

FERRIS STATE UNIVERSITY
Human Subjects Review Committee
(HSRC)

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What Is HSRC?

HSRC is an Institutional Review Board (IRB). Federal and University regulations require that all research projects involving human subjects and materials of human origin be reviewed and approved by an IRB before initiation. Under the regulations, research is defined as a formal investigation designed to develop or contribute to generalizable knowledge. A human subject of research is an individual from whom an investigator obtains data by interaction or intervention or about whom the researcher obtains confidential information.

HSRC's Composition

HSRC is comprised of a chairperson and at least 5 faculty members representing diverse backgrounds of academic study.

How the HSRC review process works

The review process begins when an investigator submits a complete application to the HSRC chairperson. Application forms are available from the chairperson or on the Web.

IRBs are required to review and approve protocols against the following criteria according to federal regulations at 45 CFR 46 and 21 CFR 56:

- Procedures and research design do not unnecessarily expose subjects to risks.
- Risks to subjects are reasonable in relation to anticipated benefits, if any.
- Selection of subjects is equitable, taking into account special problems of research involving vulnerable populations (e.g. pregnant women, prisoners, handicapped persons, etc.)
- Informed consent will be sought from each prospective subject or subject's guardian.
- Informed consent will be documented in writing (except in special circumstances).
- Where appropriate, adequate provisions are in place to monitor the collected data to ensure safety of subjects.
- Adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of data.

By federal regulation, research projects involving human subjects are assigned to one of three risk categories: **exempt from full review**, **expedited review**, or **full review**. Investigators should indicate on the application (q. 9) into which category they believe their project falls. However, any reviewer may reassign any protocol to another review category if s/he thinks it is appropriate. Federal regulation defines research activities that may be considered *exempt from full review* or *expedited review* (see charts on pp. 5, 6 & 7). All other research falls into the *full review* category. *Exempt from full review* protocols are sent to one reviewer; *expedited* protocols are sent to two reviewers; and *full review* protocols are sent to five reviewers. When the reviewer(s) is satisfied that the rights and welfare of human subjects are adequately protected, he or she forwards notice of approval to the HSRC office. However, if the reviewer has concerns, the reviewer prepares written comments which are forwarded to the applicant(s). The applicant(s) must then send a response to each comment, in writing, to the HSRC chair which will forward it to the reviewer(s). An approval letter is issued for *exempt* and *expedited* protocols as soon as the reviewer(s) has approved. However, when a protocol receives *full review*, an approval letter is issued after the protocol is discussed and approved by the full committee at its monthly meeting. **Investigators may begin gathering data from human subjects only after receiving a signed approval letter from the chair of HSRC.**

How Long Does the Review Process Take?

Applicants may submit a protocol for review at any time. The *full review* process typically requires a 10-15 days to complete, longer when modifications are necessary in order to meet the concerns of HSRC reviewers. **So that applicants will not be delayed, HSRC strongly recommends that investigators apply for approval at least one month prior to the desired starting date.** An approval letter is issued for *exempt from full review* and *expedited* protocols as soon as the reviewer(s) has approved. *Full review* protocols receive approval letters after the protocol is discussed and approved by vote of the full committee at its monthly meeting. **Investigators may begin gathering data from human subjects only after receiving a signed approval letter from the chair of HSRC.**

INSTRUCTIONS FOR COMPLETING THE HSRC APPLICATION

General Instructions;

Line By Line Instructions:

Question #1, #2, #3, #4, #5, #6, #7, #8, #9 (Category), #10, #11, #12, #13, #14, #15,
#16 (Consent)

General Instructions

Although the primary obligation of HSRC is to protect the rights and welfare of human subjects of research, it is also concerned with the timely review of research protocols. To speed the review of a project, the investigator will wish to adhere to the following guidelines.

Please complete the application in full. When submitting it, please provide all necessary attachments (any instruments, consent forms, advertisements, and the "Methods" section of your research proposal, including, for drug or device studies, an investigators' brochure) and the correct number of collated copies (see table p.14). Do not assume reviewers are familiar with previously approved protocols, other investigators' work, or instruments you will be using.

Whenever possible, please confine your responses to the space provided on the application form. Use additional, properly numbered sheets (e.g., "Item 11, continued") if necessary.

Line by Line Instructions

The following instructions and definitions are designed to help you complete each numbered item on the application.

1. Responsible Project Investigator(s)

Only regular faculty members, that is individuals holding the rank of professor, associate professor, assistant professor, or instructor may be designated as the responsible project investigator on the HSRC application. Students, staff and individuals holding other appointment titles, such as visiting, adjunct and clinical faculty, may be designated on the HSRC applications as an additional investigator, but not as the responsible project investigator. In the case of student research, the student's major advisor should be designated on the HSRC applications as the responsible project investigator and the student as an additional investigator.

The responsible project investigator's name should appear in the left-hand column and additional investigators should be recorded in the right-hand column. In the case of a student conducting research for a thesis or other project, the student's major advisor should be named in the column on the left and the student's name should appear on the right. The responsible project investigator must sign on the left-hand side.

2. Address

This is the address to which comments and/or an approval letter will be sent. Therefore, it is imperative that this be accurate and up to date. In the case of student research, please include addresses for both the Responsible Project Investigator (faculty member) and the additional investigator(s) (students).

3. Project Title

List your project title, even if you believe it may change later.

4. Contracts & Grants application number

Funded research is assigned an application number from the FSU Office of Contracts & Grants Administration. If your research is funded, enter your application number here.

5. FDA Submission

List the IND (Investigational New Drug) number, if applicable. If there is an investigators' brochure available, **three copies** should be sent to HSRC with the application.

6. Materials of Human Origin

Federal and University regulations require review of protocols using not only live humans but also those using blood or tissue of human origin, whether or not the investigator has any contact with the donor(s). When Investigators are using human blood or tissue obtained from sources other than the donor, the project will probably fall into category 1E or 2B (see pp. 5 & 6)

7. Date to Begin Data Collection

This is the date when you would **prefer** to begin data collection. However, it is not a guaranteed date, because you may not begin collecting data before obtaining HSRC approval.

8. Category

Please circle the correct category. If you believe your project is eligible for either *exempt from full review* or *expedited review*, please select the appropriate category or categories from the following tables and enter it on the line. All other research will be considered for *full review*. You may wish to submit your application under the lowest appropriate category. If a reviewer determines the project is not eligible for the category listed, the category will be changed, and the application will be reviewed by the appropriate number of reviewers.

Exempt Categories

A researcher may request exemption from full Committee review if the project involves no more than minimal risk and only involves human subjects (or materials of human origin) in one or more of the following categories:

EXEMPT CATEGORY

HUMAN SUBJECTS RESEARCH ACTIVITIES

1-A	Research conducted in established or commonly accepted educational settings, involving normal educational practices , such as: 1) research on regular and special education instructional strategies or 2) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
1-B	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
1-C	Research involving survey or interview procedures , except where one of the following conditions exists: 1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or 2) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol. All research involving survey or interview procedures is <i>exempt from full review</i> without exception, when the respondents are elected or appointed public officials or candidates for public office.
1-D	Research involving the observation of public behavior (including observation by participants) except where one of the following conditions exists: 1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or 2) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol.
1-E	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 subjects.
1-F	Research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services and which are designed to study, evaluate or otherwise examine: 1) programs under the Social Security Act or other public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
1-G	Taste and good quality evaluations and consumer acceptance studies , if wholesome foods without additives are consumed or if a food is consumed, that contains a food ingredient at or below the level, and for a use, found to be safe.

Expedited Categories

A researcher may request an expedited review of his/her project if it involves no more than minimal risk and only involves human subjects (or materials of human origin) in one or more of the following categories:

EXPEDITED CATEGORY

HUMAN SUBJECTS RESEARCH ACTIVITIES

2-A	Clinical studies of drugs and medical devices only when (a) research on drugs for which an investigational new drug application is not required. 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. Or (b) research on medical devices for which (i) an investigational device exemption application 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-B	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children ¹ , 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.
2-C	Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (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 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.
2-D	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 review, including studies of cleared medical devices for new indication.) Examples: (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 subjects 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.

¹ Children are defined in the HHS regulations as "persons who have not yet 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."

Expedited Categories (CONTINUED)

**EXPEDITED
CATEGORY**

HUMAN SUBJECTS RESEARCH ACTIVITIES

2-E	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) where the sources are not publicly available and the subjects can be identified directly or through identifiers linked to the subjects.
2-F	Collection of data from voice, video, digital, or image recordings made for research purposes.
2-G	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 , where (i) the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' response outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; unless (iii) the human subjects are elected or appointed public officials or candidates for public office.
2-H	Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
2-I	Continuing review of research , not conducted under an investigational new drug application or investigational device exemption where categories 2-B through 2-H do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

9. Multi-Site Project

ONLY answer yes if you are the Responsible Project Investigator for a Public Health Service (PHS) funded, *full review project* where data will be collected at multiple sites (e.g., hospitals or universities in the U.S. or other countries).

10. Abstract

Provide a brief (200 words or less) description of the project including its purpose and general design. This can be identical or similar to the summary required when submitting a grant application to a funding source.

11. Procedures

Describe all project activities that involve human subjects, materials of human origin or existing data originally collected from human subjects.

12. Subject Population

a. Study population: It is important to mark **all** the categories of subjects that **may** be included in your research, either by design or incidentally, not just your "target population." HSRC needs this information because certain categories of subjects, whether part of a targeted population or included as part of a random sample, may be provided special protections under the federal regulations.

b. Number of subjects: Total number of subjects to be included in your research, including controls. Approximations are acceptable.

c. Subject Recruitment: Advertising

If your project includes an advertisement, it **must** be submitted with the application.

Direct advertising (i.e., advertising that is intended to be seen or heard by prospective subjects) includes, but is not limited to, newspapers, television, bulletin boards, and the internet/world wide web. Not included are professional communications between health professionals and bona-fide media news stories. Direct advertising for study subjects is considered to be the start of the informed consent and subject selection processes. Advertisements must be reviewed and approved by the HSRC as part of the package for initial review. When the investigator(s) decide at a later date to advertise for subjects, the advertising is considered an amendment to the on-going study. The HSRC reviews the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent documents and the protocol.

When advertisements are to be taped for broadcast, the HSRC must review the final audio/video tape. The HSRC may review and approve the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording.

No claims should be made, either explicitly or implicitly, that the experimental procedure is safe or effective for the purposes under investigation, or is known to be equivalent or superior to any other procedure. Advertising for recruitment into studies should not use terms such as "new treatment" or "new procedure" without explaining that the procedure is investigational.

Advertisements should not promise "free treatment" when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid but should not emphasize the payment or the amount to be paid.

Any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items should be included in all advertisements:

- 1.the name and address of the investigator(s) and/or research facility
- 2.the condition under study and/or the purpose of the research
- 3.in summary form, the criteria that will be used to determine

- eligibility for the study
- 4.a brief list of participation benefits, if any
- 5.the time or other commitment required of the subjects
- 6.the location of the research and the person or office to contact for further information

- d, e, f. The HSRC office believes these questions are self explanatory. However, if you have questions please call the HSRC chair.
- g, h. Remember, if you answer yes to either question, corresponding information must be included in the consent form.

13. Subject Privacy

Describe procedures and safeguards you will use to insure confidentiality and/or anonymity. Researchers must propose to protect human subjects' rights with regard to privacy by using research designs that safeguard subjects' privacy during the gathering and storage of data.

Investigators should be careful to distinguish between anonymity and confidentiality. HSRC defines these terms as follows:

Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual subjects. Investigators may promise anonymity only under this condition.

Confidentiality means that although subjects' identities may be known to the principal investigator and a limited research staff, subjects' identities will be kept confidential and reports of research findings will not permit associating subjects with specific responses or findings. For confidentiality, investigators must provide adequate procedures to guarantee confidentiality, including security for data that contains subject identifiers.

In general, data gathered from subjects should be reported by investigators (e.g., articles, conferences etc.) only in the aggregate so that individual subjects may not be identified or associated with the data they provided.

14. Risk and Benefit to Subjects

Analyze the risks and benefits of your study. Completely answer the following three items:

Describe and assess any potential risks (physical, psychological, social, legal, economic or other) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe alternate methods posing lesser risk, if any, that were considered and explain why they will not be used.

Describe procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

Assess the potential benefits to be gained by the individual subjects, as well as benefits which may accrue to society in general as a result of the planned work.

If your research involves minors or those with diminished capacity, see the following section.

Minors or individuals with diminished capacity

As a general rule, HSRC does not approve research that makes use of minors or those with diminished capacity if the research and its objectives can be met by using adults and those without diminished capacity. When the research can only appropriately be conducted using minors or individuals with diminished capacity, special considerations are given to risk and to consent procedures. In determining whether children or those with diminished capacity are capable of assenting, HSRC will take into account the ages, maturity and psychological state of

the subjects. HSRC's review of risks, benefits and consent procedures for these subjects is guided by the following:

Research involving minimal risk: HSRC will determine whether adequate provisions are made for collecting the **assent** of the research subject and **consent** of the parent(s) or guardian(s).

Research involving greater than minimal risk but presenting the prospect of direct benefit to the subject: HSRC will determine whether the risk is justified by the anticipated benefit to the subject; whether the risk is at least as favorable to the subject as that presented by available alternative approaches; and whether adequate provisions are made for obtaining the assent of subjects and consent of parent(s) or guardian(s).

16. Consent Procedures

All research protocols must have a consent procedure which provides for the informed consent of human subjects. Describe the consent procedures to be followed, involving how and where informed consent will be obtained. If your research involves minors or those with diminished capacity, see the preceding section. **Include the appropriate number of copies of your consent form with this application.**

Written consent

Written consent forms are usually required. However, under certain circumstances, (e.g., when using questionnaires to collect data), investigators may incorporate the elements of consent into a letter or instruction sheet accompanying a data-collection instrument.

Verbal consent

Occasionally, informed consent may be obtained verbally in situations in which written consent is deemed culturally disrespectful or inappropriate. In all cases the IRB must review, in advance, the language that will be used to obtain verbal informed consent. Researchers proposing to obtain informed consent verbally must include a script of the verbal consent language with their HSRC application. Investigators should keep a log documenting the verbal consent process throughout the duration of the study.

Points to consider

- Think of the consent form as primarily a teaching tool and not as a legal instrument.
- The Office for the Protection from Research Risks, National Institutes of Health, suggests the following: "Use of the first person (e.g. "I understand that...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject." Therefore, the consent form should be written using the second person pronoun (e.g., "you are being asked to participate in a study. . .").
- The consent form should not include any exculpatory language whereby the subject waives or appears to waive, any of his/her legal rights, including any release of the institution or its agents.
- The consent form may not indicate in its text HSRC approval of the research.

You must retain copies of signed consent forms for at least three years past the completion of your research activities.

The consent form, instruction sheet or explanatory letter should include, but need not be restricted to, the following statements or concepts:

CONSENT FORMS SHOULD INCLUDE

ITEM	DESCRIPTION
1. Summary explanation of research	A reasonable summary explanation of the research, its purposes and procedures in language which can be understood by the research subject.
2. Estimate of subject's time	An estimate of the total amount of time required on the part of the subject (number of sessions, frequency of testing, etc.).
3. Experimental procedures	Identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject; a statement to the effect that the experiment has been explained to the subjects; and that the subjects understand it, including any inherent risks and/or discomforts.
4. Voluntary participation; Refusal to participate; Discontinuing participation without penalty	The subjects freely consent to participate; participation is voluntary; subjects may choose not to participate at all, may refuse to participate in certain procedures or answer certain questions or may discontinue the experiment at any time without penalty or loss of benefits to which the subject is otherwise entitled.
5. Confidentiality and anonymity	Data gathered from human subjects are to be treated with strict confidence on the part of the investigator except in special circumstances approved by HSRC. The subjects will remain anonymous in any report of research findings; on request and within these restrictions results may be made available to subjects. Consent forms should include the following qualifying statement regarding confidentiality: "Your privacy will be protected to the maximum extent allowable by law." All drug or medical device study consent forms should carry notice that the FDA, study sponsor and IRB may inspect all records, including subject records.
6. If a treatment is involved	If a treatment is involved, no beneficial effects are guaranteed; in the case of experimental treatment, subjects are to be informed of alternative or standard treatments available and their record of success.
7. Debriefing procedure	When appropriate, a procedure for debriefing the subjects is included (e.g., experiments involving deception).
8. Contact person for subjects	Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study. This should include the name & phone number of the IRB chairperson
9. Minor subjects	If the subject is a minor, provisions should be made for obtaining parent's or guardian's informed consent (signature) and the minor's verbal assent when feasible.
10. Consent in cover letter or face sheet	If the investigator chooses to incorporate the elements of consent in a cover letter or face sheet to a written questionnaire, the consent statement must include: "You indicate your voluntary agreement to participate by completing and returning this questionnaire."

CONSENT FORMS SHOULD INCLUDE (continued)

ITEM	DESCRIPTION
<p>11. Risk of physical injury to the subject(s)</p>	<p>If there is a risk of injury to the subject(s), <u>one of the following three statements must appear</u> on the consent form:</p> <p>If the research is performed at Ferris State University facilities or by Ferris State University employees or students:</p> <p>a) If you are injured as a result of your participation in this research project Ferris State University will provide emergency medical care if necessary. You will not be held responsible for any medical expenses incurred as a result of this injury. All such medical expenses incurred by you as a result of this injury shall be paid by (name of payee).</p> <p><u>OR</u></p> <p>b) If you are injured as a result of your participation in this research project, Ferris State University will provide emergency medical care if necessary. If the injury is not caused by the negligence of FSU you are personally responsible for the expense of this emergency care and any other medical expenses incurred as a result of this injury.</p> <p>If there is risk of injury to the subject(s) but the research is not performed at FSU facilities and is performed by persons who are not FSU employees or students and who do not identify themselves as associated with FSU:</p> <p>c) A statement must appear in the consent form that indicates: 1) who will be responsible for providing emergency medical treatment in the event of injury and 2) who will be responsible to pay for this treatment.</p>
<p>12. Placebo-control studies</p>	<p>HSRC requires that the following paragraph be placed in the consent form of placebo-control studies. It may be modified as necessary for the terms of your study:</p> <p><i>This is a placebo controlled study. There will be two (or more) groups of patients; one or more groups will receive the active drug which is being studied; the other(s) will receive a placebo. A placebo is an inactive substance which will have no direct effect on your illness. The patients in the study will be assigned at random, that is, by a method of chance, to one of the groups. You will have an equal chance of being in a placebo group or an active drug group. Neither you nor your physician will know which group you are in.</i></p>

CONSENT FORMS SHOULD INCLUDE (continued)

ITEM	DESCRIPTION
13. Economic costs to subjects	<p>This policy applies only where subjects are paying some kind of fee for service and there is a need to distinguish fees for ordinary care or service from such fees as might result from the subject's participation in research.</p> <p>In such instances, investigators must incorporate one of the following three paragraphs in their consent forms.</p> <p>a) You understand that your participation in this research project will not involve any additional costs to you or your health care insurer.</p> <p><u>OR</u></p> <p>b) You understand that your participation in this research will necessitate additional procedures (indicate procedures, e.g., obtaining medical tests and examinations) which will be discussed with you. The cost for these are usually covered by your insurance. You understand those costs not covered by the insurance will be provided by research funds. However, you will still remain responsible for the insurance deductible.</p> <p><u>OR</u></p> <p>c) You understand that your participation in this research project may involve additional costs to you for (indicate source of cost, e.g., drugs, device, diagnostic procedure, therapeutic procedure). Your health care insurance probably will not pay for all of these additional costs. You understand that (your health care provider) estimates that the additional, unreimbursed costs to you will not exceed (\$). If actual costs exceed this estimate, you recognize you are still responsible for them.</p>

CHECKLIST FOR COMPLETE HSRC APPLICATIONS

Number of Copies Required by Category of Review:

	Exempt	Expedited	Full
Completed Applications	2	3	8
Instruments (if any)	2	3	8
Consent Forms	2	3	8
Advertisements (if any)	2	3	8
Investigators' brochure	N/A	N/A	N/A
Copy of the "methods" chapter of your research proposal	1	1	1

NOTE: INVESTIGATORS MUST PROVIDE ENGLISH TRANSLATIONS OF ANY DOCUMENTS WRITTEN IN ANOTHER LANGUAGE.

RENEWING HSRC APPROVAL

HSRC approval is for one year only. Project investigators continuing to collect data from human subjects beyond the approval period must apply for renewed approval prior to the expiration date. HSRC strongly recommends that investigators wishing to continue collecting data request renewal one month before approval expires. To assist investigators, the HSRC office will send a renewal reminder letter approximately one month prior to the approval expiration date.

For annual project approval for the first four years, the responsible project investigator must complete and return to HSRC the renewal application form and a current consent form. Students who wish to renew approval of their protocols must have their major professor sign the renewal application form. Incomplete renewal applications will be returned. Embodied in the renewal application are the following four assurances:

1. The human subjects protocol is the same as in previous studies.
2. Subjects have suffered no ill effects because of their participation in the study.
3. There have been no complaints by the subjects or their representatives related to their participation in the study.
4. There has been no change in the research environment or new information that would indicate greater risk to human subjects than that assumed when the protocol was initially reviewed and approved.

A change in the Responsible Investigator and/or the co-investigator(s) is considered a change in the human subjects protocol, such a change needs to be indicated on the renewal form (Assurance #1).

With regard to ill effects, complaints and changes in the research environment or new information that would indicate greater risk to subjects, these need to be reported immediately in sufficient detail for committee review. Reports of adverse events should be addressed to the Chair of HSRC and include the following information:

- Project Title
- The project IRB #
- Name and identification number of the responsible project investigator
- Number of subject enrolled in the protocol to date
- A description of the adverse event and the investigators' analysis of whether the adverse event was related to a study drug, device or activity

The review for renewed approval for projects in the *exempt from full review* and the *expedited* categories is usually completed in ten to fifteen **working** days. Applications for renewed approval of projects in the *full review* category are reviewed by the full committee at its monthly meeting. Therefore, review of these applications may take up to one month.

Five Year Renewals

Investigators whose projects have been ongoing for five years must submit a new full application for HSRC review. Be sure to indicate the application is for a five year renewal and include the IRB number previously assigned to the project.

REVISIONS

HSRC must review any changes in procedures involving human subjects prior to the initiation of the change. A change to the Responsible Investigator and/or to the co-investigator(s) is also considered a change to the human subjects protocol. To revise an approved protocol the responsible project investigator must send a letter to the HSRC Chair containing the following information:

- The project IRB #
- The title of the project
- Name and identification number of the responsible project investigator
- A brief description of, and explanation for, the proposed change in the protocol
- A copy of the documents that include any changes (e.g. instruments, consent forms)

Students requesting revisions to their protocols must have the signature of the responsible project investigator on the request. Before implementing changes, investigators must receive a letter from HSRC approving the proposed revisions.

STUDENT RESEARCH IN COURSES

In some courses students collect data by using professional research methods, even though the students' work is not expected to contribute to generalizable knowledge. Some of the methods involve human subjects, and in some instances, subjects may be placed at risk. For this reason, student research projects should be reviewed and approved prior to initiation to assure that the rights and welfare of human subjects are adequately protected. Where student research in courses involves no more than minimal risk to subjects, HSRC has a policy of delegating to instructors the primary responsibility for assuring that the rights and welfare of human subjects are not violated. This responsibility includes communicating to students the ethical principles for the protection of human subjects. In addition, to assure that the rights of human subjects are protected, instructors are responsible for reviewing student research protocols and monitoring research activities and reports of findings. Further information for instructors is available in the short document Principles, Policies and Procedures for the Review of Research on Human Subjects: Student Research in Courses at Ferris State University, which is available in the HSRC office. Please note that student research involving more than minimal risk to subjects must be submitted to and approved by HSRC prior to any data collection.

(revised 4/99)