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3 **POLICY STATEMENT 74**
4 **PRINCIPLE INVESTIGATOR'S MANUAL FOR RESEARCH INVOLVING HUMAN**
5 **SUBJECTS**

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7 **POLICY DIGEST**

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9 **Primary Monitoring Unit: Academic Affairs**
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14 **I. THE PURPOSE OF THIS MANUAL**

15 Please read this manual carefully. It contains important information that will help you complete
16 the "Application to Use Human Subjects in Research" form. Failure to follow instructions may
17 result in a delay in the approval process.

18 This manual is intended as a guide for faculty, students, staff, and any other members of LSU
19 Eunice who plan to carry out research, whether funded or unfunded, involving the participation
20 of human subjects. It provides basic information about what materials are needed and the
21 process to use in requesting approval to use human subjects in research.

22 All research that is conducted by an individual in connection with his or her institutional
23 responsibilities and/or which involves the use of any of the University's property or facilities must
24 conform to a standard of ethics reflected in specific regulations of the United States Department
25 of Health and Human Services (DHHS) in order to assure that the rights and welfare of human
26 subjects are protected.

27 **II. INTRODUCTION**

28 Research with human subjects which is conducted by any member of the LSU Eunice
29 community or anyone using LSU Eunice facilities, must be reviewed and approved by an LSU
30 Eunice Institutional Review Board (referred to hereafter as the IRB). The IRB's interest is in
31 protecting the safety, welfare, privacy and rights of human research subjects. It is not the IRB's
32 objective to pass judgment on other aspects of the research (e.g., scientific merit). With the
33 above goal in mind, the application for review of research involving human subjects must
34 contain specific information. This information allows the IRB to evaluate the:

- 35 A. risks to subject(s);
- 36 B. specific nature of subjects' participation including:
- 37 1. recruitment of subjects,
- 38 2. voluntary nature of subject participation,

- 39 3. informed consent,
- 40 4. remuneration (if any) to subject,
- 41 5. specific procedures to be followed.

42 In order to submit research for review, investigators must complete the Application for Approval
43 to use Human Subjects in Research, which may be obtained from the office of the Vice
44 Chancellor for Academic Affairs.

45 The most important concerns of the IRB are to assure subjects' safety, preserve subjects'
46 anonymity and confidentiality, and assure that participation is voluntary. Thus, the application
47 should contain information related to these areas. For example, a question of coercion may
48 arise when an instructor solicits students from his/her own classroom for participation in a
49 research project in which the instructor is involved. Another concern is the desire for subjects to
50 be fully informed of the procedures to be employed in the study and of possible adverse effects.
51 Also, the procedures should not coerce subjects to continue in a study if they desire to stop
52 participation.

53 In order to facilitate approval of the application for use of human subjects in research, it is
54 necessary for all relevant information to be included in the application. It is of equal importance
55 that the document present a clear and concise explanation of the proposed research project.
56 Delays in approval by the IRB can be caused by: (a) insufficient information; (b) relevant
57 information being omitted from the application (or placed in appendices rather than in the text of
58 the application); (c) presenting information in a manner that is too technical and cannot be
59 understood by IRB members whose backgrounds and areas of expertise vary greatly and (d)
60 the consent document contains grammatical and/or spelling errors or its language is
61 inappropriate to the subject population being targeted.

62 **III. IRB COMPOSITION**

- 63 A. The Institutional Review Board will have the following composition: a representative from
64 each of the academic divisions, a representative from the professional staff, and a
65 representative from the LSU Eunice Board of Advisors.
- 66 B. The academic representatives will be elected by their respective academic units at their
67 first meeting of the academic year. The representative from the professional staff will be
68 selected in a manner to be determined by the Staff Senate. The representative from the
69 LSU Eunice Board of Advisors will be selected by the Academic Council.
- 70 C. The members will serve for an academic year.
- 71 D. The Vice Chancellor for Academic Affairs will call the first meeting, at which time a chair
72 will be elected by the members of the IRB.
- 73 E. Following the initial organizational meeting, the IRB will meet once a month to review
74 applications. However, if no applications have been submitted by the customary meeting
75 date, the IRB will not meet until the following month.

76 **IV. DEFINITIONS**

- 77 A. **Human Subject** - "Human Subject" is a living person about whom an investigator
78 (whether professional or student) conducting research obtains: (a) data through
79 intervention or interaction with the person, or (b) identifiable private information.
- 80 B. **Intervention** - "Intervention" includes both physical procedures by which data are
81 gathered (e.g. venipuncture) and manipulations of the subject or the subject's
82 environment that are performed for research purposes.
- 83 C. **Interaction** – "Interaction" includes communication or interpersonal contact between
84 investigator and subject.
- 85 D. **Minimal Risk** - "Minimal Risk" means that the probability and magnitude of harm or
86 discomfort anticipated in the proposed research are not greater in and of themselves
87 than those ordinarily encountered in daily life or during the performance of routine
88 physical or psychological examinations or tests.
- 89 E. **Private Information** - "Private Information" includes information about behavior that
90 occurs in a context in which an individual can reasonably expect that no observation or
91 recording is taking place and information which has been provided for specific purposes
92 by an individual and which the individual can reasonably expect will not be made public
93 (e.g. a medical record). Private information must be individually identifiable (i.e. the
94 identity of the subject is or may readily be ascertained by the investigator or associated
95 with the information) in order for the process of obtaining the information to constitute
96 research involving human subjects.
- 97 F. **Research** - "Research" means systematic investigation, including research
98 development, testing, and evaluation, designed to develop or contribute to the
99 generalizable knowledge. Activities which meet this definition constitute research for
100 purposes of this assurance, whether or not they are supported or funded under a
101 program which is considered research for other purposes. For example, some
102 demonstration and service programs may include research activities.
- 103 G. **Established and Accepted Methods** - Some methods become established through the
104 rigorous standardization procedures prescribed by law, as in the case of drugs, devices,
105 or biologicals, by operation of law, or, as in the case of many educational tests, under
106 the aegis of professional societies or non-profit agencies. Determination as to when a
107 method passes from the experimental stage and becomes "established and accepted" is
108 a matter of judgement.
- 109 H. **Legally Authorized Representative** - "Legally authorized representative" means an
110 individual or judicial or other body authorized under applicable law to consent on behalf
111 of a prospective subject to such subject's participation in the procedure(s) involved in the
112 research.
- 113 I. **IRB** - "IRB" means an Institutional Review Board established in accord with the basic
114 DHHS policy for the protection of human research subjects (45 CFR Part 46) and for the
115 purposes expressed in that policy.
- 116 J. **IRB Approval** - "IRB approval" means the determination of the IRB that the research

117 has been reviewed and may be conducted within the constraints set forth by the IRB and
118 by other applicable institutional, statutory, and regulatory requirements.

119 **V. INSTRUCTIONS FOR COMPLETING THE Application for Approval to Use** 120 **Human Subjects in Research**

121 Please Note: The application should stand on its own, without reference to any attached grant
122 proposals or articles published, in press, or under review. (Just cutting and pasting paragraphs
123 from a grant proposal causes confusion during the review process.) In addition, information
124 placed in appendices may be overlooked. The application should provide all information
125 necessary for IRB members unfamiliar with the experimenter's field of research to be able to
126 evaluate the risks to subjects, how subjects will be recruited, the potential benefits, and how
127 informed consent shall be obtained.

128 Project Title, Question 1: If you are seeking IRB approval as part of a grant application process,
129 the title of the project should be the same on both the "Application for Approval" and within the
130 grant proposal.

131 Principal Investigator (PI) and Co-PI Information, Questions 2 and 3: PI's & Co PI's may list
132 contact information other than their regular campus address in this space if they prefer to be
133 contacted elsewhere. Co-PI's who are neither employees nor students of LSU Eunice should list
134 full information about their affiliation here.

135 Status Category, Question 4: Check "Other" if you are not affiliated with LSU Eunice but are
136 seeking to conduct research involving the LSU Eunice community or the use of LSU Eunice
137 facilities.

138 Contact Information for Student Researchers and Non-LSU Eunice Researchers, Question 5:
139 Provide home address and phone number. Provide information relating to the Faculty Advisor.

140 Application Type, Question 6: Choose the appropriate type of review: The initial determination
141 about the type of review appropriate to the project will be made by the Principal Investigator.
142 However, if in the opinion of the IRB, another type of review is more appropriate, the project will
143 be reviewed under that review procedure and the PI notified. On occasion, the IRB may request
144 additional documentation in order to determine if the use of a particular type of review is
145 justified.

146 **VI. EXEMPT REVIEW PROCEDURES**

147 Federal regulations "exempt" some types of research from regular review procedures by the
148 IRB, though use of this term can be confusing. "Exempt" research is in fact reviewed, though
149 ordinarily not as much documentation is required (in these cases, only the first three pages of
150 the APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH need be
151 submitted). If found exempt, the project need not follow continuing review procedures unless
152 significant changes are made to the research protocol. Federal regulations permit the Principal
153 Investigator to make the initial determination as to whether the project is exempt. The categories
154 of research detailed below are exempt from review.

155 Categories of Research eligible for Exempt Review Procedures:

156 A. Research conducted in established or commonly accepted educational settings,

- 157 involving normal educational practices, such as: (i) research on regular and special
158 education instructional strategies, or (ii) research on the effectiveness of or the
159 comparison among instructional techniques, curricula, or classroom management
160 methods.
- 161 B. Research involving the use of educational tests (cognitive, diagnostic, aptitude,
162 achievement), survey procedures, interview procedures or observation of public
163 behavior if: i) information taken from these sources is recorded in such a manner that
164 subjects cannot be identified directly or through identifiers linked to the subjects, and ii)
165 any disclosure of subjects' responses outside the research could not reasonably place
166 the subjects at risk of criminal or civil liability or be damaging to the subjects' financial
167 standing, employability, or reputation.
- 168 C. Research involving the use of educational tests (cognitive, diagnostic, aptitude,
169 achievement), survey procedures, interview procedures or observation (including
170 observation by participants) of public behavior, that is not exempt under B of this section
171 if: (i) the subjects are elected or appointed public officials or candidates for public office;
172 or (ii) the confidentiality of the personally identifiable information will be maintained
173 throughout the research and thereafter.
- 174 D. Research involving the collection or study of existing data, documents, records,
175 pathological specimens, or diagnostic specimens, if these sources are publicly available
176 or if the information is recorded by the investigator in such a manner that subjects
177 cannot be identified, directly or through identifiers linked to the subjects.
- 178 E. Research and demonstration projects which are conducted by or subject to the approval
179 of department or agency heads, and which are: (i) designed to examine current public
180 benefit or service programs; (ii) procedures for obtaining benefits or services under
181 those programs; (iii) possible changes in or alternatives to those programs; or (iv)
182 possible changes in methods or levels of payment for benefits or services under those
183 programs.
- 184 F. Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome
185 foods without additives are consumed; or (ii) if a food is consumed that contains a food
186 ingredient at the level for use found to be safe, or agricultural chemical or environmental
187 contaminant at the level found to be safe, by the Food and Drug Administration or
188 approved by the EPA or Environment Protection Agency or the Food Safety and
189 Inspection Service of the USDA.
- 190 Non-HHS-supported research that presents no more than minimal risk to a subject (i.e., not
191 exceeding risk ordinarily encountered in daily life) may be approved by expedited review if it
192 falls into one of the following categories:
- 193 A. Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth, or
194 permanent teeth if patient care indicates a need for extraction.
- 195 B. Collection of excreta and external secretions including sweat, uncannulated saliva,
196 placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane
197 prior to or during labor.
- 198 C. Recording of data from subjects eighteen years of age or older using noninvasive

199 procedures routinely employed in clinical practice. This includes the use of physical
200 sensors that are applied either to the surface of the body or at a distance and do not
201 involve input of matter or significant amounts of energy into the subject or an invasion of
202 the subject's privacy. It also includes such procedures as weighing, testing sensory
203 acuity, electrocardiography, electroencephalography, thermography, detection of
204 naturally occurring radioactivity, diagnostic echography, and electroretinography. This
205 does not include exposure to electromagnetic radiation outside the visible range (for
206 example, x-rays, microwaves).

207 D. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in
208 an eight-week period and no more often than two times per week from subjects eighteen
209 years of age or older and who are in good health and not pregnant.

210 E. Collection of both supra- and subgingival dental plaque and calculus, provided the
211 procedure is not more invasive than routine prophylactic scaling of the teeth and the
212 process is accomplished in accordance with accepted prophylactic techniques.

213 F. Voice recordings made for research purposes such as investigations of speech defects.

214 G. Moderate exercise by healthy volunteers.

215 H. The study of existing data, documents, records, pathological specimens, or diagnostic
216 specimens.

217 I. Research on individual or group behavior or characteristics of individuals, such as
218 studies of perception, cognition, game theory, or test development, where the
219 investigator does not manipulate subjects' behavior and the research will not involve
220 stress to subjects.

221 J. Research on drugs or devices for which an investigational new drug exemption or an
222 investigational device exemption is not required.

223 Research that involves more than minimal risk, or is not covered by the categories listed
224 previously, requires full review. Reports of research approved under expedited or exempt
225 procedures are made at each regular IRB meeting.

226 **VII. HAVE QUESTIONS ABOUT WHICH TYPE OF REVIEW TO SELECT?**

227 A complete application is necessary for both full and expedited categories of research
228 proposals. According to Federal Regulations, if the IRB member(s) assigned for expedited
229 review have questions about the appropriateness of expedited review or concerns about the
230 nature of human subjects participation, the proposal is reviewed by the full IRB at its next
231 meeting.

232 The IRB can provide advice and assistance to help investigators determine if projects are
233 exempt.

234 Vulnerable Populations, Question 7: All research that involves fetuses, pregnant women,
235 prisoners, or groups who may have diminished capacity to provide consent or who may be high
236 risk, must be provided full review. Most research involving minors falls into this category as well.

237 **VIII. RESEARCH INVOLVING CHILDREN AS SUBJECTS**

238 Children are considered a vulnerable and therefore "protected" population in the context of
239 serving as research subjects. In Louisiana, children are defined as those persons who are under
240 18 years old and have not obtained the legal age for consent to treatment or procedures
241 involved in the research.

242 In addition to those materials normally required for review by the IRB on the Protection of
243 Human Subjects, a parental or guardian consent form, including all traditional elements of
244 informed consent, is required. A child assent form should be used for child subjects 12 years of
245 age or older. Language should be understandable and include a brief description of the task(s)
246 involved and a statement on the right to withdraw at any time without penalty. For subjects
247 under 12 years of age, an assent procedure should be employed. Assent is defined as an
248 affirmative agreement (as opposed to tacit consent) to participate in research.

249 If child subjects are being obtained from another institution(s), written permission from an official
250 from the institution(s) authorized to do so, must accompany the protocol.

251 Federal policy dictates that the use of prisoners as human research subjects is strictly prohibited
252 without the prior approval of the Human Subjects IRB. This restriction also applies to the
253 compassionate use of investigational agents or devices on prisoners.

254 If prisoners are to be potential subjects of a project, the researcher must indicate this in the
255 application. If a Principal Investigator plans to have prisoners as subjects in his or her research
256 project, please contact the IRB Office before finalizing the protocol. Additional time may be
257 necessary to process proposals involving prisoners as subjects since the IRB will need to refer
258 the proposed project to an individual or individuals who will have been designated as prisoner
259 advocate(s). These precautions are mandated by the Federal regulations governing research
260 involving human subjects. Copies of these regulations are available from the IRB. Written
261 permission will need to be obtained as well from the cooperating institution from which subjects
262 will be recruited.

263 Deception, Question 8: The investigator is justified in withholding information from or giving
264 incomplete or erroneous information to research subjects only when it can be demonstrated that
265 the research cannot be conducted in any other way and that subjects will not be placed at risk.
266 Research involving deception must be provided full review. At the earliest possible moment
267 consonant with the validity of the research, the subject should be informed of the actual purpose
268 of the research and procedures must be developed to relieve any distress encountered. All
269 research involving deception must have attached to it a full description of the debriefing
270 procedure to be used to the application.

271 Risk to Subjects, Question 9: Subjects at Risk: "Subjects at risk" means any individual who may
272 be exposed to the possibility of injury, e.g. physical, psychological, or social injury, as a
273 consequence of participation as a subject in any research or related activity which departs from
274 the application of those established and accepted methods necessary to meet the subject's
275 needs or which increases the ordinary risks of daily life, including the recognized risks inherent
276 in a chosen occupation or field of service. When reviewing protocols with more than minimal risk
277 to subjects, the IRB may delay approval of a protocol and make recommendations to the
278 investigator for alterations in the wording of informed consent documents or for changes in the
279 protocol to further minimize potential risks to subjects. Research may not begin until IRB
280 approval has been granted.

281 Previously Approved Study, Question 10: The IRB grants approval for one year from the date of
282 initial approval only, regardless of when research actually begins. If, for example, funding was
283 sought but not received from one source, but later received from another source, the project
284 must be reapproved if more than a year has elapsed.

285 Proposal Status and Funding, Questions 11 and 12: Answering these questions aids the IRB to
286 ensure all required documentation is in place.

287 IRB Review at Another Institution, Question 13: Certain research projects will involve hospitals,
288 schools, organizations, or other entities that are not affiliated with LSU Eunice. In such cases,
289 the Principal Investigator is required to obtain a copy of the organization's agreement to
290 participate and/or, if applicable, that institution's IRB approval before the recruitment of subjects
291 may begin. For research that requires IRB approval by more than one institution, protocols must
292 be identical.

293 Deadlines

294 The IRB's practice is to circulate applications requiring full or expedited review to IRB members
295 prior to the meeting. Any questions, comments or concerns raised by members are discussed at
296 the next meeting and transmitted in writing after the meeting to the Principal Investigator for a
297 written response.

298 It is the Principal Investigator's responsibility to see that the application is complete (i.e., all
299 questions are answered), that required materials are attached (e.g., a copy of the informed
300 consent form to be used), and that the application is submitted prior to the next IRB meeting.
301 **LSU Eunice requires submission of applications at least 10 days before the IRB meeting.**
302 **Failure to adhere to these requirements may lead to a delay in review and/or approval.**

303 Special Deadline Considerations

304 Investigators should be aware that for non-competing continuation applications, the National
305 Institutes of Health requires IRB approval coincident with the grant/contract/funding application.
306 This means that the Human Subjects review must take place prior to submission of the grant
307 application.

308 It is suggested that Investigators submit requests for Human Subjects review prior to or as soon
309 as possible after submitting the proposal to the IRB Office to prevent a delay in the awarding of
310 funds.

311 **IX. EXEMPT REVIEW**

312 To request an exemption, simply select one of the six categories on the third page of the
313 "Application" and append a written justification for your request to it. This justification should
314 include information on the subject population, the means of subject selection, how anonymity
315 will be assured and what informed consent procedures, if any, will be followed. If your research
316 involves surveys which have already been prepared, append them as well. Failure to provide
317 the IRB with a sufficient justification of your request for an exemption will result in delays in
318 approval. If for any reason the IRB finds it cannot grant your project an exemption, the project
319 will undergo either expedited or full committee review as the Chair sees fit. In such cases, you
320 may expect to be asked to provide additional information.

321 **X. EXPEDITED OR FULL IRB REVIEW**

322 Purpose of Research, Question 1: The description of your research should be in language that
323 can be understood by non-experts in your field and should be in detail sufficient for the IRB to
324 make a judgement about the adequacy of the human subjects protections proposed. Such
325 protections are the only concern of the IRB; judgement about a particular project's validity or
326 feasibility are outside its jurisdiction.

327 Subjects and Selection Criteria, Question 2: Various sub-topics follow:

328 **XI. SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN**
329 **RESEARCH**

330 When selecting subjects for research, it is important to consider carefully the category of
331 subjects being chosen. Federal guidelines require a scientific justification if women and/or
332 minorities are to be excluded from a subject population. In addition, vulnerable populations, e.g.,
333 prisoners, pregnant women, institutionalized individuals, or children, are to be studied only
334 under certain conditions, and only if the study could not be undertaken without them.

335 When recruiting subjects for research, it is important to follow procedures that will ensure that
336 subject participation is truly voluntary and that no procedures that could be construed as even
337 minimally coercive have been employed. The preferred method of recruitment is to disseminate
338 information about the research study to potential subjects and to instruct them to contact the
339 investigator if they are interested in participating. In the interest of respecting individuals' rights
340 to privacy and confidentiality, recruitment procedures should involve having interested subjects
341 identify themselves to the investigator rather than the investigator obtaining names and
342 addresses from a third party and soliciting participation directly from individuals. Some
343 acceptable and non-intrusive means of recruiting subjects are listed below.

344 **XII. ACCEPTABLE MEANS FOR THE SELECTION AND RECRUITMENT OF**
345 **SUBJECTS FOR PARTICIPATION IN RESEARCH:**

346 A. Placing an advertisement in a periodical or Web site requesting that interested persons
347 who meet relevant criteria contact the investigator.

348 B. Posting a sign or placing flyers in a public area or, with permission from the appropriate
349 authority, in a private area (such as a university, store, library, health club, etc.)
350 requesting that interested persons who meet relevant criteria contact the investigator.

351 C. Obtaining names from public records, such as telephone directories.

352 D. Obtaining names from organization membership or client records to which the
353 investigator has legal access and for which he or she has obtained permission from the
354 appropriate authority.

355 Researchers should avoid using their own patients or students as subjects due to the nature of
356 the existing relationship and the unavoidable potential coercion. When recruiting subjects from
357 hospitals, private medical or psychotherapy practices, schools, religious groups or businesses,
358 steps should be taken to ensure that potential subjects do not feel obligated to participate
359 because they wish to please an authority figure who they believe wants or expects them to
360 participate. Every effort should be made to use recruitment procedures that do not involve the

361 referring doctor, teacher, therapist, cleric, etc., knowing which individuals eventually participated
362 in the study. To fulfill this objective, subjects should be recruited in these circumstances with
363 minimum direct involvement of the referral source. Whenever possible, the investigator should
364 request that the referral person simply inform clients of the study and instruct them to contact
365 the investigator if they would like to participate. Names and addresses of potential subjects
366 should never be directly requested from referral sources unless permission has been given by
367 these individuals to release their names.

368 In a hospital-based study, particularly when there may be medical or emotional
369 contraindications to participation, it is necessary to obtain approval from patients' physicians
370 prior to their participation. Thus, in addition to selecting patients who meet specific criteria to be
371 eligible to participate, the referring physician or other health care professional should also select
372 patients on the basis of who is deemed to be both competent to give informed consent and
373 capable of carrying out the required tasks without jeopardizing his/her health and safety.

374 In certain cases, a subject's right to privacy may be superseded by a desire to minimize
375 coercion. In a corporate setting, for example, a researcher who personally has access to a
376 personnel roster may be justified in approaching subjects directly if it means that the employer is
377 thereby disassociated from the recruitment process and will not have access even to a list of
378 potential subjects. A discussion of the merits of direct recruitment should be included in the
379 Application for Approval to Use Human Subjects in Research. Steps for protecting the
380 confidentiality of the data to be obtained and the anonymity of the subjects are of paramount
381 concern when employees are being asked to participate at their place of business. In summary,
382 names of potential subjects are not to be obtained from hospitals or private practices unless the
383 referral agent has obtained permission from each individual to release the name. Whenever
384 possible, potential subjects should be informed of research indirectly and instructed to contact
385 the investigator if they are interested in participating. To reach specific populations independent
386 of a third party referral source, information can be disseminated in written form in periodicals, by
387 posting a sign in a convenient place or arranging to have flyers distributed to eligible individuals.
388 A description of a research study may also be presented verbally to groups or individuals,
389 preferably by someone whose position or relationship to potential subjects will not create
390 pressure, or perceived pressure, for individuals to comply.

391 **XIII. ACCESS TO EDUCATIONAL AND/OR SCHOOL RECORDS.**

392 Investigators who require access to educational and/or demographic records must negotiate
393 with those institutions for access to that information. The IRB will not approve any application
394 unless access to that information already has been granted by the appropriate institution. If the
395 outside institution requires IRB approval, the IRB may approve the application contingent upon
396 the outside institution's approval. Agreement to provide information by outside institutions does
397 not obligate the IRB to approve the project.

398 The IRB expects the same standards of confidentiality and anonymity to be exercised with
399 information obtained from other institutions as is required for information obtained from LSU
400 Eunice.

401 **XIV. USE OF STUDENTS ENROLLED IN A COURSE.**

402 The IRB is required to ensure that a subject's participation in research is voluntary. Thus,
403 practices such as: (i) recruiting subjects from a course in which the investigator is also
404 instructor; and/or (ii) offering extra credit and/or inducements which affect the course grade

405 unless comparable opportunities are offered to non-participants, are usually not approved by the
406 IRB.

407 Procedures to be Followed, Question 3: If for any reason your project involves experimental or
408 non-standard means of collecting data where standard procedures exist, a justification for the
409 use of the non-standard procedures should be included here.

410 Potential Harms or Benefits, Question 4:

411 In general, the higher the risk involved in the project, the more detailed the explanation,
412 precautions, and informed consent must be. The nature and type of informed consent is
413 determined by the level of risk. Accordingly, the following broad guidelines for degrees of risk
414 may be of assistance in making a necessary determination.

415 **High Risk:** Activities involving medical or behavioral science projects that may induce a
416 potentially harmful altered physical or mental state or condition are forms of personal invasion
417 and, as such, are considered to be in a "high risk" category. (Examples include biopsy
418 procedures; the administration of drugs or radiation; the use of indwelling catheters or
419 electrodes; the requirement of strenuous physical exercise; hypnotism; and subjection to deceit,
420 public embarrassment and humiliation.) In these cases there must be especially careful
421 documentation to show that the benefits outweigh the risks.

422 **Intermediate Risk:** Activities involving a wide range of medical, social, and behavioral projects
423 in which there is no immediate physical risk to the subject are considered to be in an
424 "intermediate risk" category. (Examples include personality inventories; interviews;
425 questionnaires; the dissemination of any data or information concerning an identified individual;
426 information gathering activities conducted in classrooms or elsewhere; individual or group
427 therapy sessions; or the use of photographs, taped records, and stored data.) Since some of
428 these types of procedures may involve varying degrees of dignity through the imposition of
429 demeaning or dehumanizing conditions, prior written informed consent is also required.
430 However, since this type of activity does not involve physical invasion but is an activity where
431 voluntary consent on the part of the subject is desirable, a more simplified consent is
432 acceptable.

433 **Low Risk:** Certain activities are classified as "low risk" and may not require a written informed
434 consent. (An example is the use of completely anonymous questionnaires.) If a written informed
435 consent is deemed unnecessary or undesirable in a particular instance, there follows an
436 additional responsibility to establish that:

437 A. the risk to the subject is minimal;

438 B. obtaining a consent would invalidate objectives of considerable immediate importance;
439 and/or

440 C. any reasonable alternative means for attaining the objectives have been thoroughly
441 explored and would be less advantageous to the subject.

442 Low risk involves situations in which there is no conceivable physical or mental discomfort, and
443 the measurements made on subjects can be considered to be reasonably unobtrusive. In these
444 situations written informed consent may be waived.

445 Confidentiality and Anonymity, Question 5: If a Federal Certificate of Confidentiality has been
446 obtained or is being sought, this should be noted here and a copy provided if it is available.

447 Debriefing Procedures and Revelations of Potentially Troublesome Situations, Question 6: If
448 individuals possessing any special skills or training are to be present during procedures, this
449 should be noted here. Where possible, investigators should provide the IRB with a list of
450 agencies, hospitals, professionals, etc., to whom they may refer subjects who reveal a need for
451 such assistance.

452 Informed Consent, Question 7: The informed consent form is one of the most important
453 portions of the application. The form must give a clear and concise explanation of the research
454 to be conducted and the procedures to be employed. The form must be written in language
455 appropriate for the targeted subject population (e.g., versions in English and another
456 appropriate language should be written for a multi-cultural study).

457 An informed consent document ideally should be one page in length. The form should be written
458 in language that is age- and culture-appropriate. The statement should be written clearly
459 enough for the potential participant to understand what involvement in the study entails, so that
460 she or he may make a reasonable, intelligent, and informed decision. The language should be
461 kept simple, and the sentences short. The language of the form should be understandable at
462 the eighth-grade reading level for studies using adult populations. The typeface should be large
463 enough so that even subjects with impaired vision can read it.

464 It is possible that the research may produce psychological difficulties for a subject; therefore, it
465 may be necessary to make arrangements for those difficulties to be dealt with by a professional.
466 For example, in one study of people with chronic illness, the Investigator provided all subjects
467 with a list of mutual-help organizations in the local area.

468 After review of the informed consent document, subjects should have a clear understanding of
469 the procedures which will be followed with regard to their participation. Each subject should be
470 able to make an informed decision concerning participation, free of explicit or perceived
471 coercion. Potential risks and procedures to minimize such risks must be stated in detail in clear,
472 precise language. A statement should be included in which the subject declares himself/herself
473 fully informed and agrees to participate on a purely voluntary basis. Finally, the subject should
474 be given a copy of the consent form, and/or any information sheets that he/she is required to
475 read.

476 Copies of the completed informed consent forms should be retained by the Principal
477 Investigator for a period of at least three years following termination of the project.

478 A copy of the sample consent form(s) to be used must be included with each application and
479 must be approved by the IRB. At the time of approval, the consent form will be stamped with an
480 expiration date, after which time it may not be used.

481 Elements of the Informed Consent Form

482 The following elements must be included in the informed consent form:

- 483 A. A statement that the study involves research, an explanation of the purposes of the
484 research and the expected duration of the subject's participation, a description of the
485 procedures to be followed, and identification of any procedures which are experimental

- 486 (e.g., in medical research, those procedures which deviate from standard, accepted
487 practice). If the purpose of the research cannot be fully revealed to subjects, describe
488 exactly what subjects will be told, the justification for any deception of subjects, and
489 plans to debrief subjects after their participation in the research.
- 490 B. The name(s) and affiliation(s) of the Principal Investigator(s).
- 491 C. A description of any foreseeable risks or discomforts (both physical and mental) that
492 could reasonably be anticipated.
- 493 D. A description of any benefits to the subject or to others which may reasonably be
494 expected from the research. In most research, expected results are tenuous, at best. If
495 no direct benefits due to participation are foreseen, it is appropriate to state this.
- 496 E. A statement that participation is voluntary, refusal to participate will involve no penalty or
497 loss of benefits to which the subject is otherwise entitled, and the subject may
498 discontinue participation at any time without penalty or loss of benefits to which the
499 subject is otherwise entitled. If the participant has been promised financial
500 compensation, but chooses to withdraw, state that a pro-rated portion of the fee will be
501 paid up to the point of withdrawal.
- 502 F. A disclosure of appropriate alternative procedures or courses of treatment, if any, that
503 might be advantageous to the subject.
- 504 G. A statement describing how anonymity and confidentiality will be maintained.
- 505 H. A statement describing the extent, if any, to which confidentiality of records identifying
506 the subject will be maintained which should include how records will be kept confidential,
507 (e.g., locked cabinet, erasing of tapes, etc.). If audio taping is to occur, indicate who will
508 hear the tapes, where they will be stored, and how and when they will be disposed. If
509 videotaping is to occur, indicate to whom the tapes are to be shown and where they will
510 be stored.
- 511 I. The informed consent form must have a line for the subject's and researcher's
512 signatures, and the date of consent. If the participation must be anonymous and the form
513 is to be signed with an X, then the signature of a witness must also be obtained. The
514 Investigator should retain a copy of the signed consent form and provide a copy to the
515 subject.
- 516 J. An explanation of whom to contact for answers to pertinent questions about the research
517 and research subject's rights, and whom to contact in the event of research-related injury
518 to the subject. The informed consent form should include a phrase such as the following:
519 "If you have any questions concerning your rights as a participant in this study, you can
520 call the Office of the Vice Chancellor of Academic Affairs."

521 A Note on Language Style

522 The language used in the consent form must be appropriate to the subject's level of education
523 and understanding. Exculpatory language through which the subject is made to waive his/her
524 legal rights or releases or appears to release the institution from liability for negligence may not
525 be included. When applicable, a consent form should be translated into the subjects' first

526 language.

527 The consent form, and any materials used to recruit subjects should be submitted to the IRB at
528 the time application for human subjects approval is made. If these materials are written in a
529 foreign language, both the forms to be used and their English translations are to be submitted.

530 **Informed Consent with Minors as Subjects**

531 Children under age 18 are considered legally incompetent to give informed consent. As human
532 subjects, children are especially vulnerable. The following definitions are important for research
533 with minors: (a) "Children" are persons who have not attained the legal age for consent to
534 treatments or procedures involved in the research, under the applicable law of the jurisdiction in
535 which the research will be conducted. (b) "Assent" means a child's affirmative agreement to
536 participate in research. Mere failure to object should not, absent affirmative agreement, be
537 construed as assent. (c) "Permission" means the agreement of parent(s) or guardian to the
538 participation of their child or ward in research. (d) "Parent" means a child's biological or adoptive
539 parent. (e) "Guardian" means an individual who is authorized under applicable State or local law
540 to consent on behalf of a child to general medical care.

541 The IRB has decided that written assent should be obtained from children aged 12 and older;
542 verbal assent should be obtained from children under 12 years of age. Assent from a child
543 should be requested only after the child's parents or guardians have agreed that the child may
544 participate. In most cases, the signature of one parent or guardian is sufficient. However, in
545 studies involving greater than minimal risk, signatures of both parents or guardians may be
546 required.

547 Information provided during the procedure to obtain consent or assent from children should be
548 presented in a form understandable by the children selected for the study. We encourage
549 researchers to consider alternatives to the conventional consent form used with adults.
550 Appropriate alternatives include: a checklist, pictures, role playing and audio-visual methods.
551 The basic information about procedures, purpose, selection, risks, benefits and willingness of
552 the researcher to answer questions should be provided to children serving as research subjects.

553 **Oral Consent**

554 In certain cases, the Principal Investigator may determine that oral consent is more appropriate
555 and more adequately safeguards the subject. The oral consent form shall consist of a written
556 consent document presented orally to the subjects (or his/her legally authorized representative).
557 The IRB shall approve the written text of what is said to the subject or representatives. A copy of
558 the information that is read to the subject should be given to the subject or the representative to
559 keep. There should be a witness to the oral presentation who can attest that the information was
560 given as stated.

561 **When It Might be Appropriate to Omit the Use of a Consent Form**

562 As a general rule, the IRB believes informed consent should be obtained from all research
563 subjects. However, if the Principal Investigator believes that obtaining a signed consent form
564 would be inappropriate, such a request must be justified according to the following criteria:

565 A. The only record linking the subject and the research would be the consent form and the
566 principal risk would be potential harm resulting from a breach of confidentiality.

567 B. The research presents no more than minimal risk and involves no procedures for which
568 written consent is normally required outside the research context. For example, in a
569 sample survey of volunteers, investigators would describe the nature of the interview to
570 the subjects. Rather than seek written approval, participation here is regarded as de
571 facto consent.

572 C. Tacit Consent. When participation entails only the completion of anonymous written
573 questionnaires, consent may be considered to be tacit. Provided that responses can in
574 no way be used to identify subjects, written consent is not necessary. (To ensure that
575 participation is voluntary, the investigator should not be present when subjects are filling
576 out the instruments and subjects must not be required to hand back their responses
577 directly to the investigator.)

578 When the use of a consent form is waived, the IRB requires the Principal Investigator to provide
579 subjects with a written statement regarding the research.

580 Signatures: A student researcher must obtain the signature of his or her faculty advisor before
581 the IRB will consider the application.

582 Reporting Unanticipated Problems and Changes in Protocol: Any unanticipated problems
583 involving risks to subjects or others participating in a research study, or proposed changes to a
584 previously approved application must be promptly reported in a written memorandum to the IRB.
585 This includes changes in the (approved) consent form, sample composition, sample recruitment,
586 or study procedures.

587 Applicants Seeking External Funding: Federal regulations require that protocols be "tracked" to
588 grant proposals, although IRB review and grant proposal preparation are independent activities.

589 **XV. FREQUENT OVERSIGHTS IN APPLICATION MATERIALS AND CONSENT** 590 **FORMS**

591 A. The language in the consent form must be understandable to the population being
592 addressed (e.g., children). In the event that consent forms may be best understood in
593 another language, that version must be submitted along with an English translation.

594 B. The name and status of the investigator, as well as the University, school and
595 department identifiers should be incorporated into the consent form text. The address
596 and telephone number where the researcher can be reached should questions arise also
597 must be included; where appropriate, the name of and telephone number of a faculty
598 advisor should be included as well.

599 C. When cooperating institutions are involved, a letter of cooperation from an authorized
600 official should be included. If a letter is not available at the time of application, it must be
601 submitted before research may begin.

602 D. Methods for maintaining confidentiality of the data should be described in detail (i.e.,
603 coding procedures, who has access to the files, where files are kept, and how anonymity
604 is protected).

605 E. When treatment or services are involved, an affirmation should be included indicating
606 that an individual's decision not to participate will in no way affect the availability of

- 607 services to which individuals are entitled.
- 608 F. When students are involved, an affirmation should be included indicating that non-
609 participation will in no way affect academic standing.
- 610 G. When children are involved, both parental permission and children's consent or assent
611 are required.
- 612 H. When video or audio taping is involved, an opportunity to review the completed tape
613 must be given so that subjects may ask that it not be used (either in whole or in part).
- 614 I. Requests to have proposals classified as exempt must be accompanied by a supporting
615 statement, detailing which category of exemption is being claimed, and why the
616 researcher believes the activity falls into this category. In the case of minors (individuals
617 under 18 who are participants in research), exemptions are limited to the following
618 categories of research:
- 619 1. studies that constitute normal educational practices in educational settings;
- 620 2. educational tests, where identifiers are not recorded;
- 621 3. collection or study of existing data, documents, records, pathological or diagnostic
622 specimens, if these sources are publicly available, or if the information is recorded so
623 that subjects cannot be identified.
- 624 4. observation (as opposed to participation) by the principal investigator of public
625 behavior where identifiers are not recorded by the principal investigator and there is
626 neither a risk of harm to subjects nor observation of sensitive aspects of the subjects'
627 own behavior

**LSU EUNICE INSTITUTIONAL REVIEW BOARD
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**

Please note: Step-by-step instructions and other information relevant to filling out this form are contained in LSU Eunice's Principal Investigator's Manual for Research involving Human Subjects. All investigators are expected to be familiar with the policies and procedures it contains. Failure to follow the instructions may result in a delay in the approval process.

1. Project Title: _____

2. Principal Investigator: _____

Department: _____ Phone: _____ Fax: _____ Email: _____

3. Co-PI (if any) _____

Department: _____ Phone: _____ Fax: _____ Email: _____

4. Status (check one): Faculty _____

Undergraduate Research _____

Other (please explain) _____

5. For students and non-LSU Eunice researchers only, please give your home address and phone number:

Faculty Advisor: _____

Department: _____ Phone: _____ Fax: _____ Email: _____

NOTE: The IRB will not review protocols submitted by students without the signature of a faculty advisor on the final page of this application.

6. Type of review requested: _____ Exempt _____ Expedited _____ Full IRB

(for an explanation of the three types of review, see the Investigator's Manual):

7. Does your study involve the collection of data from a vulnerable population? ____yes ____no

If yes, please specify: _____

For a complete list of categories of vulnerable populations, as well as the special safeguards required when conducting research with them, the Investigator's Manual. Special Informed Consent procedures are necessary when conducting research with minors. For more detail, see the Manual.

8. Does this study involve deception (research in which the subject is purposely lead to have false beliefs or assumptions)? ____yes ____no

9. If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks?
_____ yes _____ no

10. Has this study been previously approved by the IRB? _____ yes _____ no

11. Check if this proposal is _____ new or _____ revised in response to previous IRB review.

12. Is funding being sought for this study? If yes, through what sponsoring agency?

13. Is this study being reviewed by an Institutional Review Board at another institution? If yes, please list cooperating institutions below and attach an official letter of cooperation.

Documentation of IRB reviews of this study conducted at other institutions must be provided when it becomes available. Research may not begin until IRB review has been concluded at all institutions involved.

For EXEMPT reviews, submit original and 1 copy of this APPLICATION.

For FULL IRB reviews, submit original and 6 copies one month before approval is needed.

The IRB may meet once per month from September through May.

Please submit all applications to the Vice Chancellor for Academic Affairs.

Special Deadline Information is contained in the Investigator's Manual

EXEMPT REVIEW

Requests for exemption from IRB review must include the information requested below. If exempt status is granted, the study will no longer be under the jurisdiction of the IRB, unless procedures are revised which deviate from those originally reviewed by the IRB. Research involving protected populations, e.g. prisoners, pregnant women or fetuses, is not eligible for exempt status.

Exemption may be claimed under the following categories: (for a complete description of these categories, see details in the Investigator's Manual)

1. Research involves the study of normal educational practices in commonly accepted educational settings.
2. Research involves the use of educational tests, surveys, or interviews where identifiers are not recorded by the PI or where there is neither a risk of harm to subjects nor information sought concerning sensitive aspects of the subjects' own behavior. Research involves observation of public behavior where identifiers are not recorded by the PI and there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior. This exemption does not apply to research with children when the investigator[s] participate in the activities being observed; for example, in classroom situations where the researcher is taking part in the classroom activities being studied or surveys and interviews with children.
3. Research involves the use of educational tests, surveys, interviews, or observation of public behavior that is not exempt under the above category if: (a) subjects are elected or appointed public officials or candidates for public office or (b) federal statute(s) require(s), without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involves merely the collection or study of existing data, documents, records, pathological or diagnostic specimens, where publicly available or where the information is private by identifiers not recorded by the PI.
5. Research to examine current public benefit or service programs, or alternatives to existing programs.
6. Taste and food quality evaluation and consumer acceptance studies, if food or additives consumed meet FDA safety standards.

I believe my research can be classified as exempt under category number(s) _____ above.

PI Signature _____ Date _____

Co-PI Signature _____ Date _____

Faculty Advisor's Signature _____ Date _____
(required for student research)

Please append to this document a description of your research sufficiently detailed to justify exemption under one or more of the above categories. Final judgment on exemptions rests with the IRB.

You will be notified if your study is found to be exempt from further IRB review.

FULL IRB REVIEW

Please consult the Investigator's Manual for an explanation of expedited and full IRB review and the types of research which may be reviewed under each procedure. Request for expedited review may be referred to the full IRB if the Chair of the IRB deems it appropriate.

Please answer the following questions on a separate sheet and attach to application form:

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received IRB approval from another institution. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.
2. Describe the source(s) of subjects and the selection criteria. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. The Investigator's Manual discusses equity in subject selection and protected populations). The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects must be attached.
3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects' involvement.
4. Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety.
5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.
6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

Upon approval of the study, the consent document will be stamped with an expiration date. Only this document may be used when enrolling subjects. Studies extending beyond the expiration date must be submitted for a continuation review. Any changes in the consent form must be approved by the IRB.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent contained in the Investigator's Manual. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and a consent form for research involving minors under the age of 12. When the consent form to be used will be in a language other than English, an English translation must be provided. Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:
 - a) A fair explanation of the procedures to be followed and their purposes, including any procedures that are experimental.

- b) A description of any possible attendant discomforts and risks reasonably expected.
- c) A description of any benefits reasonably expected.
- d) A disclosure of any appropriate alternative procedures.
- e) An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request. A contact person and phone number should be provided.
- f) An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.
- g) A statement that the data are confidential and that the subject will not be identified by name in writing or orally.
- h) Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate.

8. Please provide any other information that might be pertinent to the IRB's decision.

All applicants: I agree to use procedures with respect to safeguarding human subjects in this activity that conform to University policy. If significant change in investigative procedure involving human subjects is called for during the activity covered by this application, I shall seek prior approval for such change from the IRB and agree to follow the advice of the IRB. The faculty sponsor's signature indicates that s/he has reviewed this application and accepts the responsibility of insuring that the procedures approved by the IRB are followed.

PI Signature _____ Date _____

Co-PI Signature _____ Date _____

Faculty Advisor Signature _____ Date _____
(required for student research)

For applicants seeking external funding only:

I certify that the research plan and safeguards to human subjects described in this application conform to that which has been submitted/will be submitted to an external funding source.

PI Signature _____ Date _____

Co-PI Signature _____ Date _____

Grants Officer Signature _____ Date _____

Name of Sponsor _____ Internal Reference # _____

Before submitting this form, consult the Frequent Oversight section of the Investigator's Manual.