IRB BASICS

Renee K. Gonzales
Compliance Officer

WHAT IS THE IRB?

- Institutional Review Board
- Membership (2 reps from each College and 2 community members)
- Charged with protecting Humans participating in Research being conducted by TAMU-CC faculty, staff & students

HISTORY

- 1932-1972
  - The Tuskegee Syphilis Study
    - 600 low-income African-American males, 400 infected with Syphilis are monitored for 40 years. Proven cure became available in the 1950's but the study continues till 1972 with participants being denied treatment. ~100 died of Syphilis during the study.
History

Germany - 1940's
- Pilot survival testing
  - Air Pressure
    - 40 of 200 "participants" died
  - Cold Water Survival
    - 90 of 300 "participants" died
- Battlefield medicine
  - Re-create victim ailments
    - Mutilation
    - Chemical weapons testing
    - Transplants
    - Mortality rate over 25%

History

Nuremburg Doctors Trial (1946)
- 23 defendants (including 20 doctors)
  - Charged with murder, torture and other atrocities committed in the name of science.
  - 19/23 found guilty
  - 7/15 sentenced to death
- Resulted in the "Nuremburg Code" (1947)
  - Informed consent without coercion
  - Human experimentation should be based on prior animal experimentation
  - Only qualified scientists should conduct medical research
  - Physical and mental suffering should be avoided
  - There should be no expectation of death or disabling injury

History

• Thalidomide Tragedy (1950s and early 60's)
  - Approved in Europe as a sedative
    - Distributed to US doctors paid to study efficacy and safety by prescribing to patients.
  - Did not harm Mother, but impaired normal development of arms and legs of fetuses.
    - 2nd generation impacted
History
Thalidomide Tragedy (1950's and early 60's)
- Mothers were not informed drug was experimental or of any possible negative side effects.
  - Required informed consent when administering experimental drugs.

WHY THE IRB?
- Federal Mandate - Code of Federal Regulations Title 45 Part 46
- Annual Assurance of Compliance reported to the OHRP (Office of Human Research Protection) within the Department of Health & Human Services

The Belmont Report
- Published in the Federal Register in 1979
- Cornerstone statement of ethical principles upon which the federal regulations are based
- Three Basic Principles
  - Respect for persons
  - Beneficence
  - Justice
RESEARCH CATEGORIES

• Exempt – 7.1.2
  - 1. Normal Educational Practice
  - 2. Surveys, Interviews, Pre/Post Tests
  - 3. Same as above but using public officials
  - 4. Collection of existing data
  - 5. Evaluation of public benefit or service programs
  - 6. Taste and food evaluation

RESEARCH CATEGORIES (CONT.)

• Expedited – 7.2.1
  - 1. Clinical studies of drugs/medical devices.
  - 2. Collection of blood samples.
  - 3. Collection of hair/nail clippings, saliva, sweat, etc.
  - 4. Collection of data using physical sensors applied to the surface of the body, flexibility testing, weight/measurement collection, etc.
  - 5. Collection of data such as medical treatment/diagnosis
  - 6. Voice recording for research on speech defects

RESEARCH CATEGORIES (CONT.)

• Expedited (cont)
  - 7. Research using survey, interview, focus groups that is not qualified for Exempt review.
  - 8. Continuing review of research approved by Full Committee at prior convened meeting that is consistent with categories 27.
  - 9. Continuing review of research that was approved at prior convened meeting that does not fit categories 27.
RESEARCH CATEGORIES (CONT.)

• Full Review - 7.3.1
  – All protocols that do not qualify for exempt or expedited review.

CHECKLIST

• Form A or Form B completed (signed by Investigator AND faculty advisor).
• Copy of survey instrument and/or interview questions if applicable.
• Copy of Assent Form
• Copy of Consent Form

ASSENT FORM

• Form that informs child of their rights as a participant. Key components include:
  – Participation is voluntary
  – May withdraw at any time
  – List any risks and benefits
  – List PI's contact information

**All in 3rd grade language!!**
CONSENT FORM

• Form that informs adults of their rights as participants as well as their children's rights as participants if applicable. Should contain:
  - Participation is Voluntary
  - All answers will be anonymous/confidential
  - You may withdraw at anytime
  - List risks/benefits
  - List contact information for PI as well as contact information for Compliance Officer
  - Have signature line for participant

**Entire form in 8th grade language!**

U.S. Adult Reading Levels

51% of U.S. adults can not read at the 8th grade level

- <3.5 grade
- Between 3.5 and 7.4 grade
- >7.4 grade

TAMU-CC COMMITTEE MEETINGS

- Exempt Review (daily)
- Expedited Review (as needed)
- Full Review (First Friday of each month)
  - Requires 50% of committee for a quorum
  - Protocols must be on the agenda one week prior to the meeting
IRB RESOURCES

• http://research.tamucc.edu/irb/

• http://www.hhs.gov/ohrp/

• Renee.gonzales@tamucc.edu

• Eve.Layman@tamucc.edu
Institutional Review Board

Training Manual

Texas A&M University-Corpus Christi

September 2008
How to Determine if the Project is Research Involving Human Participants

Is the project research?
- Systematic - development, testing, and evaluation
- Designed - intent
- Develop or Contribute to generalizable knowledge - just because it isn't published does not mean it isn't generalizable

45 CFR 46.102(d)

Does the research involve human participants?
- Living individual - about whom
- Professional or student - conducting the research
- Collects data through intervention - physical procedures, manipulations of individual or individual's environment
- Collects data through interaction - communication between researcher and individual(s), includes interpersonal contact
- Data contains identifiable information - readily ascertained by researcher or associated with the data (codes)
- Data contains private information - behavior, context in which an individual can reasonably expect no observation or recording is taking place, and/or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (medical records, school records, etc.)

45 CFR 46.101(f)

Check FDA or other applicable regulations

HUMAN PARTICIPANTS RESEARCH
8 CRITERIA FOR APPROVAL...

Risks to subjects are minimized

Risks to subjects are minimized
Risks are reasonable in relation to anticipated benefits

Risks to subjects are minimized

Selection of subjects is equitable
Will later discuss...

Privacy and Confidentiality

Vulnerable Populations
The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

Protection of Human Subjects


AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four day period of discussions that were held in February 1976 at the Smithsonian Institute's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of ethical problems that surround the conduct
of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of the Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission

- Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
- Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
- Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
- Dorothy L. Height, President, National Council of Negro Women, Inc.
- Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.
- Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
- Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.
- * David W. Louisell, J.D., Professor of Law, University of California at Berkeley.
- Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.
- Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.

* Deceased.
Belmont Report

Ethical Principles and Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes (1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals (2). By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions
to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project(3).

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

**B. Basic Ethical Principles**

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence and justice.

1. **Respect for Persons.** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals
lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. **Beneficence.** -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.
The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children - even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. **Justice.**—Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions
have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. **Informed Consent**. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

   While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

   **Information.** Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement
offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

**Comprehension.** The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the
subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and benefits. The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and
comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

**The Nature and Scope of Risks and Benefits.** The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk benefit assessments are concerned with the probabilities and magnitudes of possible harms and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

**The Systematic Assessment of Risks and Benefits.** It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible.
This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. — Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk, benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized
mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

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**footnote1**
Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

**footnote2**
Although practice usually involves interventions designed solely to enhance the well being of a
particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

footnote3
Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.
1. GENERAL

1.1 Texas A&M University-Corpus Christi has a responsibility to protect the rights and welfare of prospective research subjects and to provide a favorable climate for the conduct of scientific inquiry. In compliance with federal regulations, the University requires all research involving human subjects to be approved by the Texas A&M University-Corpus Christi Institutional Review Board (IRB).

1.2 Researchers seeking approval for projects may obtain the appropriate forms from the IRB Chair, an IRB member, or the Office of Sponsored Programs.

1.3 This document shall automatically be updated to comply with changes in federal regulations. Other changes will go through the regular University review process.

1.4 The Chair of the IRB will report to the Provost and Vice President for Academic Affairs in January of each year as to the adequacy of this document and such other matters that should be brought to the attention of the faculty related to this document.

2. SCOPE OF INSTITUTIONAL REVIEW BOARD

All activities involving research with human subjects in all fields of University activity shall come under the purview of the Institutional Review Board. This committee has the primary responsibility for maintaining ethical standards of research involving human subjects at the University. All projects will be reviewed at least annually. The IRB has authority to approve or disapprove such research. It may require modifications as a condition for approval. Following the review of the research, the IRB will notify the investigators and the institution in writing of its decision. If the IRB decides to disapprove a research activity, it will provide the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Federal regulations require the IRB to conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year. The IRB has authority to observe or have a third party observe the consent process and the research.

3. ETHICS

3.1 TAMU-CC will use the following documents as guides for the conduct of human subject research:

(1) the World Medical Association’s “Declaration of Helsinki,”

(2) the American Psychological Association’s statement, “Ethical Principles in the Conduct of Research with Human Participants,”

(3) the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and


3.2 The subjects have recourse to the IRB at any time through its Chairperson, if they feel they have not been dealt with fairly. Copies of this document and those listed above will be available for the investigator, as well as any other interested persons, upon request to the Office of the Provost/Vice President for Academic Affairs or the offices of the Deans. These materials are also available from the Office of Sponsored Programs.

4. MEMBERSHIP OF THE IRB

4.1 The membership of the IRB shall be composed of a member of the Ethics Council, two faculty members from each of the Colleges, a representative from the Library, and two persons from the community. All members are voting members. The faculty members are appointed by the process described in “University Committees and University Councils.” The community members are appointed by the President or the President’s designee. In addition, the committee make-up will reflect the guidelines established in the Code of Federal Regulations, 45 CFR 46, section 46.107, titled IRB membership. As stated in the guidelines, the membership will include persons of varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The members will have expertise and experience in a variety of specified areas. Also, the membership should reflect diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to community attitudes. (For more information, see 45 CFR 46.)

4.2 Terms of membership for faculty members shall be three years on an alternating basis. The community members shall serve two-year terms. The Ethics Council member will have a re-appointable, three-year term. The Chairperson of the IRB shall be elected from within the membership of the IRB for a two-year term by the IRB and shall be eligible for re-election. A vice chair will also be elected for a two-year term from within
5. MEETINGS OF THE IRB
The IRB shall meet monthly during the two regular semesters and at the call of the Chair. A quorum shall be a simple majority. The IRB may establish its own operating procedures within these prescribed guidelines. Projects for review at its monthly meeting shall be received at least 10 working days prior to its monthly meeting.

6. CRITERIA FOR APPROVING RESEARCH
To be approved by the IRB, human subjects research which is covered by federal policy must meet all the following criteria:

1. risks to subjects are minimized by using procedures that are consistent with sound research design and whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes;
2. risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result;
3. selection of subjects is equitable in terms of the purposes of the research and the setting in which it will be conducted;
4. informed consent is sought from each prospective subject and documented to include all appropriate information;
5. the protocol makes adequate provision for monitoring the data collected to ensure the safety of the subjects;
6. adequate provision is made and documented to protect the privacy of subjects and to maintain the confidentiality of the data; and
7. where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect their rights and welfare.

7. RESEARCH REVIEW CATEGORIES
The extent of the IRB review will depend upon the nature of the research. There are three research review categories: exempt research, expedited review, and full review.

7.1 Exempt Research

7.1.1 Certain categories of research are exempt from the Protection of Human Subjects policy in the Code of Federal Regulations 45 CFR 46. The IRB Chair will determine, based on the federal guidelines, whether a research activity qualifies for exemption. Although exempt research is not regularly reviewed by the IRB, the exempt research form (and the informed consent form, if applicable) must be on file with the IRB, and the research may be reviewed at the committee's discretion. If the committee deems necessary, it may require a full review.

7.1.2 Unless otherwise required by federal departments or agencies, research activities in which the only involvement of human subjects will be in one or more of the following categories are generally exempt from full review by the IRB:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as
   i. research on regular and special education instructional strategies, or
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   ii. any disclosure of human subjects' responses 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.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude,
achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous paragraph, if:

i the human subjects are elected or appointed public officials or candidates for public office; or

ii federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine:

i public benefit or service programs;

ii procedures for obtaining benefits or services under these programs;

iii possible changes in or alternatives to those programs or procedures; or

iv possible changes in methods or levels of payment for benefits or services under those programs.

7.1.3 Research involving special or protected populations, such as children, the elderly, prisoners, pregnant women, and the handicapped, is subject to full review.

7.2 Expedited Review

7.2.1 Expedited review procedures are available for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Specifically, research is eligible for expedited review if it involves no more than minimal risk (see 45 CFR as amended) to the subjects and the only involvement of human subjects will be in one or more of the categories listed below:

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

(2) Collection of excreta and external excretion including sweat, unannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

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

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.*

(5) Collection of both supra- and subgingival dental plague and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recording made for research purposes such as investigation of speech defects.

(7) Moderate exercise of healthy volunteers.**

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

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

(10) Research on drugs and devices for which an investigational new drug exemption or an
investigational device exemption is not required.

(11) Any other category specifically added to this list by HHS and published in the Federal Register.
* Subjects must be informed orally of the risk of bruising and infection.
** Moderate exercise does not include stress testing.

7.2.2 Informed consent is required, but the requirement to obtain a signed consent form may be waived if:

(1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

7.2.3 In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

7.3 Full Review
All those projects not exempt or qualifying for expedited review shall be subject to full review by the IRB.

8. REVIEW PROCEDURES

8.1 Exempt Review
Under the exempt procedure, the researcher shall submit Form A to the Chair of the IRB. The IRB Chair shall determine whether a project is exempt from further review. Although exempt research requires no action by the IRB, the board may choose to review the forms on file at its discretion. If the Board deems necessary, it may require a full review.

8.2 Expedited review
8.2.1 Research which involves no more than minimal risk to the subject and falls under the categories established by the Secretary of Health and Human Services (46 FR 8392), or research previously approved needing minor changes, will normally be reviewed by the expedited review procedures. However, the IRB may consider any such research through a full review procedure, if it so chooses.

8.2.2 Informed consent is required in the expedited review, but the IRB may waive the requirement to obtain a signed consent form, in accordance with the guidelines discussed above in section 7.2.2.

8.2.3 In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

8.2.4 Under the expedited review procedure, the researcher shall submit Form B to the IRB Chair. The Chair will appoint a committee member to review the proposal. A member of the IRB shall not review his/her own proposal. If the reviewer finds that the research falls under the guidelines for expedited procedures, the reviewer has the authority to approve the project, require modifications in the project, or recommend a full review by the IRB. The reviewer will report his/her action at the next IRB meeting. A research activity may be disapproved only after a review by the full IRB. The reviewer shall forward to the IRB Secretary the research proposal and his/her decision to approve the proposed research activity, or his/her modifications required to secure the reviewer's approval, or a recommendation for full IRB review. The IRB Secretary will make the proposal and decisions available to all members of the IRB.

8.3 Full Review
8.3.1 Investigators are required to submit proposals to the IRB Chair on Form B at least 10 days in advance of the meeting in order to provide time for prior review. The committee may approve the research as proposed; it may approve the research pending specified modifications; or it may reject the research proposal. If the IRB gives approval pending specified modifications, the principal investigator is required to submit written assurance that conditions, restrictions, report requirements, or changes imposed on the project will be followed.

8.3.2 The ultimate protection of safety, confidentiality, and the rights of human subjects will in all cases take precedence over the importance and results of the project. The definition used to determine if the
subject is “at risk” will be contained in the Code of Federal Regulations on Protection of Human Subjects (45 CFR 46 as amended).

8.3.3 No project or activity which involves humans will be approved unless assurances of legally effective informed consent are provided for or a waiver of signed informed consent is approved on Form B by the IRB. The elements of informed consent as outlined by article 46.116 of 45 CFR 46 are to be observed in all projects. The Board will decide whether the method for securing consent of the subject (by the principal Investigator) is sufficient and appropriate. Additionally, in connection with any project involving fetuses or pregnant women, the IRB will oversee the actual process by which individual consents are secured by sampling and monitoring the progress of the activity at timely intervals.

9. RECORDS

9.1 The IRB Secretary will obtain and maintain all appropriate records—including, but not limited to, copies of all projects, documentation of informed consent procedures, minutes, and records of formal notification to/from principal investigators of official actions—in the Office of Sponsored Programs. All such records will be reviewed for informational content and follow up by the Chair of the IRB.

9.2 All records obtained for compliance with 45 CFR 46 are considered privileged institutional records and principal investigators must protect and maintain the confidentiality of information on individual subjects. Certification of approval of federally funded projects including any required changes will be forwarded by the IRB Chair to the Department of Health and Human Services.

10. STATEMENT ON STUDENT RESEARCH

10.1 According to federal regulations, research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.” If student projects are not designed to contribute to further academic knowledge in the discipline (e.g., conference presentations, professional publications), then they are not considered research for the purposes of this rule and therefore are not under the review of the IRB. Student projects that are designed to contribute to generalized knowledge should be submitted for review to the IRB just as any other research project.

10.2 Research conducted by students must follow the same ethical guidelines as all university research. The responsibility for the ethical conduct of student research is jointly held by the instructor and the student, each being fully responsible for the research.

Contact for Interpretation: Chair, Institutional Review Board

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§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.
(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 0990-0260.)
§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 0990-0260.)
REQUEST WAIVER - CONSENT OR DOCUMENTATION OF CONSENT
Texas A&M University
Protocol for Human Subjects in Research

Project Title:

Waiver of Consent
I certify that my research study meets 'all four' of the following criteria:

☐ 45 CFR 46.116

1. The research involves no more than minimal risk to the participants;
2. The waiver of alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

OR

Waiver of Signed Consent
I certify that my research study meets 'at least one' of the following criteria:

☐ 45 CFR 46.117

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Signature of Investigator: _____________________________ Date: ______

Typed/Printed Name: _____________________________
CONSENT FORM

[Insert Title of Study]

Introduction
The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. If you decide to participate in this study, this form will also be used to record your consent.

You have been asked to participate in a research project studying [insert general statement about study]. The purpose of this study is to [explain research questions and purpose in lay language]. You were selected to be a possible participant because [explain how participant was identified]. This study is being sponsored/funded by [name sponsor/funding source]. *If research is not sponsored/funded, do not include this sentence.*

What will I be asked to do?
If you agree to participate in this study, you will be asked to [explain tasks and procedures [include details about completing surveys, interviews, tests, and/or focus groups, as applicable]]. This study will take [insert length of time for participation, frequency of procedures, etc.]. (If the study involves several different procedures, include the time involved for each [e.g., The study will last a total of 12 weeks. During week one, you will be asked to eat a diet of soy 3 times daily. On Friday of the first week, you will be asked to take a physical. This will take about 2 hours and will consist of the following tests...].)

Your participation will [may] be audio [video] recorded. *If participants will not be audio/video recorded, do not include this sentence.*

What are the risks involved in this study?
The risks associated with this study are [explain risk, including the likelihood of the risk occurring]. *If risks are minimal, you may state: The risks associated in this study are minimal, and are not greater than risks ordinarily encountered in daily life.*

What are the possible benefits of this study?
The possible benefits of participation are [insert benefits that may be reasonably expected]. Monetary compensation should not be categorized as a benefit. *If there are no direct benefits to the research participant, you may state: You will receive no direct benefit from participating in this study; however,[explain potential benefits to society].*

Do I have to participate?
No. Your participation is voluntary. You may decide not to participate or to withdraw at any time without your current or future relations with Texas A&M University [include any other cooperating institutions] being affected.

Will I be compensated?
*If there is no compensation, do not include this section.*
You will receive [insert payment, reimbursement, or participation credit]. Disbursement will occur [explain conditions of payment]. Include circumstances if any where partial payment or no payment may occur.
"If participants will receive class points or credit, [include information about points]. [Explain alternative task if participant does not want to participate but wants to obtain class points.]

Who will know about my participation in this research study?
This study is [anonymous OR confidential, "cannot be both"] and [describe how confidentiality or anonymity will be maintained].

*Possible text: The records of this study will be kept private. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only [insert names of individuals who will have access to this data] will have access to the records.

If you choose to participate in this study, you will be [may choose to be] audio [video] recorded. Any audio [video] recordings will be stored securely and only [insert names of individuals who will have access to recordings] will have access to the recordings. Any recordings will be kept for [insert length of time] and then erased. *If no audio/video recordings will be made, do not include this section.

Is there anything else I should consider?
[Use this section to discuss any other information that may affect the participant's decision to participate in this research. Possible information may include conditions in which the participant may be withdrawn from this study, costs to participant, financial interests of PI, or any other disclosure.] *If there is no additional information, remove this section.

Whom do I contact with questions about the research?
If you have questions regarding this study, you may contact [list PI name, phone number, email address] or [list alternate contact, phone number, email address].

Whom do I contact about my rights as a research participant?
This research study has been reviewed by the Human Subjects' Protection Program and/or the Institutional Review Board at Texas A&M University. For research-related problems or questions regarding your rights as a research participant, you can contact these offices at (979)458-4067 or irb@tamu.edu.

Signature
Please be sure you have read the above information, asked questions and received answers to your satisfaction. You will be given a copy of the consent form for your records. By signing this document, you consent to participate in this study.

*Only include the following if recording is optional:
____ I agree to be audio [video] recorded.
____ I do not want to be audio [video] recorded.

Signature of Participant: ___________________________ Date: __________

Printed Name: __________________________________________

Signature of Person Obtaining Consent: __________________________ Date: __________

Printed Name: __________________________________________
Exempt Processing Sheet

Protocol Number: 2006-0161
Review Date: 7.30.08
Reviewer: MCILHANAY

Exemption Categories

☐ 45 CFR 46.101(b) (1) - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☒ 45 CFR 46.101(b) (2) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses 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.

☐ 45 CFR 46.101(b) (3) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human 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.

☐ 45 CFR 46.101(b) (4) - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ 45 CFR 46.101(b) (5) - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ 45 CFR 46.101(b) (6) - Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Provisions/Comments

Qualifies for exemption – processed as “expedited” during amendment last year (in error) – set to exempt 2

Reviewer Instructions

☐ Hold For Revisions
☒ Exempt, Process Letter
<table>
<thead>
<tr>
<th>Subject Recruitment</th>
<th>Y</th>
<th>N</th>
<th>I/I</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Is subject recruitment selection fair and equitable?</td>
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<td>Are recruitment materials provided in final format?</td>
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<tr>
<td>Are recruitment materials appropriate?</td>
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<tr>
<td>Are there additional safeguards for subjects that are likely to be vulnerable to undue influence?</td>
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<tr>
<td>Is the amount of payment or the proposed method and timing of disbursement coercive or does it present undue influence?</td>
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</tbody>
</table>

Questions/Comments for PI:

<table>
<thead>
<tr>
<th>Consent</th>
<th>Y</th>
<th>N</th>
<th>I/I</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Will informed consent be obtained from research participants or their legally authorized representatives?</td>
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<tr>
<td>Will informed consent be documented appropriately?</td>
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<tr>
<td>Does the consent process provide sufficient opportunity for participant to consider whether to participate?</td>
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<td>Does the consent process minimize the possibility of coercion and/or undue influence?</td>
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<td>Is consent discussion in a language understandable to the participant?</td>
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<td>Does the consent form include exculpatory language?</td>
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<tr>
<td>Are assent procedures age appropriate?</td>
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</table>

Questions/Comments for PI:
## Risks & Benefits

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>I/I</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Does the proposed research design unnecessarily expose participants to risk?</td>
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<tr>
<td>Are the risks to participants reasonable in relation to anticipated benefits?</td>
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<td>Are risks to participants minimized?</td>
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<tr>
<td>Are additional safeguards required to protect the rights and welfare of subjects?</td>
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</table>

**Questions/Comments for PI:**

## Privacy & Confidentiality

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>N</th>
<th>I/I</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Are provisions made to protect participants' privacy?</td>
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<tr>
<td>Will confidentiality of identifiable data be adequately maintained?</td>
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</table>

**Questions/Comments for PI:**

### Questions/Comments for PI

## Reviewer Instructions

- [ ] Hold For Revisions
- [ ] See Approval Notice
- [ ] Place on Next Available Agenda

**Reviewer Signature:**

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Texas A&M University
Human Subjects' Protection Program
Expedited Review Sheet
Version 01.31.08
Expedited Approval Notice

Protocol Number: D Initial Review
Review Date: 9.19.08
Reviewer: MCILHANEY

Expedited Review Categories

- 45 CFR 46.110(b)(1) - Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.
  - 1. Clinical studies of drug and medical devices only when condition (a) or (b) is met.
  - 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as described.
  - 3. Prospective collection of biological specimens for research purposes by non-invasive means.
  - 4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
  - 5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
  - 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
  - 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.
  - 8. 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.
  - 9. Continuing review of research, not conducted under an investigational device exemption where categories two (2) through eight (8) 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.

- 45 CFR 46.110(b)(2) - Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Provisions/Comments

Reviewer Instructions

- Approved, Process Letter

Reviewer Signature: