?  Yes  No

If not, explain why an additional presentation has significant value added.

13. Other benefits from attending the conference for you, your division and IUS?

## FINANCIAL CONFLICTS OF INTEREST DISCLOSURE FORM

*Please submit your completed form to the campus official responsible for research compliance. Please make sure all the information asked for is provided.*

*You must update this form (1) annually, and (2) at any time during the year when new disclosable interests arise or new research projects or sponsored programs are undertaken that relate to existing financial interests. Forms must be completed and reviewed by research compliance coordinator by October 18, 2004.*

Name (please print or type): \_\_\_\_\_

Campus: \_\_\_\_\_

Primary Unit, Title, Rank: \_\_\_\_\_

Administrative Position(s): \_\_\_\_\_

Other departments, schools, and units in which you hold appointments (please indicate percentages): \_\_\_\_\_

1. Do YOU, your spouse, or your dependent children expect to receive during the next twelve months compensation in any form or amount from an external (non-IU) entity that operates in areas relating to any medical or clinical trial research in which you are engaged at IU and which involves the participation of human subjects?

No  Yes

If you checked "Yes," please describe on a separate page the outside financial interests and how they relate to your human subject-based medical or clinical research, and attach.

Please note that disclosable interests include any royalty income or sale-of-equity distributions under the University's Intellectual Property Policy, as these are made by the IU Research and Technology Corporation, an external entity.

2. Do YOU, your spouse, or your dependent children expect to receive during the next twelve months compensation in any form that, when aggregated for all of you, exceeds \$10,000 in value and comes from an external (non-IU) entity that operates in areas relating to your research or sponsored program activities at IU? Please do NOT include (a) the salary component of a University sponsored program, (b) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; or (c) income from service on advisory committees or review panels for public or nonprofit entities. Please do include royalty income or sale-of-equity distributions under the University's Intellectual Property Policy, as these are made by the IU Research and Technology Corporation, an external entity.

No  Yes

If you checked "Yes," please describe on a separate page the outside financial interests and how they relate to your IU research or sponsored program activities, and attach. Please indicate whether any of your related IU research or sponsored programs involves (a) NIH or NSF funding, and/or (b) the use of human subjects.

3. Do YOU, your spouse, or your dependent children currently hold, or expect to hold at some point during the next twelve months, equity that when aggregated for all of you, exceeds *either* a value of \$10,000 or five percent (5%) ownership in an external (non-IU) entity that operates in areas relating to your IU research or sponsored programs?

**PLEASE NOTE: DO NOT INCLUDE SHARES HELD IN MUTUAL FUNDS OR OTHER SIMILAR ARRANGEMENTS IN WHICH THE SHARES ARE COMBINED WITH OTHER EQUITY AND BOUGHT/SOLD BY A THIRD PARTY IN SUCH COMBINATION**

No  Yes

If you checked "Yes," please describe on a separate page the outside equity interests and how they relate to your IU research or sponsored program activities, and attach. Please indicate whether any of your related IU research or

sponsored programs involves (a) NIH or NSF funding, and/or (b) the use of human subjects.

**PLEASE NOTE:** If YOU, your spouse, or your dependent children own, in whole or part, an outside business that expects, during the next twelve months, to enter into one or more contracts with the University that are valued in the aggregate at \$250 or more, please complete the Indiana State Conflicts of Interest Disclosure Form at [http://www.indiana.edu/~rschinfo/Forms/coi\\_state.pdf](http://www.indiana.edu/~rschinfo/Forms/coi_state.pdf), following the instructions for submission attached to that form. The types of contracts with or purchases by the University that should be disclosed on the state conflicts of interest form include, but are not limited to, contracts and purchases relating to your research or sponsored programs. An example of a disclosable transaction relating to your research or sponsored program is when you wish to purchase equipment or services from a business owned in whole or part by your, your spouse, or your dependent child, for use in your research or sponsored program.

---

---

*I hereby affirm that the above information (and the information contained in the attached statements, if any) is true to the best of my knowledge, and that I will update promptly if my circumstances change.*

**Faculty Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**INDIANA UNIVERSITY - IUS  
ANIMAL CARE AND USE APPLICATION PACKET**

Federal regulations require that all procedures involving the use of animals be approved by an Animal Resource Committee prior to initiation of the project or award of extramural funding. To comply with these regulations, this form must be completed by the person proposing the animal use. All documents must be typed or they will be returned to the investigator.

The procedure for submitting and obtaining approval for the research proposal will be as follows:

1. **APPLICATION** - Submit the completed Animal Care and Use Application to: IUS Institutional Review Board c/o Academic Affairs, LB 153.
2. **REVIEW BY THE IRB FUNCTIONING AS THE CAMPUS ANIMAL RESOURCE (CARE AND USE) COMMITTEE**  
(Note: the IRB may request an opinion regarding the scientific merit of internally funded projects.)
3. **DISPOSITION** (principal investigator will be notified in writing)
  - a. Approval
  - b. Provisional Approval (returned to the principal investigator for additional information before approval.)
  - c. Denial
4. **ANNUAL REVIEW** - A status report must be filed with the Animal Resource Committee on an annual basis. An Annual Review form will be furnished for your completion. It is important that the investigator or the investigator's department chairperson complete this annual form if the study is discontinued for any reason prior to receiving this form. This annual review form must be completed even if the study was never initiated or was terminated for any reason.
5. **AMENDMENTS** - Investigators are required to report any changes related to their research study via an amendment form. The revisions or additions to the research study should be underlined or highlighted and reference made to the IRB study number assigned by the Animal Resource Committee.
6. **FILE MAINTENANCE** - It is important for the investigator to KEEP A COPY of every document related to the research study which is submitted to the Animal Resource Committee. For audit purposes, these documents must be kept for at least three (3) years after terminating the study. The campus Animal Resource Committee will NOT be responsible for duplicating any information submitted.

**IMPORTANT:** Written approval must be obtained prior to initiating the research, making amendments to the research, or ordering the animals.

**INDIANA UNIVERSITY - IUS  
ANIMAL RESOURCE COMMITTEE  
ANIMAL CARE AND USE APPLICATION INSTRUCTIONS**

In response to growing scientific and public concern for animal welfare, the Public Health Service and the USDA have broadened policies governing the use of live, vertebrate animals in teaching and research.

The principal investigator or instructor is the person who has specific investigative responsibility for the described project. If the project is a funded project, please provide the agency project number.

1. **Training/experience documentation:** Federal law requires that all personnel be trained prior to initiating projects with living animals. Please check with the Animal Care Subcommittee chairperson of your respective campus for assistance in meeting the training requirements.
2. **Purpose of the proposed research:** Since the Campus Animal Resource Committee is mandated to include non-scientists, it is important to provide a concise rationale for the objectives of the project. This statement should provide enough general background for a layperson to appreciate why the research is being done, and why it uses live animals as opposed to in vitro preparations or simulation alternatives.
3. **Goal/Hypothesis (research studies):** It is important that all Subcommittee members who review the proposed experiment can determine that the experiment has a logical hypothesis, and that the experimental methods chosen are appropriate to test the hypothesis.
4. **Assurance that proposed work is not duplicative research:** List the sources that were consulted to determine that the proposed work has not previously been done. Current Contents is not considered an acceptable response.
5. **Animal husbandry & use:** Provide the exact number of each species and/or strain of animal that you propose to use. List the locations where animals will be housed and any other areas/laboratories where animals will be used.

To justify the choice of the model, list some of the important characteristics of the animal that make it suitable for use in the proposed experiment. Cost alone is not considered a valid reason for selection of one particular species over another. The facility veterinarian can be consulted for guidance in selection of appropriate animal models.

The Animal Care and Use Committee recommends that a statistician be consulted to determine appropriate experimental group sizes prior to using animals for the experiment. Group sizes can also be roughly approximated using previously published data on the model. When no previous information exists on the type of experiment proposed, it is acceptable to propose a pilot study using a small number of animals, with future group sizes to be determined following evaluation of pilot project data.

STUDY # \_\_\_\_\_  
SPECIES \_\_\_\_\_

**INDIANA UNIVERSITY ANIMAL REVIEW COMMITTEE  
ANIMAL CARE AND USE APPLICATION**

CAMPUS \_\_\_\_\_ HOOL/DEPARTMENT \_\_\_\_\_

PRIN. INVEST/INSTR. \_\_\_\_\_ S.S.# \_\_\_\_\_  
CO-PRIN. INVEST/INSTR. \_\_\_\_\_ S.S.# \_\_\_\_\_  
Campus Address \_\_\_\_\_ Telephone(0) \_\_\_\_\_

RANK: Faculty \_\_\_\_\_ Res. Scientist \_\_\_\_\_ Post-Doc \_\_\_\_\_ Staff \_\_\_\_\_  
Student \_\_\_\_\_ if yes, name of faculty advisor \_\_\_\_\_

PROJECT TITLE: \_\_\_\_\_  
TITLE OF GRANT UNDER WHICH PROJECT WILL BE CONDUCTED (if different than project title) \_\_\_\_\_

If this research involves other sites, please indicate which ones: \_\_\_\_\_

Have you submitted an Animal Care and Use Form to those campuses? \_\_\_\_\_

FUNDING SOURCE \_\_\_\_\_ APPLICATION DEADLINE \_\_\_\_\_

PROJECT TYPE: Research \_\_\_ Project # \_\_\_\_\_ New \_\_\_ Renewal \_\_\_  
Teaching \_\_\_ Course # \_\_\_\_\_ New \_\_\_ Renewal \_\_\_

TERM OF PROJECT: START \_\_\_\_\_ END \_\_\_\_\_

**Completion and signing of this form are the responsibility of the principal investigator or faculty member in charge. Completion of the approval process will fulfill Public Health Service and USDA Animal Welfare Act requirements, and will serve to remind users and the public of Indiana University's commitment to humane care and use of animals. For proper review and action, this completed application is to be submitted according to the enclosed instructions.**

**In signing this form, I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of valid scientific research or teaching. I have consulted with a veterinarian when potentially painful procedures are to be performed. I agree to comply with the Indiana University Letter of Assurance, and all applicable state and federal laws governing animal welfare.**

Principal Investigator \_\_\_\_\_ Date \_\_\_\_\_

Departmental/Peer Review Committee: \_\_\_\_\_ Date \_\_\_\_\_

**FOR CAMPUS ANIMAL REVIEW COMMITTEE USE ONLY:**

APPROVED (\_\_\_) DISAPPROVED (\_\_\_)

RESTRICTIONS \_\_\_\_\_

**SIGNATURES:**

Campus Animal Review Committee  
for Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Attending Veterinarian \_\_\_\_\_ Date \_\_\_\_\_

1. **TRAINING/EXPERIENCE DOCUMENTATION:** Provide the names and social security numbers of all investigators, fellows, students and technicians who will have direct animal contact. Specify those persons performing anesthesia and

surgery. For each person, briefly state their experience/qualifications to perform the procedures described within this application, or how training will be obtained.

2. **PURPOSE OF PROPOSED RESEARCH:** Please provide a brief lay-oriented statement outlining the purpose of the research project or course and the animal use in it. Provide a sentence that describes why this project is important to the public/scientific community.

3. **HYPOTHESIS/GOAL:** Describe the goal of the project, the hypothesis to be tested, and a brief summary of the experimental methods.

4. **ASSURANCE THAT PROPOSED WORK DOES NOT UNNECESSARILY DUPLICATE PREVIOUS RESEARCH:**

Have you conducted a thorough literature search of journals indexed by national libraries (Medline, Agricola) or contacted the Animal Welfare Information Center for information?

\_\_\_ yes

\_\_\_ no

Please provide sources consulted \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. **ANIMAL HUSBANDRY AND USE:**

<u>SPECIES</u>	<u>TOTAL</u>		<u>LOCATION OF ANIMALS</u>	
	<u>NUMBER</u>	<u>SOURCES</u>	<u>HOUSING</u>	<u>USE AREAS</u>

Describe the characteristics of the animals that justify their use in the proposed study and how the number of animals needed was determined.

Are all husbandry and handling practices standard (routinely performed in the facility) \_\_\_ yes \_\_\_ no

If no, describe all deviations from standard procedures and practices.

Will animals be kept for 12 hours or longer in any area other than the main housing facility? \_\_\_ yes \_\_\_ no

If yes, indicate the location (building and room #), number of animals and explain why animals must be kept outside of the main facility.

Disposition of animals:

Euthanasia \_\_\_\_\_ Return to Colony \_\_\_\_\_ Return to Wild \_\_\_\_\_  
 Transfer to Different Project Entitled \_\_\_\_\_  
 Other (Explain) \_\_\_\_\_

6. **EUTHANASIA:**

The Indiana University Animal Care and Use Committee requires that following euthanasia by chemical methods, death be assured through physical means, such as the creation of a bilateral pneumothorax, decapitation, severance of major blood vessels or organ removal.

Check the method that will be used for euthanasia.

- Lethal injection using a commercial or laboratory prepared euthanasia solution at the recommended dosage (Succomb, Euthol, Beuthanasia-D).
- Physical method (cervical dislocation or decapitation). Describe the scientific justification for selection of these methods under Comments.
- Inhalation of anesthetic gases (eg., isoflurane, halothane)
- Inhalation of carbon dioxide (rodents, amphibians, birds)
- Other. Explain and justify under Comments.

Comments:

7. **EXPERIMENTAL MANIPULATIONS:** Yes answers to the following questions require that additional sections be completed.

<b>YES</b>	<b>NO</b>	<b>SITUATION</b>
—	—	Will surgery be performed? If yes, complete <b>Section A.</b>
—	—	Will tranquilizers, sedatives, or anesthetics be administered? If yes, complete <b>Section B.</b>
—	—	Will animals have a serious natural or experimentally-induced disease, perceive pain and discomfort, or be subjected to prolonged restraint or aversive stimuli? If yes, complete <b>Section C.</b>
—	—	Does this project require the use of radioactive materials, other hazardous agents (chemicals/tissues), or biohazardous agents in living animals? If yes, complete <b>Section D.</b>
—	—	Does this project require the use of live animals in teaching exercises? If yes, complete <b>Section E.</b>

### **Section A: Surgery**

In order to comply with federal regulations (Animal Welfare Act and the Public Health Service Policy), all survival surgery in vertebrate animals must be performed using aseptic procedures, including surgical gloves, masks, sterile instruments and aseptic techniques. Non-rodent mammalian survival surgery must be performed in an operating room used only for surgery.

The surgery proposed will be:

\_\_\_ survival: The animal will awaken from anesthesia

\_\_\_ acute/non-survival: The animal will remain anesthetized during the entire procedure and will be euthanized without awakening.

Describe the operative procedure:

For survival surgical procedures, include aseptic preparation of the operative site, the location and size of incisions, size and placement of catheters or devices that will be implanted, suture types used, and estimated time to complete the procedure. For acute procedures, include operative site preparation, description of procedures to be performed and estimated duration of the experiment.

Room where surgery will be performed \_\_\_\_\_

**For survival procedures, please provide the additional information requested below:**

If more than one major surgical procedure will be done on any animal, explain and justify why multiple procedures must be performed.

Provide the names of the persons who will be responsible for providing post-operative care.

List the location where the animal will be kept during recovery from anesthesia.

**Describe postoperative care:** Include how often animals will be observed and all drugs (except analgesics) to be administered following surgery.

**Analgesic Drugs:** Provide the drug name(s), dosage(s), route, frequency. If analgesic drugs cannot be administered, provide scientific justification for withholding them.

What postoperative complications can be reasonably anticipated and how will they be resolved?

## **Section B: Anesthesia**

**Sedatives/tranquilizers administered:** Include drug, dosage, and route of administration.

**Preoperative regimen:** Include length of withholding of food and/or water and drugs administered (dosage and route).

**Anesthetic regimen:** Provide a listing of all drugs (including dosages and routes of administration) that will be used.

I. Preanesthetic drug(s):

II. Induction drug(s):

III. Maintenance drug(s):

IV. Monitoring: Check all methods that will be used.

Visual examination \_\_\_\_\_ Heart rate \_\_\_\_\_ Respiration \_\_\_\_\_

Instruments: EKG \_\_\_\_\_ Blood pressure \_\_\_\_\_ Temp \_\_\_\_\_ O<sub>2</sub> \_\_\_\_\_ EEG \_\_\_\_\_

Other: \_\_\_\_\_

Describe procedures that will be used to indicate that adequate depth of \_\_\_\_\_ anesthesia is being maintained. Include the frequency of monitoring the animal, the criteria that will be used to determine that administration of additional anesthetic agent is required, and how records of anesthetic procedures are kept.

**Muscle Relaxants:** If neuromuscular blocking agents will be used, provide the drug(s), dosage(s), and route of administration. Describe in detail the monitoring procedures that will be used to determine the sufficient anesthesia/analgesia is present. Paralytic agents cannot be used without anesthetics and assisted ventilation.

**Section C: Animals Will Have a Serious Natural or Experimentally-Induced Disease, Will Perceive Discomfort, or be Subjected to Periods of Restraint or Aversive Stimuli**

Procedures that would be expected to cause pain or distress in a human should also be considered painful for animals (antibody production studies are included). Prolonged restraint means the animal is kept confined or immobilized for time periods in excess of those required for administration of treatments or routine handling procedures.

**Consideration of alternatives:**

What consideration have you given to using other species, using fewer numbers of animals, or non-animal alternatives?

What information sources did you consult to determine that non-animal alternatives cannot be used in the proposed study?

Will the animal's death be used as an experimental endpoint or will suffering animals be euthanized? (If animals are euthanized, death is not considered the endpoint and an explanation is not necessary).

\_\_\_\_\_ Death is endpoint  
\_\_\_\_\_ Euthanasia is allowable

List the specific criteria that will be used to determine when animals can be euthanized?

If the animal cannot be euthanized, justify and explain why an endpoint other than death cannot be used.

**If the animal will have a serious natural or experimentally-induced disease, answer the following questions.**

What disease will the animals have?

How will progression of the disease be monitored?

What measures will be taken to alleviate or minimize pain/distress?

**If any of the methods/techniques listed below will be used, check the appropriate space and provide the details under Comments.**

\_\_\_ Injection of a hazardous/toxic substance into a living animal: substance name, site, volume, frequency

\_\_\_ Immunization protocols: adjuvant(s) used, injection site & volume/site, frequency of immunization; method, frequency and volume of blood withdrawal (including anesthetic, if used)

\_\_\_ Prolonged restraint: method, duration, frequency, adaptation of animal to restraint device

\_\_\_ Food/water deprivation: duration, frequency, extent (total/partial), methods that will be used to assess & monitor distress

\_\_\_ Abnormal environment: temperature, humidity, light, duration

\_\_\_ Hybridoma protocols: priming agent, cells injected, schedule for collection of ascites, number of abdominal taps, size of needle used

\_\_\_ Aversive stimuli: type and intensity of stimulus, duration, justification for use

**Comments:**

**Section D: Radioactive materials, other hazardous agents (chemicals/tissues), or biohazardous substances will be injected into living animals.**

Check all agents that apply.

infectious agent

carcinogen \_\_\_\_\_

toxic chemical \_\_\_\_\_

recombinant DNA \_\_\_\_\_

radioisotope \_\_\_\_\_

transplantable cell line \_\_\_\_\_

Describe agent, amount, route:

List specific safety precautions and procedures for handling animals:

Has the necessary approval been obtained from:

Radiation Safety Committee	_____yes	_____no	_____not applicable
Biosafety Committee	_____yes	_____no	_____not applicable

**Section E: Teaching Proposals**

Will students be informed of the use of live animals in the courses prior to the end of the first week of classes?

\_\_\_\_\_yes \_\_\_\_\_no

Will alternative exercises be available for students who object to the use of live animals? \_\_\_\_\_yes \_\_\_\_\_no

If yes, please describe the alternatives that are available:

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD  
FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**INSTRUCTION PACKET  
FOR SUBMITTING A RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS**

Indiana University requires that all research utilizing human subjects **be approved BEFORE THE RESEARCH BEGINS (including subject recruitment)**. This satisfies a number of federal, state and institutional regulations and, more importantly, assures protection of the rights and welfare of persons used in research. Your cooperation is essential in following the procedures outlined.

PLEASE READ THIS ENTIRE INSTRUCTION PACKET. SUBMIT **ONLY** THE DOCUMENTS THAT APPLY.

1. A packet must be prepared for each research study using human subjects that is submitted to the IRB for review. Assistance in preparation of materials for IRB review is available. Contact the IRB at 812-941-2210. **Route the completed packet to the IRB, c/o Academic Affairs, LB-152, IUS.** Please allow a minimum of 2 weeks for processing of Exempt and Expedited reviews. Studies that require full Committee review will take longer.

2. Research projects involving human subjects can be reviewed by the Committee in three ways:

A. **EXEMPT RESEARCH REVIEW** (Special subject populations do not qualify. See page 4 for eligibility requirements.)

Documentation of Review and Approval ..... (page 3)  
Exempt Research Checklist .....(page 4)  
Exempt Research Statement ..... (page 5)  
Study Information Sheet.....(see pages 2 [item B] & 14)  
Other supporting documents.....(see page 2, items F-G)

B. **EXPEDITED REVIEW** (See page 6 for eligibility requirements.)

Documentation of Review and Approval..... page 3)  
Expedited/Full Review Checklist..... (page 6 & 6a)  
Summary Safeguard Statement..... (pages 7-9)  
Informed Consent Statement.....(see pages 2 [item D] & 10-13)  
Other supporting documents.....(see page 2, items F-G)

C. **FULL COMMITTEE REVIEW** (See page 6 for eligibility requirements. Circling any of items 14-17 will indicate the need for a full review.)

Documentation of Review and Approval.....(page 3)  
Expedited/Full Review Checklist..... (page 6 & 6a)  
Summary Safeguard Statement.....(pages 7-9)  
Informed Consent Statement.....(see pages 2 [item D] & 10-13)  
Other supporting documents.....(see page 2, items E-G)

3. **DOCUMENTS**

- All documents must be neatly typed and legible. **USE TYPE SIZE NO SMALLER THAN ARIAL 11 POINT.** Use lay language. Use of technical language will result in delays.
- **INCOMPLETE INFORMATION OR USE OF SMALL TYPE SIZE WILL RESULT IN DELAYS.**
- Do not type on the reverse side of any form.

A. **DOCUMENTATION OF REVIEW AND APPROVAL.** (Page 3, required for all types of review.) The IRB will assign the study number upon receipt of the application. A response must be provided for each blank. Project Duration dates should be when **data collection (analysis, in the case of use of existing data) begins** (this should be after the submission date) and when **data analysis will be completed**. List only one Principal Investigator on this page (see page 5, section D & 9, section I). Address should be where written notices will reach PI fastest. Signatures must be originals and by the person (no "per"). **Page 3 must be on a single page; do not carry it over to a second sheet of paper.**

## INSTRUCTIONS (continued)

- B. **EXEMPT RESEARCH.** Complete only pages 4 & 5 if the project falls in one or more of the categories listed on page 4. A **Study Information Sheet** must be used with most types of projects in this level of review (not required for category 4). A signed consent form will be required in some instances, and may be substituted for the Study Information Sheet if the researcher wishes proof of participation. *A sample format is provided on page 14.* The Study Information Sheet should contain the information listed in items 1-9 on page 10. Indicate how the information will be given (written or oral). If the Study Information Sheet is to be in a foreign language, submit the foreign language version and an English translation. **Type size must be no smaller than ARIAL 11 point or TIMES NEW ROMAN 11 point.**
- C. **SUMMARY SAFEGUARD STATEMENT.** Complete pages 6-9 if the project requires expedited or full review. A response must be provided for each item. This document can be typed on plain paper maintaining the identical order and wording if additional space is needed for responses. **Type size must be no smaller than ARIAL 11 point or TIMES NEW ROMAN 11 point.**
- D. **INFORMED CONSENT STATEMENT.** Expedited and full-review studies are required to obtain a signed consent form from each subject. Careful review of the attached Informed Consent Statement checklist (pages 10 & 11) is important in the preparation of this document (*see sample format on pages 12 & 13*). If the investigator is unable to include an Informed Consent Statement for any reason, a written explanation is required. Requests for deviations from standard documentation of consent must be reviewed by full committee. If the Informed Consent Statement is to be in a foreign language, submit the foreign language version and an English translation. **Type size must be no smaller than ARIAL or TIMES NEW ROMAN 11 point.**
- E. **FULL REVIEW.** In addition to a detailed Summary Safeguard Statement, applications for full review **MUST** include a review of pertinent literature and a description of procedures for data analysis.
- F. **INSTRUMENTS (all levels).** Include any instrument to be used; e.g., questionnaires or surveys. In the case of interviews, include a list (or representative sample) of the questions to be asked. If subjects will do a task, provide a sample copy of the task. Copy for any advertising should be submitted. All information that will be used to recruit subjects (precontact, letters, phone scripts, follow-up, etc.) must be submitted. If instruments are to be in a foreign language, submit the foreign language version and an English translation. All documents must be in the actual format that will be used.
- G. **COOPERATING INVESTIGATORS, DEPARTMENTS OR INSTITUTIONS.** If it is anticipated that another investigator or department may be involved in the research, include a co investigator from each cooperating department (see page 5, section D & page 9, section I). If the study will be conducted with another institution, include a letter of cooperation from that institution.
4. **AMENDMENTS** Investigators are required to report any proposed changes whatsoever to their research study via a **Study Amendment** form (send one copy with original signatures). Be sure to reference the original title of the study and the principal investigator.
5. **CONTINUING REVIEW** A status report must be filed with the IRB on at least an annual basis (send one copy with original signatures). The IRB will generate these reports for your completion. However, it is important for the investigator or the investigator's department chairperson to complete this form if the study is discontinued for any reason prior to receiving this form. This form must be completed even if the study was never initiated or was terminated for any reason.
6. **FILE MAINTENANCE** It is important for the investigator to **KEEP A COPY** of every document related to the research study which is submitted to the Committee. For audit purposes, these documents must be kept for at least three (3) years after terminating the study.
7. **ACTIONS** Much of the detail in these forms is required by Federal regulation. The Committee recognizes that this process can be frustrating and is willing to help in whatever way we can. Investigators will receive written notification of the results of the research proposal reviews within one week after the meetings. If immediate approval is not received, approval can be obtained with modifications of the original proposal in the vast majority of cases. The Committee will provide feedback on the appropriate changes which will result in acceptance of the proposal. Please refer to the principal investigator, exact title, and protocol number when submitting any documents related to a particular study. Please remember that research (or amendments to the research) may not begin until this written approval is secured.

**INDIANA UNIVERSITY SOUTHEAST  
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH  
DOCUMENTATION OF REVIEW AND APPROVAL**

of  
Research Project Utilizing Human Subjects

Study # \_\_\_\_\_

TITLE of PROJECT \_\_\_\_\_

PROJECT DURATION - START DATE \_\_\_\_\_ END DATE \_\_\_\_\_

PRIN. INVESTIGATOR \_\_\_\_\_ SCHOOL/DEPARTMENT \_\_\_\_\_  
ADDRESS \_\_\_\_\_ E-MAIL \_\_\_\_\_ PHONE \_\_\_\_\_

RANK: Faculty \_\_\_ Res. Scientist \_\_\_ Post-Doc \_\_\_ Staff \_\_\_ Student: undergrad \_\_\_ masters \_\_\_ PhD/EdD \_\_\_

**If PI's rank is OTHER than faculty, name of faculty overseeing the research (SPONSOR)** \_\_\_\_\_

SPONSOR'S E-MAIL & CAMPUS ADDRESS \_\_\_\_\_ PHONE \_\_\_\_\_

FUNDING AGENCY \_\_\_\_\_ APPL. DEADLINE \_\_\_\_\_

AGENCY PROJECT # \_\_\_\_\_ New \_\_\_ Continuation \_\_\_

*As the principal investigator, my signature testifies that I pledge to conform to the following:*

As one engaged in investigation utilizing human subjects, I acknowledge the rights and welfare of the human subject involved.

I acknowledge my responsibility as an investigator to secure the informed consent of the subject by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation.

I assure the Committee that all procedures performed under the project will be conducted in accordance with those Federal regulations and University policies which govern research involving human subjects. **Any deviation from the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the Committee in the form of an amendment for its approval prior to implementation.**

PRINCIPAL INVESTIGATOR:

\_\_\_\_\_  
(typed/printed name) (signature) (date)

***As the faculty sponsor, my signature testifies that I have reviewed this application and that I will oversee the research in its entirety, through the termination report.***

FACULTY SPONSOR:

\_\_\_\_\_  
(typed/printed name) (signature) (date)

\*\*\*\*\*  
**CAMPUS LEVEL REVIEW**

This protocol for the use of human subjects has been reviewed and approved by the Indiana University Southeast Institutional Review Board for the Protection of Human Subjects in Research

\_\_\_ Exempt Review ¶#\_\_\_, \_\_\_ Exempt ¶#\_\_\_ with signed/documentation of consent,

\_\_\_ Expedited Review ¶#\_\_\_, \_\_\_ Full Review, \_\_\_ Not Approved, \_\_\_ Withdrawn

Chairperson/Agent IUS IRB \_\_\_\_\_ Date \_\_\_\_\_

logged in \_\_\_\_\_ approval logged \_\_\_\_\_ copy to PI \_\_\_\_\_ rank code of sponsor \_\_\_\_\_

test: PI \_\_\_\_\_ sponsor \_\_\_\_\_ co-PI \_\_\_\_\_

**EXEMPT RESEARCH CHECKLIST**

**DIRECTIONS:** This form is to be completed and submitted to the IRB **only** when the investigator plans a research project which, in the investigator's judgment, is exempt from expedited or full Committee review. Even Exempt studies require at least one member or Agent of the IRB to review it. *Research activities are exempt from regulations for the protection of human research subjects when the **only** involvement of human subjects falls within one or more of the categories below.*

**STUDIES INVOLVING PRISONERS, FETUSES, OR PREGNANT WOMEN as subjects, OR involving HUMAN IN VITRO FERTILIZATION WILL NOT BE ACCEPTED AS EXEMPT FROM COMMITTEE REVIEW.**

If you are doing research in Indiana public schools, or your research is funded by the US Department of Education, and minors are involved, certain additional restrictions apply. Contact the IRB, 941-2210, for further information.

**Circle the appropriate category #s that apply to your research project & underline, or highlight, the specific section within the category:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (i) Information obtained is recorded in such a manner that the human subject can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. **See page 2, item F.**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2, **if:** (i) The human subjects are elected or appointed public officials or candidates for public office; **or** (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **See page 2, item F.**
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs (e.g., social security, welfare, etc.); (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**BE SURE YOU HAVE CIRCLED AT LEAST ONE ITEM THAT APPLIES TO YOUR PROJECT AND UNDERLINED THE SPECIFIC SECTION WITHIN THE ITEM, THEN COMPLETE PAGE 5.**

INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH

EXEMPT RESEARCH STATEMENT

Use type size no smaller than ARIAL 11 point.

A. Provide a brief description, in lay terms, of the purposed study and the procedures to be used. If interviewing, will you tape? What happens to the tapes at the end of the study? If they are to be kept, how long? For use of existing data provide a description of the data to be used and the source of the data.

B. Describe the process by which subjects will be recruited/selected (see item F on page 2), how many (or estimate) will be involved, and any benefits to the subjects. In the event of monetary gain, include all payment arrangements. If merchandise or service is given, indicate the value. If class credit will be given, list the amount and the value as it relates to the total points needed for an A. Describe other ways to earn the same amount. Tell how much payment/credit will be given if the subject withdraws prior to completion of the study. If minors are used, indicate the approximate age range. If only using male or female subjects, explain why. Disclose any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher; employer/employee. For use of existing data, provide the number of records to be used

C. Where will this study be conducted? If done during regular class time, what will non-participants do? How much time will be required of the subjects? If using questionnaires, how will they be distributed and collected? Describe methods for preserving confidentiality. How will data be recorded and stored, with or without identifiers? If identifiers are used describe the type: names, job titles, number code, etc. How long are the identifiers kept? If coding system is used, is there a link back to the subject's ID? If yes, where is the code list stored in relation to data, and when is the code list destroyed? How will reports be written, in aggregate terms or will individual responses be described? Will subjects be identified in reports (see item 5 on page 10)? For use of existing data tell whether identifiers are still attached to the data.

D. Co-investigators, not listed or signing on page 3, are to be listed here and should sign here, pledging to conform to the statements on page 3. **Please provide the person's name & e-mail address.**

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**EXPEDITED/FULL REVIEW CHECKLIST**

**DIRECTIONS:** This form is to be completed and submitted to the IRB when the investigator plans a research project which, in the investigator's judgment, requires expedited or full Committee review. Items 1-7 are the categories which may qualify for expedited review. **If "yes" is the response to any of items 10-13, the study will most likely require full Committee review.**

STUDIES INVOLVING *minors, pregnant women, fetuses, prisoners, persons with mental disabilities and economically or educationally disadvantaged persons* **MAY**, IN THE DISCRETION OF THE CHAIR, REQUIRE FULL COMMITTEE REVIEW.

**APPLICABILITY:**

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve ONLY procedures listed in one or more of the following categories, may be reviewed by IRB through the expedited review procedures authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedures when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

**CIRCLE THE APPROPRIATE CATEGORY NUMBERS THAT APPLY TO YOUR RESEARCH PROJECT AND UNDERLINE, OR HIGHLIGHT, THE SPECIFIC SECTION WITHIN EACH CATEGORY.**

1. Clinical studies of drugs and medical devices only when condition (a) **OR** (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture **as follows:**

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; **OR**

(b) from other adults and children\* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH  
EXPEDITED/FULL REVIEW CHECKLIST continued**

3. Prospective collection of biological specimens for research purposes by noninvasive means.
- Examples of biological specimens:** (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated (not by a tube inserted into the mouth) saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- Examples of procedures:** (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(3). This listing refers only to research that is not exempt.)
8. Use of minors under age 18, or economically or educationally disadvantaged persons.
9. Use of deception. (See item 14 on page 11.)
10. ***Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.***
11. ***Collection of information or recording of behavior which, if known outside of the research, could reasonably place the subject at risk of civil or criminal liability or damage the subject's financial standing, employability, insurability, reputation, or be stigmatizing.***
12. ***Collection of information regarding sensitive aspects of the subject's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.***
13. ***This project includes procedures that present more than minimal risk to the subject.***
14. This project includes procedures not listed above.

\* Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH

SUMMARY SAFEGUARD STATEMENT

Project Title (if you wish to use a different title in the consent statement than is listed on page 3, explain here):

**Do not type on the reverse side of any form.  
Use type size no smaller than ARIAL 11 or TIMES NEW ROMAN 12 point.**

A. Describe, in lay terms, the general nature and purpose of the proposed research and where the study will take place. Place the research in the context of the literature, including references.

B. Describe the process by which subjects will be recruited (see item F on page 2), how many (or estimate) subjects will be involved in the research, and how much time will be required of them. List specific eligibility requirements for subjects (or describe screening procedures), including those criteria that would exclude otherwise acceptable subjects. If your study uses only male or female subjects, explain why. For NIH-funded research only, address the inclusion of women, minorities and children in the research. Disclose any relationship between researcher and subjects - such as, teacher/student; superintendent/principal/teacher; employer/employee.

C. Check appropriate box for type of vulnerable subject population involved when investigation specifically studies:  
 minors (under age 18),  fetuses,  pregnant women,  persons with mental disabilities,  
 prisoners,  persons with physical disabilities,  economically or educationally disadvantaged,  
 other vulnerable population.

If any of the above are used, state the necessity for doing so. Please indicate the approximate age range of the minors to be involved.

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH  
SUMMARY SAFEGUARD STATEMENT (continued)**

D. List all procedures to be used on human subjects or describe what subjects will do. If done during regular class time, explain what non-participants will do. If you are taping, explain that here (see item 13 on page 11). *Asterisk* those you consider experimental. For those asterisked procedures, describe the usual method(s), if any, that were considered and why they were not used. (See item F on page 2 for more information.) Provide evidence of public domain use or permission granted for research instruments. i.e. for all survey instruments not developed by the researcher, provide references/sources.

E. State the potential risks - for example, physical, psychological, financial, social, legal or other - connected with the proposed procedures.

Briefly describe how risks to subjects are reasonable in relation to anticipated benefits. Describe procedures for protecting against, or minimizing, potential risks. Assess their likely effectiveness. If you are using an electrical device that is attached directly to subjects explain how the subjects will be protected from shock.

F. Describe methods for preserving confidentiality. How will data be recorded and stored, with or without identifiers? If identifiers are used describe the type: names, job titles, number code, etc, how long are identifiers kept? If coding system is used, is there a link back to the subject's ID? If yes, where is the code list stored in relation to data and when is the code list destroyed? How will reports be written, in aggregate terms, or will individual responses be described? Will subjects be identified in reports (see item 5 on page 10)? Describe disposition of tapes/films at the end of the study. If tapes are to be kept, indicate for how long and describe future uses of tapes.

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH  
SUMMARY SAFEGUARD STATEMENT (continued)**

G. What, if any, benefit is to be gained by the subject? In the event of monetary gain, include all payment arrangements (amount of payment and the proposed method of disbursement), including reimbursement of expenses. If using your own courses, if class credit will be given, list the amount and the value as it relates to the total points needed for an A. List alternative ways to earn the same amount of credit. If merchandise or a service is given, indicate the value. Explain the amount of partial payment/class credit if the subject withdraws prior to completion of the study.

H. What information may accrue to science or society in general as a result of this work?

I. Co-investigators, Cooperating Departments, Cooperating Institutions. If there are multiple investigators, please indicate only one person on the Documentation of Review and Approval (page 3) as the principal investigator; others should be designated as co-investigators here. **Co-investigators, not signing on page 3, should sign here, pledging to conform to the sentences on page 3.** If you anticipate that another department or institution may be involved in this research, list that here. If you are working with another institution, please include a letter of cooperation from that institution.  
**Please provide the person's name and e-mail address.**

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH**

**INFORMED CONSENT STATEMENT & STUDY INFORMATION SHEET CHECKLIST**

An **Informed Consent Statement** has two purposes: (1) to enable potential research subjects to make an informed choice as to their participation in a study, and (2) to document their decision to participate. In order to make an informed choice, potential subjects must understand the study, how they are involved in the study, what sort of risks it poses to them, and what to do if something untoward happens. **The words and language used to describe these factors must be understandable to potential subjects.**

A **Study Information Sheet** has the same purpose listed in (1) above. The subject's participation is considered consent; their signature is not required. **SAMPLES OF A CONSENT STATEMENT AND AN INFORMATION SHEET ARE PROVIDED ON PAGES 12-13 & PAGE 14.** Following the sample format will help to ensure that the necessary criteria for approval are included. Checking off an item as it is written into the statement/sheet will assist you in assuring that each element has been addressed in the document. **Assistance in the preparation of the consent statement or information sheet is available. Contact the IRB, c/o Academic Affairs, LB-152, IUS.**

**Items 1-10 are required elements of an Informed Consent Statement and each must be included in the informed consent statement submitted. Items 1-9 are required for a Study Information Sheet and each must be included in the study information sheet submitted. These elements are incorporated into the SAMPLES that follow on pages 12-14. USE TYPE SIZE NO SMALLER THAN ARIAL 11 POINT.**

1. Use the heading "Indiana University Southeast, Informed Consent Statement" or "Indiana University Southeast, Study Information Sheet".
2. List the title of the project as given on page 3 or page 7.
3. Invite the subjects to participate and state that the study involves research and describe the following:
  - a. purpose
  - b. procedures (identify any that are experimental)
  - c. expected duration of the subject's participation
  - d. reasonably foreseeable risks or discomforts
  - e. safeguards to be used to minimize risks
  - f. any benefits to the subject or to others; or the extent of contribution to the body of literature/knowledge
4. Discuss briefly alternative procedures or courses of treatment, **if applicable**.
5. Describe the extent, **if any**, to which confidentiality of records identifying the subject will be maintained. (For example: Names will be recorded with the data but names will not be used in the report and will be destroyed at the end of the study. Data will be stored securely, only research personnel will have access to it. Your identifiable data will not be available to anyone outside this research project without your additional permission. **Or** explain when and how confidentiality will be broken.) If subjects are identified in reports, signed consent is required. If research is conducted over the internet, you must tell subjects that you cannot guarantee confidentiality while their data is on the internet.
6. State the terms of subject compensation for study participation, **if any**. If the subjects will be paid (or receive other compensation) for participation, state how and when they will receive payment and/or compensation (i.e., compensation = toys, books, gifts, etc.). List value of gifts or service. If class credit will be given, list the amount. List alternative ways to earn the same amount of credit. Explain the amount of partial payment if the subject withdraws prior to completion of the study.
7. Include an invitation for the subject to ask any questions at any time about the study and its procedures, or their rights as subjects. Also, **if applicable**, include a statement that if the subject experiences adverse effects, the investigator should be contacted immediately.
8. Include the investigator's name, university address, telephone number, and e-mail address that the subject may use to ask questions and report any study related problems. For studies done outside the US, list both foreign and US contact information and the dates that apply to each. Include the Office of Academic Affairs, LB-152, 4201 Grant Line Road, New Albany, Indiana, 812-941-2210 as the place to contact with questions about participants' rights (see language in the sample formats).
8. Tell the subject that participation is voluntary. Further, state that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty, or loss of benefits to which the subject is otherwise entitled. **The Federal regulations for the protection of human subjects require these words or an equivalent statement.** Tell subjects what will happen to their data if they withdraw from the study. **NOTE:** If no identifiers are recorded with the data, then once a subject's participation is completed their data will not be identifiable to return or destroy.

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH  
INFORMED CONSENT STATEMENT & STUDY INFORMATION SHEET CHECKLIST (continued)**

10. Include a statement that says subject has read the consent form, has had questions answered to their satisfaction, acknowledges receiving a copy of the form, and agrees to take part in the study. Provide a line for signature(s) and the date. **Provide two copies of the Consent Form, one to be retained by the subject and one to be signed by the subject and, if applicable, the subject's parent(s)/guardian/legal representative and returned to you.**

If subjects are **minors** use the following guidelines for obtaining consent/assent:

- 6 years old and younger - only parent(s)/guardian/legal representative need sign;
- 7-8 years old - signature of minor is optional, requires signature of parent(s)/guardian/legal representative;
- 9 through 17 years old - requires signature of both minor and parent(s)/guardian/legal representative.

When younger children are subjects, a script that will be used to explain the study to the children must be submitted for review.

If the subject or legal representative is *unable to read and understand the written consent form*, it must be verbally presented in an understandable manner and witnessed (with signature of witness). This might apply in cases where subjects are: MENTALLY DISABLED, SERIOUSLY ILL, INSTITUTIONALIZED, INCARCERATED (PRISONERS), or OTHER VULNERABLE GROUPS.

**When appropriate, one or more of the following additional elements of information (items 11-19) shall also be provided to each subject, in either the Informed Consent Statement or Study Information Sheet:**

11. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. (Explain what will happen to data if a subject withdraws. If data are gathered that contain subject identifiers, the disposition of the data must be stated.)
12. The approximate number of subjects involved in the study should be indicated when the subject population is small in number. If subjects might be identifiable in reports because individual responses will be described (possible when the N is small), a statement to this effect should be included in the consent statement or information sheet.
13. If you plan to audio tape, videotape or film the subjects, request permission to do so in writing and indicate how you will be using this material (research purposes only?, research and instruction?, who will have access to or view the tapes?, will subjects be allowed to preview the tapes?, what will happen to the tapes at the end of the study?; what will happen to the tapes if the subject withdraws?). All possible uses of the tapes/films/photos (current & future) must be described. If tapes are kept by the PI beyond the end of the study and/or archived, then the following statement must be included: "The tapes/films/photos will not be used for any additional purposes without your additional permission." and signed/documented consent is required.
14. *IF DECEPTION IS USED*, include a statement to the effect that the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided. (Provide a copy of the debriefing script with your packet for Committee review.)
15. *Emergency Medical Treatment*. If the study is Department of Health and Human Services (DHHS) funded, or if the study involves risk procedures (exercise, medical, stress, alcohol, and so on), the following paragraph is to be included:  
"In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research."
16. A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant).
17. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
18. Any additional costs to the subject that may result from participation in the research. (If subjects will be charged for participation in the research project, then all costs must be itemized on the consent form. If alternative, non-investigational procedures are available, then these procedures should be discussed and the average costs included in the consent form.)
19. A statement that significant new findings developed during the course of the research, and which may be related to the subject's willingness to continue participation, will be provided to the subject.

**S A M P L E I N F O R M E D C O N S E N T S T A T E M E N T**  
**for expedited and full review studies**  
*(Include or exclude information as applicable.)*  
*(Item #s are keyed to the checklist for reference only-do not include in your consent.)*

Study # (IRB will fill in)

INDIANA UNIVERSITY SOUTHEAST  
INFORMED CONSENT STATEMENT *(item 1)*  
[List title of project here] *(item 2)*

You are invited to participate in a research study. *(item 3)* The purpose of this study is \_\_\_\_\_ . *(item 3-a)*

**INFORMATION**

Describe all procedures, preferably in chronological order, which will be employed in the study. Point out any that are considered experimental and explain technical and medical terminology *(item 3-b)*.

State the amount of time required of the subject per session and for the total duration of the study *(item 3-c)*.

*If applicable to your study, describe:*

Alternative procedures or courses of treatment [*when experimental procedures are being used*] *(item 4)*.

The number of subjects that will be participating in the research *(item 12)*.

Information concerning taping or filming *(item 13)*.

A disclaimer for the use of deception *(item 14)*.

**RISKS**

List the foreseeable risks or discomforts, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks *(items 3-d & e)*.

**EMERGENCY MEDICAL TREATMENT** *(item 15, if applicable add here)*

In the unlikely event of physical injury resulting from your participation in this research, emergency medical treatment will be provided at no cost to you. Be certain that you immediately notify the researcher if you are injured. If you require additional medical treatment you will be responsible for the cost. No other compensation will be provided if you are injured in this research.

**BENEFITS**

List the benefits you anticipate will be achieved from this research, either to the subjects, others, or the body of knowledge *(item 3-f)*. (There may be no direct benefits to the subjects, but benefits to the body of knowledge in general.)

**CONFIDENTIALITY** *(item 5)*

Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained. OR, explain when and how confidentiality will be broken.

**COMPENSATION** *(item 6, if applicable add here)*

For participating in this study you will receive \_\_\_\_\_. Other ways to earn the same amount of credit are \_\_\_\_\_. If you withdraw from the study prior to its completion, you will receive \_\_\_\_\_.

\_\_\_\_\_  
subject's initials

(Number pages, e.g. 1 of 2)

**CONTACT** (items 7 & 8)

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,\*) you may contact the researcher, [name], at [address], [phone number], and [e-mail].

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the Indiana University Southeast Institutional Review Board for the Protection of Human Subjects in Research, c/o Academic Affairs, LB-152, New Albany, Indiana, 47150, 812-941-2210.

**PARTICIPATION** (items 9 & 11)

Your participation in this study is voluntary; you may refuse to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

**CONSENT** (item 10)

I have read this form and received a copy of it. I have had all my questions answered to my satisfaction. I agree to take part in this study.

Subject's signature \_\_\_\_\_ Date \_\_\_\_\_

I agree to allow my child, \_\_\_\_\_, to take part in this study.

Parent's signature \_\_\_\_\_ Date \_\_\_\_\_

Witness signature \_\_\_\_\_ Date \_\_\_\_\_  
(required if form is read to subject)

Consent form date: (date you construct or revise the form)

(Number pages, e.g., 2 of 2)

**NOTE TO INVESTIGATORS:**

1. Researchers are urged by the IRB to use the wording in the checklist and sample, as it applies to their study, and to follow the format of the sample, unless researcher supported reasons are provided for the alternatives. Use of unnecessary alternative wording or different format may slow down the review process. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.
2. \*This phrase should only be included when the study also requires the use of the Emergency Medical Treatment Statement.
3. Study Information Sheets for mail surveys may take the format of a letter, as long as all required information is included.
4. For studies done in a foreign country or with subjects speaking a foreign language, indicate if the Informed Consent Statement or Study Information Sheet is to be in a foreign language, submit the foreign language version and an English translation.
5. Be sure to follow the directions in item 10 on the checklist for preparing the signature lines. **Separate forms should be prepared when young minors are used; one for the minors and one for the parents. If the minors are age 15 and above a single form may be acceptable with signature lines for both the minor and parent.** A script of what will be said to young children should be submitted.
6. If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained. All pages must be numbered.
7. Be sure to include any of items 11-19 on the checklist that are appropriate to your study. While items 16-19 are not specifically covered in the sample, if they apply to your study they must be included.
9. Leave a blank space of at least 1 ½" high by 3" wide at the bottom of the last page for the approved and expires stamps that will be affixed by the HSC. A copy of the stamped version will be returned to you for your use.

**S A M P L E   S T U D Y   I N F O R M A T I O N   S H E E T**  
**for exempt studies only**

(Include or exclude information as applicable.)

(Item #s are keyed to the checklist for reference only-do not include in your information sheet.)

Study # (IRB will fill in)

INDIANA UNIVERSITY SOUTHEAST  
STUDY INFORMATION SHEET (item 1)  
[List title of study here] (item 2)

You are invited to participate in a research study. (item 3) The purpose of this study is to \_\_\_\_\_ . (item 3-a)

**INFORMATION**

Describe all procedures, preferably in chronological order, which will be employed in the study (item 3-b).

State the amount of time required of the subject per session and for the total duration of the study (item 3-c).

If applicable to your study, describe:

The number of subjects that will be participating in the research (item 12).

Information concerning taping or filming (item 13)

**BENEFITS**

Describe the benefits you anticipate will be achieved from this research, either to the subjects, others, or the body of knowledge. (Item 3-f)

**CONFIDENTIALITY** (item 5)

Describe the extent, IF ANY, to which confidentiality of records identifying the subject will be maintained. OR explain when and how confidentiality will be broken.

**COMPENSATION** (item 6, if applicable add here)

For participating in this study you will receive \_\_\_\_\_. Other ways to earn the same amount of credit are \_\_\_\_\_. If you withdraw from the study prior to its completion, you will receive \_\_\_\_\_.

**CONTACT** (items 7 & 8)

If you have questions at any time about the study or the procedures, you may contact the researcher, [name], at [address], [phone number], and [e-mail].

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have not been honored during the course of this project, you may contact the Indiana University Southeast Institutional Review Board for the Protection of Human Subjects in Research, c/o Academic Affairs, LB-152, 4201 Grant Line Road, New Albany, IN, 47150, 812-941-2210.

**PARTICIPATION** (items 9 & 11)

Your participation in this study is voluntary, you may refuse to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

Information Sheet date (date you construct or revise the form)

(Number pages, e.g., 1 of 1)

(Indicate on a separate page whether this information will be presented orally or given to the subjects in written form. If provided in written form, duplicate copies are not necessary, as no signature is required.) In nearly all cases the IRB will require that the information be provided in written form. Check with the office for cases where oral presentation is acceptable.

**INDIANA UNIVERSITY SOUTHEAST INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN  
SUBJECTS IN RESEARCH  
CONFLICT OF INTEREST - ADDENDUM TO APPLICATION PACKET**

Effective 7/1/04

Please provide the following information as the last section of your research statement, regardless of the source of funding for the proposed research or the level of review:

1. Does anyone who will participate in the design, conduct, or reporting of the proposed research have a "significant financial interest," as defined in the University's Policy on Conflict of Interest, {<http://www.indiana.edu/~resrisk/conflict.html>} that is related to the subject matter of the research? If so, please describe the interest(s)
2. If the answer to (1) is yes, would that interest reasonably appear to affect, or be affected by, the design, conduct, or reporting of the proposed research? Please explain why or why not.
3. If the answer to (2) is yes, has this significant financial interest already been disclosed through a conflicts of interest disclosure form? If so, please append to this application a copy of the disclosure form and any other information indicating when and by whom the disclosure was reviewed, whether or not a conflict was identified, and if a conflict was identified, any steps taken to avoid, manage, resolve, and (where applicable under federal law) report that conflict. If a conflicts management plan was entered into, please attach a copy of that plan.

If a potential conflict of interest related to the proposed research is identified, based on external financial interests of the person(s) designing, conducting, or reporting the research, the Committee will work with the investigator(s) to develop appropriate language for the Informed Consent Statement or Study Information Sheet addressing the potential conflict.

~~~~~

Below are examples of conflicts of interests in hypothetical situations where human subjects are involved. They may also raise general conflict of interest questions which would be handled pursuant to the campus procedures on conflicts of interests.

- X has a grant to conduct trials of a new hearing aid. The year before, X who designed the new hearing aid licensed the product to Clear as a Bell, Inc. In return, X received a 10% share of the Company. X has a conflict of interest: His financial interest in the business that makes the product may bias his research into its effectiveness. The conflict must be disclosed to the IRB, which may decide that X's conflict be disclosed to the subjects in the informed consent, and will need to consider whether or not any further conflicts management may be required.
- X, a faculty member at the School of Education, sets up a corporation to do educational testing of children with learning disorders. X is president of the corporation and owns 80% of the shares of the company. X had devised a new instrument and wishes to test its validity. Her protocol to the IRB states X will test children in a number of schools in the state. If the test proves to be effective, X intends to license use of the test to her corporation. X has conflict of interest. Her financial interest is significant. The IRB needs to know of the conflict so that it can determine whether or not the subjects (the children and the parents) need to be informed of the conflict of interest, and how to best monitor the conflict.
- X is a faculty member at HPER. X has developed a plan of exercise for obese adults. X's plan is set forth in his book on exercise. X has human subjects approval to run an exercise clinic for both therapeutic and research purposes. X requires participants to buy X's book and video-tape on exercise. X has a conflict of interest which needs to be disclosed to and evaluated by the IRB.