

*Committed to new
Faculty Affairs Committee
(1/16/82)*

TO: The Senate
FROM: Human Subjects Committee
DATE: December 2, 1981
SUBJECT: IPFW Handbook on the Use of Human Subjects

DISPOSITION: Upon approval, to the Academic Vice-Chancellor for implementation.

Resolved, that the Senate approve the
"IPFW Handbook on the Use of Human Subjects."

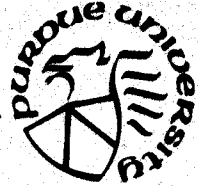
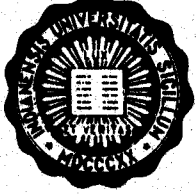
Approving

Bruce Abbott
Charles Champion
Elaine Cowen
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William Ludwin
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David Young
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Not Approving

Abstaining

Dr. John Kay, M.D.
(outside member)
Edward Nicholson
(Ex Officio)

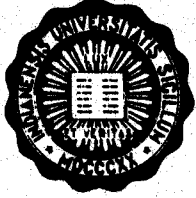


October 15, 1981

IPFW HANDBOOK ON THE
USE OF HUMAN SUBJECTS IN RESEARCH

Policies and Procedures of the
IPFW Institutional Review Board
on the Use of Human Subjects in Research

Revised July 1, 1981



Vice Chancellor's Memorandum

No.81-2

SENATE DOCUMENT SD 81-12

October 15, 1981

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CONTENTS

	Page
PREFACE.....	1
PART I: HUMAN SUBJECTS POLICIES.....	1
A. Purpose and function of the IPFW Institutional Review Board.....	1
B. Responsibilities and authority of the IRB in the review of research.....	2
C. Types of research to be reviewed.....	2
1. Pedagogical research.....	2
2. Academic research.....	3
3. Administrative research.....	3
4. Consulting research.....	3
5. Research conducted by outside agencies.....	4
6. Cooperative research.....	4
D. Types of IRB review.....	4
1. Full review.....	4
2. Expedited review.....	4
3. Risk-screening review.....	5
E. Criteria for obtaining IRB approval of a project.....	6
F. Informed-consent guidelines.....	7
1. Elements of informed consent.....	7
2. Waivers and alterations of informed consent.....	8
3. Documentation of informed consent.....	9
G. Liability at IPFW.....	10
H. IRB membership requirements.....	10
PART II: HUMAN SUBJECTS PROCEDURES.....	11
A. Initial review procedures.....	11
Phase I: Risk screening.....	11
Phase II: Expedited review.....	12
Phase III: Full IRB review.....	12
Phase IV: Review of HHS, FDA, and funded research proposals.....	12
B. Continuing review procedures.....	12
C. Observation procedures.....	13
D. Problem-reporting procedures.....	13
E. IRB record-keeping and documentation procedures.....	13
REFERENCES.....	13
APPENDIX A: DEFINITIONS.....	14
APPENDIX B: FORMS.....	15
IPFW-IRB Proposed Research Form.....	15
IPFW-IRB Research Review Form.....	18
IPFW-IRB Notification of IRB Decision.....	19
IPFW-IRB Report of Problems Involving Risks to Human Subjects.....	20
Sample Informed-Consent Form.....	21

This document contains the policies and procedures which govern human-subjects research conducted by faculty, students, and administrative staff at IPFW. The forms to be used with these procedures are included here, as are a glossary of relevant terms and a sample informed-consent form.

On July 1, 1981, revised Health and Human Services (HHS) guidelines governing the use of human subjects in research took effect. Due to the presence of exempted categories of research in the HHS guidelines, some researchers may erroneously be led to assume that all research falling within these categories is automatically exempt from review. At IPFW all research, either funded or unfunded, continues to need some form of review. General review of research proposals, in the form of a risk screening, will determine whether a project is exempt from further review, is eligible for expedited review, or requires full review. These procedures and policies are consistent with the IPFW policy of protection of human subjects in research.

All IPFW researchers are strongly urged to read this document carefully and address any questions to the chair of the IPFW Institutional Review Board (IRB).

PART I: HUMAN SUBJECTS POLICIES

A. Purpose and function of the IPFW Institutional Review Board

The Indiana University-Purdue University at Fort Wayne IRB exists to safeguard the wellbeing of human subjects used in any form of research project. The IRB also exists to safeguard the research interests of student, faculty, and administrative researchers. To accomplish these goals the IRB reviews all research on human subjects. The IRB approves projects which are carried out in an ethical manner conforming to the ethical standards of Indiana and Purdue universities and of those professional associations which have adopted ethics and research guidelines. The IPFW regulations supersede those of a professional association.

The functions of the IPFW-IRB are as follows.

1. To conduct initial and continuing reviews of research, and report findings and actions to the investigator and, in annual summary form, to the Vice Chancellor and Dean of the Faculty and the Indiana and Purdue universities' all-university committees;
2. To conduct its reviews of research (except risk screening and expedited review) at convened meetings at which a majority of IRB members are present;
3. To classify projects as requiring risk screening only, expedited review, or full IRB review;
4. To determine which projects require review more often than annually and which projects need verification from sources other than the investigators, with the concurrence of a majority of attending IRB members, on the basis of information provided by the researcher(s) and, as necessary, outside experts (Any project judged as having moderate or high risk will require continuing review. At any level of review IRB members may request outside experts to review and verify a proposal);
5. To review proposed changes in research activities (e.g., changes in methodology, subject selection, or questionnaire or instrument design) to insure that such changes do not harm the subjects of a previously approved project;
6. To create procedures so that the IRB, HHS, and Indiana University and

Purdue University receive reports of problems involving risks to human subjects and others (i.e., assistants, interviewers, families of subjects);

7. To report in writing to the Vice Chancellor and Dean of the Faculty, to the universities, and to HHS any continuing or serious noncompliance by researchers with IRB requirements and determinations. The IRB has authority to suspend or terminate approval of research that does not comply with IRB's determinations or which has resulted in the unexpected harm of subjects. The IRB, through its chair, shall promptly report a suspension or termination to the Vice Chancellor and Dean of the Faculty, and to university officials, citing the reasons for its action.

B. Responsibilities and authority of the IRB in the review of research

In conducting the review of research proposals, the IRB:

1. Reviews and has the authority to approve, require modification in, or disapprove all human-subjects research, funded or unfunded, on the IPFW campus. If research is conducted on the campus without IRB approval or despite IRB disapproval, the IRB, through its chair, is empowered by Purdue University Executive Memorandum B-13 (26 March 26 1973) to suspend such research until it is brought into compliance with these policies. Indiana University employees at IPFW are also subject to this memorandum;
2. Requires that information given to subjects as part of informed consent be in accordance with IRB requirements on informed consent, and that additional information as deemed necessary by the IRB be provided to subjects to add to the protection of their rights and welfare;
3. Requires that informed consent be documented or waived in accordance with IRB requirements;
4. Notifies researchers and, in summary form, the universities of decisions to approve or disapprove proposed research activities, and of modifications necessary to secure IRB approval. Researchers receiving IRB disapproval will be given a statement of reasons for the decision and an opportunity to respond to the IRB;
5. Conducts continuing review of moderate- or high-risk research at intervals appropriate to the degree of risk, but not less than once annually. Further, the IRB has the authority to observe (or have a third party observe) the informed-consent process and research;

C. Types of research to be reviewed

The IRB recognizes six types of research involving human subjects.

1. Pedagogical research is research designed to contribute to the knowledge and training of students by increasing their understanding of techniques and substantive subjects. In practice, much of this research requires no IRB action other than risk screening.

Research conducted, directed, or designed by a faculty member or student and undertaken within a single classroom context for learning purposes, and where students serve as human subjects, does not normally require IRB approval. These classroom research projects should provide the students with sufficient information and opportunity to consider whether to participate, and should minimize the possibility of coercion or undue influence. A faculty

member conducting such research should adhere to the ethics policy published in the Indiana University Academic Handbook or the Purdue University Faculty Handbook. An ideal classroom research situation is one in which a faculty member designs the research and a student assistant not taking the class obtains the students' informed consent and collects the data or performs the experiment, thus removing the authoritative influence of the faculty member from the research context.

Pedagogical research other than that discussed above requires IRB approval. Such research may be of any type (i.e., experiment, survey, observational study). Where a diversity of such small-scale studies are included in a course, the responsible faculty member may submit a single proposal to the IRB. This proposal must contain sufficient information concerning each mini-research project to enable the IRB to make either group or individual-project decisions. To further the learning process, students could actively participate in the drafting of the IRB proposal for their mini-projects.

Student internships in Fort Wayne community agencies do not require IRB approval except when students are engaged in gathering primary data (i.e., interviewing) for an agency or in conducting pedagogical research which normally requires IRB approval.

2. Academic research is basic or applied research conducted, directed, or designed by a faculty or staff member with the aim of furthering knowledge. All academic research which involves human subjects requires IRB approval. Academic researchers are further advised of the special HHS policies governing clinical investigations and research in special populations of prisoners, persons under the age of 18, pregnant women, and women of childbearing age; further information on HHS policies is available from the chair of the IPFW-IRB.

Research involving the collection of primary data from human subjects is subject to IRB approval. Research involving the secondary analysis of data collected by other researchers does not require IRB approval; however, researchers using secondary data sets should endeavor to maintain the confidentiality of the subjects who were used in the original data collection and adhere to any informed-consent agreements entered into during the original research.

3. Administrative research is research conducted by administrative staff or administrative units (e.g., departments, schools, divisions) for the purpose of collecting data or information which extends beyond that required in the normal course of institutional functioning. Evaluations of faculty, staff, and administration are not considered research activities, since they are considered necessary for the administrative functioning of the university. Such activities as alumni surveys, student surveys for course and department planning, administrative-staff or management-information surveys, and management-training experiments are considered research and are subject to IRB approval.

4. Consulting research is research conducted, directed, or designed by a faculty or staff member, either with or without a pedagogical component, for an agency, group, or organization outside the university community. Research activities which are considered community service are considered consulting research. Only when a university member does not conduct, direct, or design such research, but functions solely in an advisory capacity, does such research not require IRB approval.

5. Research conducted by outside agencies is research or polls conducted, directed, or designed by agencies and organizations (e.g., newspapers, local government, social service agencies) which wish to use students, faculty, or staff of IPFW as subjects of the research. Research of this type requires IRB approval, approval of the IPFW administration, and--where students are to be polled in classrooms--approval of the faculty member(s) in charge. Outside researchers are also held to the criteria and conditions for proposal approval that apply to academic research.

6. Cooperative research is research conducted by a faculty or administrative staff member in cooperation with another university, agency, or organization. If this cooperative research is HHS-funded, the grantee or primary contractor remains responsible for safeguarding the rights and welfare of human subjects, and each cooperating institution must comply with the regulations of the primary contractor. At IPFW, cooperative research will receive at minimum a risk screening, if the primary contractor has received IRB approval elsewhere, and full review if no IRB approval has been received elsewhere.

D. Types of IRB review

The IRB conducts three types of review.

1. Full review requirements and procedures are fully described in Part II and apply to all projects which are ineligible for the two types of limited review described below.

2. Expedited review is available for projects involving no more than minimal risk (as determined by an IRB risk screening) if the involvement of human subjects lies completely in one or more of the following areas and if only standard research methods are used.

a. Collection of hair and nail clippings, in a nondisfiguring manner; of deciduous teeth; and of permanent teeth if patient care indicates a need for extraction;

b. Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;

c. Recording of data from subjects aged 18 or above, using noninvasive procedures routinely employed in clinical practice. These include the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. They also include such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. They do not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves);

d. Collection of blood samples by venipuncture, in amounts not exceeding 450 ml in an eight-week period, and no more often than two times per week, from subjects aged 18 or above who are in good health and not pregnant;

e. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylac-

tic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

- f. Recording the voice for such research purposes as investigating speech defects;
- g. Administering moderate exercise to healthy volunteers;
- h. Studying existing data, documents, records, and pathological or diagnostic specimens;
- i. Studying individual or group behavior or characteristics, including studying perception, cognition, game theory, or test development, if the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;
- j. Studying drugs or devices for which an investigational new drug or device exemption is not required.

3. Risk-screening review of all projects involving human subjects is required to determine which projects require further IRB review. Research which normally presents little or no risk (minimal risk) to human subjects is exempt from further IRB review.

A risk screening normally results in the following types of research being exempted from further review.

a. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., staff evaluations); research on regular or special instructional strategies (e.g., student evaluations of faculty performance); and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom-management methods. Pedagogical research conducted on students or by students is not exempted except as outlined above;

b. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, and achievement tests) if information taken from these sources is recorded so that the subjects cannot be identified, directly or through identifiers linked to subjects. New educational tests or clinical testing which identifies subjects are not exempted;

c. Research involving survey or interview procedures of minimal risk, or research involving observation (including observation by participants) of public behavior, except where all of the following conditions exist:

(1) Responses and observations are recorded so that the human subjects can be identified, directly or through identifiers linked to subjects;

(2) Responses or recorded observations, if they became known outside the research, could reasonably cause harm or place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing or employability; and

(3) The research deals with sensitive aspects of the subject's behavior, such as illegal conduct, drug abuse, sexual behavior, or use of alcohol;

d. Research involving survey or interview procedures when the respondents are elected or appointed public officials or candidates for public office;

e. Research involving the collection or study of existing data, documents, records, or pathological specimens, if these sources are publicly available or if the information is recorded by the investigator so that the subjects cannot be identified, directly or through identifiers linked to them.

E. Criteria for obtaining IRB approval of a project

The IRB will insure that all research projects fulfill the following requirements.

1. Risks to subjects are minimized by the use of the safest procedures consistent with sound methodology and research design. Ill-formulated research methodologies are considered as invasions of subject privacy and are not approved. Whenever possible, research should be conducted with established procedures; new procedures and techniques will be carefully reviewed for their effects on subjects.

2. Risks to subjects are reasonable in relation to the anticipated benefits to subjects, the importance of the knowledge gained through the research, and the pedagogical significance to students, when applicable. The IRB does not assess possible long-range political, social, or economic effects arising from applications of knowledge gained in the research, but does assess both long- and short-term effects of research on subjects.

3. The selection of subjects is equitable, considering the purposes of the research. Sound methodological considerations call for research assignment or random selection of sample subjects from a population. Convenience samples, such as students, which are not equitable, require justification by the researcher.

4. Informed-consent and consent-documentation requirements are met.

5. In some research situations where the quality of the data collected may harm the subjects, adequate provisions are made to monitor the collection of data. This situation is most likely to occur in dental or medical research where poor-quality data might cause misdiagnosis and consequent harm.

6. Adequate provisions are made to protect the privacy of subjects and to maintain confidentiality of data collected.

The principle of subject confidentiality involves the determination of "reasonable identifiability"--the minimal amount of subject identifiability without which the research could not be conducted. In survey research and some experiments, this concept principally applies only in the choice of sampling frame and sample. Researchers should take steps to insure that their lists do not enter the public realm, and are not sold, bartered, or exchanged. Where written informed consent is used, the additional element of documentation is added, and researchers should keep these records for a three-year period, again preventing their entrance into the public realm.

Confidentiality should be maintained through the analysis phase of research, where only an identification number should be used on data records. Subject

names and other unique identifiers should be eliminated from all data analysis. By reporting the data in grouped or statistical-summary form, the subject's confidentiality is further guaranteed. Where computerized data bases are to be used, these files should always be password-protected and limited to the specific originating research project.

Should a researcher desire to release data to other researchers for secondary analysis, all subject identifiers and unique variables should be removed before release. Researchers should consult the U.S. Census guidelines on the release of data files for more information on this subject.

When maintaining more than minimally identifiable records and data is essential, the researcher should clearly present and document such necessity in the IRB proposal, and provide detailed plans for guarding subject confidentiality.

The issue of the invasion of subjects' privacy is very sensitive. Each subject may have a unique conception of invasion and privacy. Adequate steps to minimize this problem are (1) following the informed-consent guidelines; (2) developing an instrument which minimizes sensitive questions; (3) creating an instrument which adequately and clearly addresses the research problem and contains no extraneous questions which are not germane to the research (Background and socioeconomic questions are not considered extraneous, as they form major variables for sociocultural analysis.); and (4) providing training for data collectors, so that their demeanor toward subjects is not offensive.

7. Additional safeguards are taken when vulnerable subjects (e.g., children, women of childbearing years, pregnant women, handicapped or mentally retarded persons, and students) are involved in the research, in order to protect against coercion and rewards. Academic performance evaluations (grades) may not be used as incentives in any research context.

The Vice Chancellor and Dean of the Faculty, as a representative of IPFW and the universities, may review, approve, or disapprove research covered in these regulations after IPFW-IRB approval. However, the universities and their agents may not approve research covered here after it has received IRB disapproval. Research involving moderate or high risk to subjects will be approved only after further review by the Purdue or Indiana university IRB.

F. Informed-consent guidelines

1. Elements of informed consent

Informed-consent procedures must normally contain elements a. through j. below; where appropriate, these procedures must also include elements k. through p.

Subjects under age 18 must have parental consent prior to any research; prior consent from minor subjects should also be obtained when these subjects are competent to grant or deny it.

Informed-consent procedures must:

- a. Include a reasonable opportunity for the subject to consider participation;
- b. Be expressed in understandable language;

- c. Exclude language which in any way (1) relieves the researcher of obligation and responsibility to the subject for consequences arising from the project, or (2) waives a subject's civil or legal rights;
- d. Contain a reasonable explanation, free from gross deception, of the research, its purposes, procedures, and duration of participation;
- e. Describe any benefits to the subject or community to be gained from the knowledge discovered in the research;
- f. Describe any alternative procedures, where appropriate, for conducting the project (e.g., if a subject does not want an interview tape recorded, an alternative procedure would be to take notes);
- g. Describe the extent to which confidentiality of records will be maintained;
- h. Explain the availability of treatment and compensation if an injury should occur (compensation considerations must be negotiated with the Vice Chancellor and Dean of the Faculty);
- i. Contain instructions concerning who may be contacted for answers to questions posed by subjects (e.g., the phone number of the researcher, so that a survey respondent may check on the legitimacy of an interviewer);
- j. State any other conditions of participation (e.g., that participation is voluntary, that subjects may remove data at a later time);
- k. State that the procedure may involve unforeseeable risks;
- l. State the circumstances for termination by the investigator of a subject's participation;
- m. Describe any consequences of a subject's withdrawal from participation;
- n. State that any significant new findings will be provided to the subject;
- o. State the approximate number of subjects in the study;
- p. Inform subjects, where appropriate, that they will be debriefed fully upon completion of the research (particularly experiments), under a debriefing plan approved by the IRB.

2. Waivers and alterations of informed consent

The IPFW-IRB may approve certain projects which do not include or which alter some or all of the informed-consent elements. Such a change of some or all informed-consent requirements does not exempt the research as a whole from IRB review. Where written documentation is waived, the IRB may require the investigator to provide the subject with a written statement regarding the research.

- a. In the case of minimal-risk research only, when the researcher is dealing with individuals of varying degrees of capacity to understand, the complexity of the informed consent may be varied. Such individuals

of impaired or limited capacity might include those with chronic or acute mental disabilities, victims of accidents, persons being treated with drugs which impair mental functioning, aged persons with diminished capacity, and persons of limited intelligence. Under these circumstances, alterations or waivers will be approved only (1) for use with subjects who are functionally and legally competent to give consent and (2) if the purpose is to insure that these subjects receive information they can reasonably be expected to understand in order to make knowledgeable decisions regarding their participation. The IRB assures that such subjects are presented consent information when they can make a reasonable judgment, and determines that each subject has sufficient capacity to give consent.

b. Informed consent may be waived for large-scale evaluations if obtaining informed consent is impractical or impossible, as in the case of studies of federal, state, or local benefit or service programs which affect all residents of a large population.

c. Informed consent may be waived if the researcher shows that the only record linking the subject to the research would be the consent document, and that the principal risk would be the potential harm resulting from a breach of confidentiality. All subjects in such research will be asked if they want documentation linking them to the research, and each subject's wishes shall govern.

d. Informed consent may be waived if the research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

3. Documentation of informed consent

Such documentation of informed consent as the IRB requires will generally consist of one of two types:

a. A written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy of this form is to be given to the person signing it. The form may be read aloud to the signer, but the signer must also be allowed an opportunity to read the form;

b. A short-form written-consent document approved by the IRB and presented orally to the subject or the subject's legally authorized representative. An oral presentation requires that a witness be present. The short form is signed by the subject or representative, and the witness.

In the case of a telephone interview, the researcher must include the basic elements of informed consent in the verbal introductory statement to the subject approved by the IRB. A specific question regarding the consent given must be included and documented in the interview schedule.

In the case of mailed surveys, the informed-consent information should be included as part of the cover letter approved by the IRB. The subject should be clearly informed that returning the instrument to the researcher implies informed consent.

G. Liability at IPFW

While providing guidelines for human-subjects research, HHS has declined to assume any financial or legal responsibility for researchers or IRB members who may be sued in the course of a project, or for approving the human-subjects content of a project. As Purdue University is the fiscal agent for IPFW, the general Purdue liability policy protects all personnel so long as they are acting within the scope of their duties:

"The insurance coverage applies to individual staff members involved in human subject activities only if the particular activity has been approved by the committee on the use of Human Subjects. The individual staff member is not protected by the University's insurance if the activity has not been approved or has been disapproved by the Committee. Also, there would be no protection for a staff member who does not follow the procedures established by the Committee for a particular activity."

--Purdue University Liability Document, 17 May 1976

H. IRB membership requirements

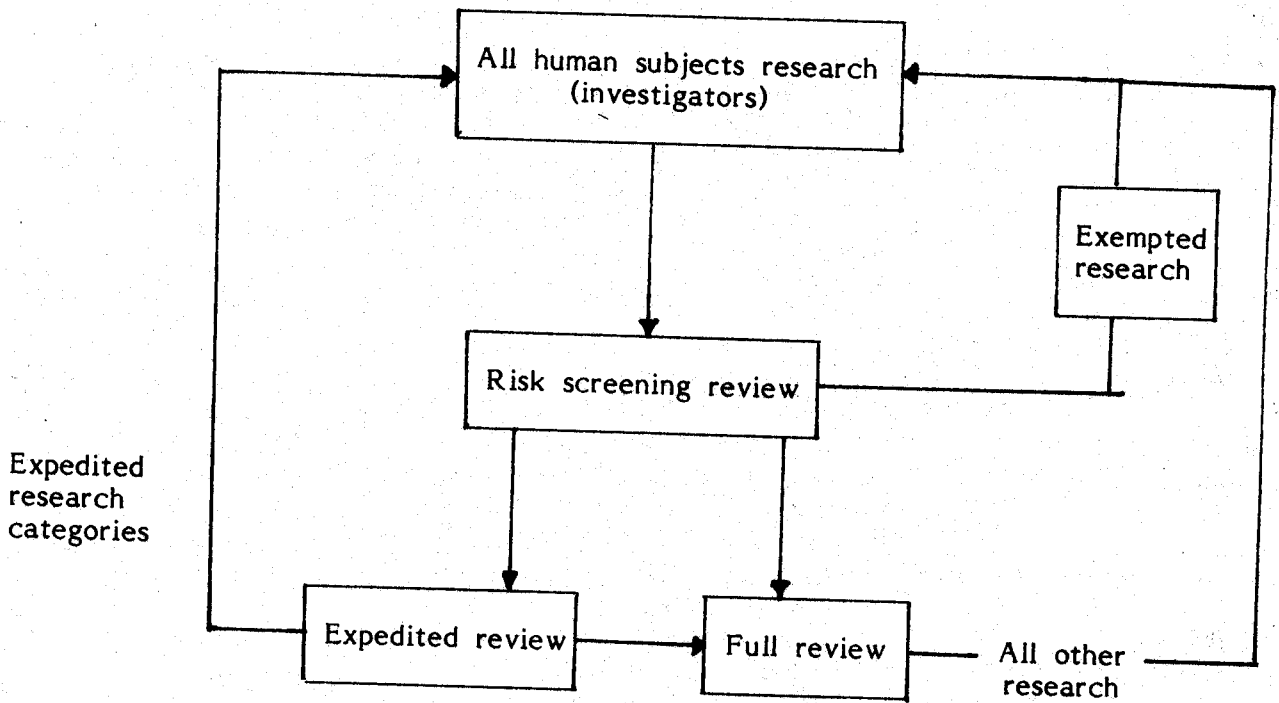
The IRB membership list shall be annually distributed to IPFW faculty. To insure representation of sufficiently diverse backgrounds, the IPFW-IRB:

1. Should include persons who vary in racial and cultural backgrounds and sensitivities to issues and community attitudes;
2. Should assure representation of academic units that use human subjects in research: Dental Auxiliary Education, Medical Education, Nursing, Education, Supervision, Business and Economics, Psychology, Biology, Communication, Sociology and Anthropology, Public and Environmental Affairs, etc.;
3. Shall include persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable law, and professional standards;
4. Shall include members of both sexes;
5. Shall include at least at least one member whose primary concerns are in non-scientific areas (e.g., Philosophy);
6. Shall consist of members representing more than one profession;
7. Shall include a member who is not affiliated with or related to a person affiliated with IPFW;
8. Shall include persons who are primarily concerned with the welfare of vulnerable subjects;
9. Shall not permit its members to participate in any review of a project in which the member has a conflicting interest, except to provide information requested by the IRB.

PART II: HUMAN SUBJECTS PROCEDURES

A. Initial review procedures

Review responsibilities have been distributed among the diverse members of the IPFW-IRB. The three procedures for review are risk screening, expedited review, and full review. The figure below depicts these procedures.



Phase I: Risk screening

All human-subjects research at IPFW receives risk screening. The investigator, or in the case of student research the faculty advisor, submits a completed Proposed Research Form (See Appendix B) to the departmental IRB member or IRB chair. Investigators do not assign their own risk levels. The IRB member assesses the degree of risk and any possible harm to subjects in accordance with the guidelines in this document. Problems with the proposal, incomplete proposals, methodological flaws, etc., will be discussed with the investigator at this level. Using a Research Review Form (See Appendix B), the IRB member (a) assigns a risk level to the project, (b) determines whether informed consent is necessary, (c) gathers any additional expert opinions of the project, and (d) makes a recommendation to the chair of the IRB. The recommendation may be (a) to approve the project as exempted research involving minimal risk and requiring no further IRB action; (b) to refer the project to expedited review; or (c) to refer the project to full committee review. For projects judged to be of minimal risk in an exempted category, the chair notifies the investigator of IRB approval to begin research.

Processing time for risk screening ranges from 24 to 72 hours. Approval covers a period of one year from the date of approval.

Phase II: Expedited review

Should the research fall into one of the expedited-review categories, the risk-screening procedure will recommend an expedited review if the project has no more than minimal risk. Expedited review will also be used for review of minor changes in previously approved research during the authorized approval period.

Expedited review is conducted by three IRB members designated by the chair. Two of these members are chosen for their expertise in the research area; the third member has an area of expertise outside that of the proposal topic. The reviewers exercise all of the authorities of the IRB, except that they may not disapprove a research proposal. The expedited-review subcommittee may (a) approve or request modifications in a proposal, or (b) recommend the proposal for full IRB review. The expedited-review subcommittee makes its decisions in accordance with the guidelines in this document. The vote and any additional comments and recommendations are forwarded to the IRB chair, who notifies the investigator of the subcommittee vote.

Review time is about one to two weeks.

Phase III: Full IRB review

Research which falls into the exception categories under exempted research, research which has been recommended for full review by an expedited-review subcommittee or risk screening, all research which is to be HHS or FDA funded, and all moderate- or high-risk research will receive full IRB review. After risk screening, the investigator forwards fifteen copies of the research proposal and all additional documentation to the IRB chair, and a meeting of all members is called within two weeks of receipt. After reviewing the proposal in accordance with this document, a majority of the IRB members vote to determine the disposition of the proposal: (a) approval, (b) modification and resubmission, or (c) disapproval. The IRB members, under the second and third possibilities, are required to furnish their comments and criticisms of the proposal in writing to the chair, who notifies the investigator of the IRB decision.

The investigator receives copies of IRB members' criticisms, comments, and suggestions, and may respond to the IRB in writing or in person. A disapproved or modifiable project is eligible for resubmission to the IRB only after the criticisms and comments of IRB members have been integrated into a new proposal. Resubmissions from either expedited or full review undergo full IRB review.

Phase IV: Review of HHS, FDA, and funded research proposals

After IPFW-IRB approval of funded proposals, the proposals are forwarded for final approval to either the Indiana University or the Purdue University IRB.

B. Continuing review procedures

If the expedited-review subcommittee or the IRB recommends continuing review of a project, periodic review will be set at intervals during the year for which approval has been given. The investigator's report to an expedited-review subcommittee established for the purpose of continuing review must cover items listed by the IRB. Failure to comply with continuing-review requirements results in the withdrawal of a project's approval.

C. Observation procedures

For some research, an IRB member may be required to observe or witness the informed-consent process. The IRB chair designates an IRB member to this observer task, and the IRB member and investigator arrange times for observing the consent process.

D. Problem-reporting procedures

After receiving approval, investigators receive a problem report form (See Appendix B) from the IRB. Harm to human subjects must be reported immediately to the IRB chair, the Vice Chancellor and Dean of the Faculty, and the universities; research must be voluntarily halted until completion of an IRB investigation of the problem. The IRB may recommend suspension or resumption of the research, compensation for subjects, or other actions recommended by the Vice Chancellor and Dean of the Faculty or the universities.

E. IRB record-keeping and documentation

The IRB chair, in conjunction with the Vice Chancellor and Dean of the Faculty, maintains for three years, accessible for inspection and copying by the universities and by HHS representatives, the following documentation.

1. Copies of all research proposals, scientific or expert evaluations, approved sample consent documents, progress reports, and reports of problems or injuries to subjects;
2. IRB meeting minutes, in sufficient detail to show attendance at meetings, actions taken by the IRB, the number of members voting for and against these actions, the basis for requiring changes in or disapproving research, and written summaries of discussions of controversial issues and the resolution;
3. Records of continuing-review activities;
4. Copies of all correspondence between the IRB and investigators;
5. IRB membership lists;
6. Written procedures (this document) of the IRB;
7. Statements of significant new findings provided to subjects.

REFERENCES

- Federal Register, 27 January 1981, part IV: "HHS: Protection of Human Subjects"
Indiana University Academic Handbook
Purdue University Executive Memorandum B-13, 26 March 1973
Purdue University Faculty Handbook
Purdue University Liability Insurance Memorandum, 17 May 1976

APPENDIX A

DEFINITIONS

Harm

Physical harm: injury, external or internal, to the human body

Psychological harm: damage which produces feelings of guilt, embarrassment, humiliation, degradation, worthlessness, depression, anxiety, or stress

Social harm: libel, slander, or subjection to public humiliation

Human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information

Interaction: communication or interpersonal contact between investigator and subject

Intervention: physical procedures by which data are gathered (e.g., venipuncture), or manipulations of the subject or the subject's environment that are performed for research purposes

Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record); private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects

Research: a systematic investigation designed to develop or contribute to general knowledge

Risk

Minimal risk: a condition under which the risks of harm anticipated in 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

Moderate risk: a condition under which the risks of harm anticipated in proposed research are greater than those normally encountered in daily life, but exclude the potential for severe physical or mental harm to subjects

High risk: a condition under which the risks of harm anticipated in proposed research include the potential for severe physical or mental harm to subjects

APPENDIX B

FORMS

IPFW-IRB Proposed Research Form
(Revised 7/81)

1. Type of review

<input type="checkbox"/>	Risk screening	Date: _____
<input type="checkbox"/>	Expedited review	Date: _____
<input type="checkbox"/>	Full review	Date: _____

2. Name(s) and title(s) of investigator(s) Department Phone

3. Project title

4. Grant, project, or contract number and agency

5. Proposed starting date of research

6. Purpose/background of research

7. Statement of research problem (include definitions and operationalizations of critical concepts and variables)

8. Research design (e.g., survey, experiment, observation; describe in detail)

9. Mode of subject selection (e.g., random, convenience, judgmental sampling, volunteers, classes, etc., and criteria for selection and/or assignment of subjects to groups)

10. Data collection procedure/method (e.g., how data will be collected, how stimuli or questionnaires will be administered; attach copy of research instrument [questionnaire] or describe apparatus to be used, with documentation of instructions to subjects and assistants)

11. Informed-consent procedure (if appropriate; attach copy of informed-consent form)

12. Other procedures to protect subjects (describe possible risks and benefits to subjects arising from research)

13. Debriefing plans/follow-up (describe any plans for subject debriefing and/or follow-up when appropriate; explain how subjects will be informed about findings)

14. Other necessary documentation attached (e.g., articles, outside expert opinions)

STATEMENT OF IRB REGULATION COMPLIANCE

To the best of my knowledge, the plan of conduct for this research conforms to accepted ethical procedures and the policies and procedures of the IPFW-IRB and Indiana University or Purdue University. I agree to keep appropriate records for three years following completion of this study and to give such records to my supervisor or department head if I leave the IPFW campus. I agree immediately to notify the IRB of any problems, injuries, or unanticipated harm to subjects, and will suspend research if this occurs. I further agree to notify the IRB of any changes in the research or in expected risks to subjects.

Signature

Date

IPFW-IRB Research Review Form

Name(s) of investigator(s)

Type of review

- Risk screening
 Expedited review
 Full review

Project title

- | 1. Risk criteria | Satisfactory | Unsatisfactory |
|---|--------------|----------------|
| 1. Risks to subjects minimized by use of safe testing methodology and problem formulation | _____ | _____ |
| 2. Risks to subjects reasonable, given benefits to subjects, knowledge gained, and pedagogical significance | _____ | _____ |
| 3. Equitability of subject selection | _____ | _____ |
| 4. Adequacy of informed-consent procedure | _____ | _____ |
| 5. Adequacy of informed-consent documentation | _____ | _____ |
| 6. Protection of subject privacy | _____ | _____ |
| 7. Confidentiality of data | _____ | _____ |
| 8. Additional safeguards | _____ | _____ |
| 2. Detailed reviewer comments, criticism of research | | |
| 3. Recommended risk level | | |
| <input type="checkbox"/> Minimum risk
<input type="checkbox"/> Moderate risk
<input type="checkbox"/> High risk | | |
| 4. Recommended IRB action | | |
| <input type="checkbox"/> Approval
<input type="checkbox"/> Disapproval
<input type="checkbox"/> Modification
<input type="checkbox"/> Expedited review
<input type="checkbox"/> Full review | | |
| 5. Explanation of risk level | | |

Signature of IRB member

Date

IPFW-IRB Notification of IRB decision
(Revised 7/81)

Risk screening _____
Expedited review _____
Full review _____

1. Action date
2. Project title
3. Responsible individual
4. IRB action

The responsible individual identified above (has) (has not) been granted approval to use human subjects in the above-titled activity following the procedures stated in the proposal, with the following stipulations.

The IRB, by a vote of _____ in favor and _____ against, has designated the project named above as (minimum) (moderate) (high) in risk, and has decided to (approve) (disapprove) (require modifications in) (require expedited review of) (require full review of) this project. Reviewers' comments are attached.

Further, IRB members have agreed that additional action (will) (will not) be necessary to review the proposed project.

This IRB action applies to this project only, and only under the conditions and procedures described in the proposal. Any change in the protocol or conditions set forth in the application will require separate approval. This approval may be followed by surveillance procedures which will require periodic review of the project by consultation with the responsible individual, and the examination of the appropriate records of the activity, as well as a complete review at the beginning of each project year.

Identification of individual human subjects in any publication is an invasion of privacy and requires a separate, executed informed consent document.

Prior to initiation of activities involving human subjects, unless specifically exempted, properly executed informed consent must be obtained from each subject and/or the person legally responsible for each subject, and such formed must be retained by the responsible individual for a minimum of three years after termination of the project.

Additional information and advice on matters relating to the use of human subjects may be obtained from members of the IRB or by calling the _____ department, extension _____.

Chair, IPFW-IRB

Date

IPFW-IRB Report of Problems Involving Risks to Human Subjects

Investigator(s)

Project title

Problem description

Signature(s) of investigator(s)

Date

IRB Action

Signature of IRB chair

Date

Sample Informed-Consent Form

This research is designed to investigate _____
_____ and is being conducted by _____
_____. You are being asked to _____
_____ dealing with _____.

This project has been approved for its protection of human subjects by the Institutional Review Board of Indiana University-Purdue University at Fort Wayne.

(Paragraph explaining any potential risks or benefits to subjects)

Any information you provide will be held in strict confidence by the researchers. At no time will your name be reported along with your responses to these questions. All data will be reported in grouped or statistical form and not individually.

Your participation in this study is totally voluntary. You are free to refuse to answer any questions. In addition, you are free to withdraw from this study at any time, and to remove any data which you may have contributed.

If you have any questions you may contact _____
at _____ for more information.

I acknowledge that I have been informed and understand the nature of this study and that I freely consent to participate. I acknowledge further that I am at least eighteen years of age.

Signed _____

Date _____