

THE PARKER UNIVERSITY INSTITUTIONAL REVIEW BOARD GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH STUDIES

The purpose of this document is to state clearly and definitively the Parker University research policy, and to assist investigators in the preparation and submission of research proposals for review by the Research Committee (RC) and the IRB. The IRB Guidelines present the major focal points of IRB review: subject selection, risk/benefit analysis, and informed consent. The guidelines, which serve as the official governance document for human subject research at Parker University, reflect both the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the Federal Regulations (45 CFR 46, 21 CFR 50, 21 CFR 56) which govern human subject research. The review procedures described in the guidelines are designed to 1) assure an informed judgment that the results likely to be achieved by the study justify the possible physical risks, stresses, or violations of privacy of the human participant; 2) assist the investigator in the protection of the safety and privacy of the individual subject; and 3) assure that adequate informed consent is obtained from the subject. The review process is also designed to protect both the investigator and the institution

In conducting research involving human subjects, all investigators at Parker University need to follow procedures which will assure the protection of all human subjects involved in research projects. These procedures apply to **all research conducted by anyone on the premises of PARKER UNIVERSITY and to all research conducted elsewhere by faculty, students, staff, or other representatives of Parker**, whether or not the research is sponsored by agencies of the U.S. Government.

In order to comply legally with federal regulations relevant to the involvement of human subjects in research, on the one hand, and to fulfill its commitment to protecting such subjects regardless of the funding source and/or methodology employed, on the other, Parker University has established an institutional committee competent to review such research projects. Under the provisions of the Department of Health and Human Services, Regulations for Protection of Human subjects (45 CFR 46), this committee has been designated as the Institutional Review Board (IRB).

The primary function of the IRB is to assist the investigator in the protection of the rights and welfare of human subjects. Investigators should not bear the sole responsibility for determining the standards for ethical conduct of research involving human subjects. It is necessary for others, who are independent of this research, to share this responsibility. The PARKER UNIVERSITY IRB is this institution's responsible agency for such review.

Any research that involves the use of human subjects is to be conducted under these guidelines. In order for this policy to be effective, **all research proposals involving human subjects in research must go through a process that includes their being received and approved by the Parker University IRB prior to implementation of such research. All members** of the Parker community are expected to comply with both the spirit and the letter of these guidelines, regulations and policies.

Parker University has provided a formal guarantee to the Department of Health and Human Services (DHHS), Office for the Protection of Research Risks, that it will follow procedures which will assure the protection of all human subjects involved in research projects. This guarantee applies to faculty, students, staff, or other representatives of Parker, whether or not the research is sponsored by DHHS.

In order to comply with this assurance, Parker University has established an organization competent to review research projects that involve human subjects. Following the provisions of the DHHS Regulations for Protection of Human Subjects (45 CFR 46), this organization, the Research Committee, has designated a review group called the Institutional Review Board (IRB).

A main function of the Research Committee and the IRB is to assist the investigator in the protection of the rights and welfare of human subjects. Investigators should not bear the sole responsibility for determining the standards for ethical conduct of research involving human subjects. It is necessary for others, who are independent of this research, to share this responsibility. ANY proposal that involves the use of human subjects is to be conducted under these guidelines.

A. INVESTIGATIONAL ACTIVITIES REQUIRING IRB APPROVAL

1. Any systematic investigation involving human subjects which is designed to develop or contribute to general knowledge. This includes investigations conducted by faculty, students, staff or others associated with Parker University as well as investigations conducted elsewhere by any representative of Parker University.
2. If an investigator wishes to submit a protocol that does not qualify technically as research (e.g., approved therapeutic procedure not widely utilized) the RC will accept the protocol for review.

B. SUBMISSION OF RESEARCH PROPOSALS

All investigators are asked to review carefully the IRB submission requirements. Submission of incomplete protocols may result in delay of the review and approval process.

1. What to Submit: In order to facilitate efficient review of research proposals, one signed original and an electronic copy of the following must be submitted in the sequence listed:
 - a. Request for Review (see attachment A)
 - b. Informed Consent/Assent Form [Adult, Parental, Youth, Child]
 - c. Detailed Research Protocol
 - d. Letter of Approval from any non-Parker facility or agency to be utilized for the proposed investigation
 - e. Where to Submit. Proposals that require review must be submitted to the IRB through the Research Institute, including those likely to be exempt from full or expedited review. They must be sent to:

Institutional Review Board
c/o Research Institute
Parker University
2540 Walnut Hill Lane
Dallas, TX 75229-5668
hndetan@parker.edu

Upon receipt of a protocol, an acknowledgment of receipt will be forwarded to the investigator.

- f. Detailed Research Protocol. The detailed research protocol must include the following information in a format to be determined by the investigator:
 1. Background
 2. Objectives of the research project
 3. Significance
 4. Methodology
 5. Criteria for subject selection
 6. Method of subject selection
 7. Experimental design
 8. Procedures applied to human subjects
- g. Investigators who have questions concerning the development, submission or status of their proposal should contact the Director of Research, (214) 902-2472.

C. THE IRB REVIEW PROCESS

1. In order to approve a research project involving human subjects, the IRB must be assured that
 - a. any risks associated with the research project are minimized to the greatest extent possible,
 - b. the risks to the subject are outweighed or balanced by the potential benefit to the subject and/or by the importance of the knowledge to be gained,
 - c. the prospective subject population is appropriate and the number of subjects is no larger than necessary,
 - d. the selection of subjects is equitable,
 - e. the methods used to obtain informed consent are adequate,
 - f. the experimental design of the study is sound,
 - g. the principal investigator has the appropriate qualifications, experience and facilities to conduct the research.
2. Determination of Risk:
 - a. First, the IRB will make a decision based on common sense and sound professional judgment as to whether or not the proposed research places the subject "at risk". A subject is considered to be at risk if he/she may be exposed to the possibility of harm, whether physical, psychological, sociological, economic, or other, as a consequence of any activity which goes beyond the application of those established methods necessary to meet his/her needs.
 - b. Risk as applicable to Federal regulations is most obvious in Chiropractic, medical, and behavioral science research projects involving procedures that may induce a potentially harmful altered physical state or psychological condition. The most obvious examples include invasive procedures, the administration of drugs or radiation, the requirement of strenuous physical exertion and interventions that precipitate emotional disturbance. There are social and behavioral research projects in which, although there may be no immediate risk, procedures may be introduced which constitute a threat to the subject's dignity, right to privacy, or economic welfare. There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the routine performance of medical services, which obviously involve no element of physical risk to the subject, but their use for certain research, training, and service purposes may present psychological, sociological, or legal risks to the subject or authorized representatives. The risk element will also be examined for those studies dependent upon existing information

or stored data which may have been obtained for non-research purposes but which, when used in a research context, may present risk to the human subject.

- c. If it is determined that a subject will be placed at risk the IRB will perform a risk/benefit analysis which involves an assessment of the degree of risk, probability of occurrence, reversibility and relation to anticipated benefits. The IRB will consider the fact that certain subject populations (e.g., children, pregnant women, prisoners, mentally disabled, physically debilitated) may be at greater risk than others.

3. Risk/Benefit Analysis

- a. In research involving a non-therapeutic intervention, the potential risk to the subject **MUST** be outweighed or balanced by the potential benefit to the subject and/or by the knowledge to be gained.
- b. In therapeutic research involving more than minimal risk, the potential risk should be outweighed or balanced by the potential benefit to the subject. In addition, the relation of the anticipated benefit to the risk must be at least as favorable to the subject in the non-research context. No subject is allowed to continue participating in a research protocol if therapy of proven superior nature becomes available to the subject.
- c. In research where a standard therapy not part of the research protocol is employed solely for the benefit of the subject along with additional procedures performed solely for research purposes, the anticipated benefits of the therapy cannot be used to justify exposing subjects to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Conversely, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.
- d. In research involving a therapy employed for the potential benefit of a subject suffering from a life-threatening illness, the risk of serious adverse effects may be acceptable providing there are no other therapeutic alternatives available to the subject that offer a more favorable risk/benefit ratio.
- e. In research where no direct benefits to the subject are anticipated, the IRB will evaluate whether the risks and/or discomfort presented by procedures performed solely to obtain general knowledge are ethically acceptable.
- f. In child research involving greater than minimal risk and no prospect of direct benefit to the subject, the following conditions must be met:
 - 1. the risk represents only a minor increase over minimal risk,
 - 2. the research will likely result in an increase in general knowledge which is of vital importance for the understanding of the subject's disorder, condition or state of health
 - 3. the intervention or procedure presents experiences to the subject that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situation.
- g. Research involving pregnant women as subjects, the following condition must be met:
 - 1. the purpose of the research is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs
 - 2. the risk to the fetus is minimal. Only those research procedures that would be acceptable for a fetus going to term may be performed. In addition, whenever there is a potential conflict of interest (e.g. likeliness of abortion or planned abortion), the investigator must not be involved in any decision as to the timing, method, and procedures used to terminate the pregnancy or in the determination of viability of the fetus at termination of pregnancy.

- h. Research involving fetuses in utero, the following conditions must be met:
 - 1. the purpose of the research is to meet the health needs of the fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs
 - 2. the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. Only those research procedures that would be acceptable for a fetus going to term may be performed. In addition, the investigator must not be involved in any decision as to the timing, method and procedures used to terminate the pregnancy or in the determination of viability of the fetus at termination of pregnancy.
 - i. In research involving fetuses ex-utero where viability has not been ascertained, the following condition must be met:
 - 1. there is no risk to the fetus imposed by the research and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means
 - 2. the purpose of the research is to enhance the possibility of survival of the fetus. Once a fetus is determined to be viable it is designated an infant and is, therefore, subject to the federal regulations governing child research.
4. Review of Prospective Subject Population
- a. The IRB will review the prospective subject population and must be assured that:
 - 1. the subject population and number of subjects is appropriate with respect to the nature and goals of the research, and
 - 2. the selection of subjects is equitable with regard to the potential risks and benefits.
5. Review of Investigator Qualifications
- a. The IRB will review investigator qualifications and must be assured that:
 - 1. the investigator has the appropriate qualifications and/or licensure to carry out the procedures involving human subjects with an acceptable degree of potential risk,
 - 2. the investigator has adequate facilities and equipment to conduct the research with an acceptable degree of potential risk.
6. Review of Experimental Design and Scientific Merit
- a. The **IRB** will review experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits maximized by using procedures consistent with sound research design.
7. Review of Informed Consent
- a. The IRB will review the consent procedure and the informed consent form to determine if it conforms to Parker University IRB standards and contains all appropriate elements of informed consent as required by Federal regulations.

D. IRB PROTOCOL REVIEW CATEGORIES

- 1. Expedited Review
 - a. If an investigation involves minimal risk activities that qualify for expedited review status under **45 CFR 46:110**, the proposal will be reviewed by the Chairperson of the IRB using an expedited review procedure. Reviewed proposals will be assigned to one of three categories:
 - 1. Approved: The proposal is approved and released. The investigator may begin the study.

2. Approved contingent upon specific modifications: The investigator will be notified in writing as to the nature of the required modifications. As soon as the investigator complies with all required modifications, a release will be issued and the investigator may begin the study.
 3. Referred for full IRB review: The IRB Chairperson has a serious concern and has determined the proposal should be reviewed by the full IRB.
2. Full Board Review
 - a. Proposals that do not qualify for expedited review will be submitted to the full IRB. Within approximately ten (10) working days after the Institutional Review Board meeting, the investigator will be notified of the IRB's decision concerning the proposal. Reviewed proposals will be assigned to one of four categories:
 1. Approved: The proposal is approved and released. The investigator may begin the study.
 2. Approved contingent upon specific modifications: The investigator will be notified in writing as to the nature of the required modifications. As soon as the investigator complies with all required modifications, a release will be issued and the investigator may begin the study.
 3. Deferred: The Board requires additional information and/or has a serious concern.
 - a. The Executive Secretary and/or a member of the Board will be assigned to discuss the proposal with the investigator.
 4. Disapproved: If a proposal is disapproved, the investigator has the right of appeal to the IRB.
 3. Exempt Review
 - a. If a submitted proposal is determined by the Research Director and the IRB Chair to qualify for exemption status, the investigator will be notified within approximately five (5) working days following receipt of the proposal.

E. THE REQUIREMENT OF INFORMED CONSENT

1. It should be clearly kept in mind that, although there are both governmental and Parker regulations that require the subject or the subject's legally authorized representative to give consent prior to the subject's participation in an experiment, the principal reason for informing subjects, about an experiment is that they have a moral and ethical right to know what is to be done to them and what risk this entails before they give their consent. The use of human subjects is a privilege—a favor—granted to the experimenter, rather than a right. An experiment is something that is done TO the subject, and, therefore, differs from the usual medical practice where something is done FOR the patient.
2. It is required that the principal investigator obtain informed consent from the subject. The investigator must seek consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate. Unless the IRB issues a specific waiver, written informed consent of subjects is required for ALL research projects where there is any risk to the human participants. An acceptable standard of informed consent, although not necessarily written consent, is also required for exempt research projects.

F. DEVELOPMENT OF THE INFORMED CONSENT FORM

1. The most common reason for delay of approval of a proposal is an inadequate consent form.

- a. Stationery
 1. The informed consent form must be written on official Parker University letterhead stationery or on paper that indicates that PARKER UNIVERSITY is an involved/affiliated institution.
- b. Language, Style and Level
 1. The informed consent form should be written in the second person throughout. When combined with conditional language and the invitation to participate, utilization of the second person communicates that the investigator believes there is a choice to be made by the prospective subject. [Utilization of the first person may be interpreted as presumption of subject consent before consent has been legally obtained.
 2. The informed consent form should be written in simple enough language so that it is readily understood by the least educated, least sophisticated of the subjects to be utilized. It is recommended that the language consist of short concise sentences. It should be remembered that terms which are commonly used by members of a profession are a part of the professional's language. Many people outside that profession do not understand the language. Common words in biology and medicine, such as "catheter, intravenous (let alone IV), prognosis, symptomatology, etc." are not understood by many laymen. Terms in the fields of psychology/sociology such as "cognitive style, attribution and social sufficiency" are equally misunderstood. If there is any doubt that a term may not be understood, a definition should be added, e.g., ".4cc (a teaspoon)...". If some of the anticipated subject population does not understand English, appropriate translation should be provided.
 3. If the consent form will be used for Parents or other legal representative consenting behalf of a minor or other legally incompetent subjects, the consent form should be written in a style that reflects the fact that it is the minor or other subject who is the participant and the consenter is agreeing to allow said subject to participate in the study.
- c. Length
 1. The informed consent form should be lengthy enough to explain consent factors adequately, but not so lengthy as to lose the attention of the subject or to cause confusion. If it is necessary to use multiple sheets, an optional blank for the subject to initial can be placed at the bottom of all sheets where the signature blank does not appear.

G. ELEMENTS OF INFORMED CONSENT

An informed consent form must be structured to fit each project. In order to increase consent form readability, however, the consent form should be written to include the appropriate elements of information in the same sequence as described in this document. Each element (or appropriate combination) should be identified by a subheading in bold type.

1. Title of Protocol - The official title of the protocol should be placed at the top of the consent form.
2. Invitation to Participate - The consent form should begin with a clear invitation (not a request or demand) to the individual to participate in the research study.
3. Basis for Subject Selection- The consent form, when appropriate, should state why the prospective subject has been selected (e.g., subjects with specific diseases, conditions, characteristics, backgrounds). This statement should help the subject to assess the

nature and importance of participation. When appropriate, the approximate number of subjects involved in the study should be stated. When appropriate, criteria for subject exclusion should be stated (e.g., pregnancy, age limitations, and health restrictions).

4. Overall Purpose- The consent form must contain a clear statement of the overall purpose of the research which should help the subject assess the importance of the study relative to individual values. When appropriate, this statement should include not only the immediate purpose of the study, but also any larger, ultimate purpose.
5. Explanation of Procedures - The explanation of procedures section of the consent form should include, where appropriate, the following:
 - a. A description of the study design (e.g., longitudinal, single-blind, placebo), method of subject assignment to groups (e.g., randomization) and probability of assignment (e.g., 50-50 chance). Despite the fact that subjects may be kept unaware of treatment assignments in blinded studies and research involving placebos, subjects must be made aware of all the possible interventions and the method of assignment. Thus, prospective subjects are invited to remain ignorant of treatment assignment without the element of deception.
 - b. A description of each procedure to be applied to human subjects and how often it will be performed. All procedures, both experimental and non-experimental, must be described/disclosed.
 - c. Identification of the individual (s) who will perform the procedures and/or interact with the subject. Procedures involving human subjects should be performed only by qualified individuals.
 - d. A statement of where the research will be conducted, when the research will be conducted, and how much time (per session/in total) will be required of the subject.
 - e. A statement concerning any medications, therapeutic regimens, foods, or other substances that are contraindicated/disallowed either before or during participation in the study (e.g., drug "washout").
 - f. If the research study involves incomplete disclosure or deception, all subjects must be debriefed as soon as possible after participation. The consent form for nondisclosure/deception studies should normally contain a statement concerning when and where the debriefing session will be held. If, however, debriefing may be harmful to subjects/the investigator may request a waiver of the debriefing requirement.
6. Potential Risks and Discomforts
 - a. A risk is a potential harm that a reasonable person, in what the investigator knows or should know to be the subject's position, would be likely to consider significant in deciding whether or not to participate in the research. Risks can be classified generally with some obvious overlap as:
 - b. Physical (e.g., infection associated with venipuncture or surgery, adverse reactions to drugs, heart attack induced by maximal exercise test);
 - c. psychological (e.g., depression, confusion, feelings of guilt);
 - d. social (e.g., invasion of privacy, loss of community standing);
 - e. legal (e.g. criminal prosecution, revocation of parole); and
 - f. economic (e.g., loss of employment, loss of potential monetary gain).
7. Both immediate and latent risks of any Procedure involving human subjects must be clearly and adequately described. The estimated probability, severity, average duration, and reversibility of any potential injury should be stated.

8. Certain populations of subjects (e.g., pregnant women, children, mentally retarded, physically debilitated) may be at greater risk than others. The investigator should consider the potential risk characterization of the subject population when describing risk(s).
9. Any pain and/or discomfort (e.g., pain associated with venipuncture, drug induced nausea, muscle soreness) associated with any procedure involving human subjects must be clearly and adequately stated. The description of discomforts often overlaps with associated risks and, therefore, may be combined. If there are no known risks and/or discomforts associated with the research, this should be so stated.

10. Potential Benefits

- a. A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to the subject directly (e.g., improvement of health status) and those that accrue to society (e.g., acquisition of knowledge). If any substantial benefits to the subject or to others can reasonably be expected, they should be described. It must be stated in the description that the benefits are hoped-for (or anticipated where appropriate) but not guaranteed by the investigator. Financial compensation or other forms of remuneration are not considered a benefit to be derived from research participation and, therefore, should not be described in the same section as physical, health, psychological or social benefits. If there are no benefits to the subject it must be so stated.

11. Alternatives to Participation

- a. If the prospective subjects are students who are invited to participate in a research project in exchange for receipt of academic credit, the consent form must state an alternative way the student can earn the academic credit. The option (s) must be comparable to research participation in terms of time, effort and educational benefit THIS IS NOT THE SAME AS "EXTRA-CREDIT", which is a compensation for participation (see #9 below).

12. Financial Compensation

- a. Any economic incentives or rewards for participation should be clearly stated. Economic incentives are usually cash payments, but may also include, when appropriate, free physical examinations, free treatment, free medications, treatment at lower cost, free food, etc. Cash payments should be stated in dollar amounts, and any conditions such as partial payment or no payment for early termination and bonuses for completion should be stated. The nature and amount of financial or other compensation must not constitute undue inducement of the subject (e.g., the compensation alone should not serve as sufficient inducement for the subject to volunteer). When establishing the amount/type of compensation, the investigator should consider the background and socioeconomic status of the subject population.
- b. If students who participate in research projects are given EXTRA academic credit the amount/nature of the extra credit must be stated. In addition, the weight of the extra credit with respect to the award of grades must not be unduly influential.

13. Assurance of Confidentiality

- a. This section of the consent form should state that any information that is obtained in connection with the study and that could identify the subject will remain confidential and will be disclosed only with the subject's permission. If the investigator intends to release any information, the consent form must state the person (s) or agency to whom

information will be furnished, the nature of the information to be furnished, the purpose of the disclosure, and whether the subject's name will be used as an identifier. When appropriate, the ultimate disposition of data should be described.

- b. Particular care concerning confidentiality should be exerted with respect to data in the form of media, such as audio or visual recordings. Confidentiality safeguards must also be strong where a breach of confidentiality may result in social or economic harm to the subject. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, sexual behavior, and illegal activities.
- c. Any proposal involving the investigation of a drug (Phase IV), non-approved use of a drug or substance, or investigation of a medical device or substance that is subject to FDA regulations, must have the following standard statement added to the assurance of confidentiality: "Representatives of the United States Department of Health and Human Services, or the United States Food and Drug Administration may inspect your (insert medical records or research records as appropriate) to assess the results of this _____ (insert "drug treatment, medical device therapy, or research" as appropriate).

14. In Case of Injury Compensation

- a. Low Risk Compensation Statement
 1. For research studies involving more than minimal risk, the consent form must contain the following standard IRB compensation statement: "If injury occurs as a direct consequence of the research procedures described above, the emergency care required to treat the injury will be provided by Parker at no expense to you, providing that the cost of such care is not reimbursable through your own health insurance. However, no additional compensation for physical care, hospitalization, loss of income, pain, suffering, or any other form of compensation will be provided as a result of non-negligent injury."
- b. Commercial Sponsor Compensation Statement
 1. If a commercial sponsor has agreed to provide compensation in case of injury to research subjects, the extent/limitations of the compensation should be stated clearly. Parker University standard compensation statements should not be used when a commercial sponsor has agreed to provide compensation for subject injury.

15. Withdrawal from the Study

- a. The consent form must contain the following standard IRB non-coercive disclaimer~ "Participation is voluntary. Your decision whether or not to participate will not affect your (insert "grade or treatment" or "present or future relationship with" as appropriate) Parker (and/or other named institution as appropriate). If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time."
- b. When appropriate, the consent form should include a statement that any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation will be provided to the subject. The investigator must provide both the subject and the IRB with a written statement concerning any significant finding that may potentially influence a subject's decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent.
- c. When appropriate, the consent form should state any anticipated circumstances (e.g., adverse reactions, non-adherence to protocol instructions) under which the subject's participation may be terminated by the investigator without regard to the subject's

consent.

16. Offer to Answer Questions

- a. The consent form must contain an offer by investigators to answer all immediate and subsequent questions that the subject may have. The following should be used: “If you have any additional questions concerning the rights of research subjects, you may contact _____, the principal investigator (include phone number and campus address), or _____, Chairperson of the Parker University Institutional Review Board (IRB), telephone _____”

17. Concluding Consent Statement

- a. The consent form must contain the following standard concluding consent statement in bold type: **“YOU ARE VOLUNTARILY MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE. YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP”**. Must include Signature of Subject, Date, Signature of Witness, and Signature of investigator (if required).
- b. The signature of a witness is required for all research studies involving more than minimal risk. If possible, the witness should be someone who is not involved in the study.

18. Identification of Investigator

- a. The name, professional degree, and office telephone number of the investigator(s) must be provided. For research studies involving MORE than minimal risk, the home/night phone number (s) of the investigator (s) must be provided.
- b. Also, the name, address, and office telephone number(s) of the Principal Investigator’s department head must be listed on the consent form.
- c. For research studies conducted by students, the name and office telephone number of the student’s advisor must be provided.
- d. The identification of the investigator(s) section of the informed consent form can be placed either at the end of the consent form, following the standard concluding consent statement, or at the beginning under “institution”.

H. CONSENT/ASSENT PROCEDURES FOR MINORS

1. Research involving children is governed by 45 CFR 46:401-409 (48 Fed. Reg. 9818, March 8, 1983). Children are considered a vulnerable research population because their intellectual and emotional capacities are limited. Where appropriate, studies should be conducted first on animals and adult humans, then on older children prior to involving younger children.
2. Legally, children cannot give consent on their own behalf. The consent of their parent(s) or a legal guardian is, therefore, required before they can participate in any non-exempt (and some exempt) research projects. Under special circumstances (e.g. research involving neglected/abused children) the IRB may approve waiver of parental consent.
3. If the research involves only minimal risk activities (e.g. venipuncture, skin biopsy, EEG, EKG, urine collection, moderate exercise, standard psychological testing), consent of only one parent or legal guardian must be obtained. If, however, the research involves greater than minimal risk activities, consent of both Parents must be obtained unless one parent is

deceased, unknown, incompetent, or not reasonably available, or when only one parent has the legal responsibility for the care and custody of the child.

4. In addition to the obtainment of parental/legal guardian consent, the investigator must also solicit assent of minor subjects age seven or older, unless the subject displays intellectual/emotional development below that of the average seven year old child. In most circumstances a child's deliberate objection should be regarded as a veto to his or her involvement in the research. However, parents or guardians may, with IRB approval, override a young child's objections to interventions that hold the prospect of direct benefit to the subject
5. In the state of Texas, a minor attains majority at age 18. Pregnancy does not confer majority status. A minor may, however, with IRB approval, legally consent on his/her own behalf (as a mature minor) if the research involves a treatment for which minor consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or drug abuse). In addition, if the subject is registered as a student at Parker University, and the proposed investigation is no more than minimal risk, a request for waiver of parental consent may be submitted to the IRB.

a. PARENTAL CONSENT FORM

1. If the subject is under the age of 7, only a Parental (legal guardian) Consent Form is required. The Parental Consent Form should include all relevant elements of informed consent as outlined previously and be written in a style that indicates it is the parent or legal representative who is consenting to allow the minor to participate in the study. The Parental Consent Form must contain the following standard concluding consent statement in bold type: **“YOU ARE VOLUNTARILY MAKING A DECISION WHETHER OR NOT TO ALLOW YOUR CHILDLLEGAL WARD TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT, HAVING READ THE INFORMATION PROVIDED ABOVE, YOU HAVE DECIDED TO PERMIT YOUR CHILDLLEGAL WARD TO PARTICIPATE. YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.”** Include: Signature, Date, Relationship to Subject, Signature of Investigator, and Witness (if required)

b. CHILD ASSENT FORM

1. If the subject is 7 to 12 years of age, both a Child Assent Form and a Parental Consent Form is required. The Child Assent Form must be brief and contain extremely simplistic language written at the appropriate age level. Only the following elements must be present on the Child Assent Form:
 - a. statement of the purpose of the research
 - b. description of the procedures to be applied to the minor
 - c. description of the potential risks and discomforts associated with the research
 - d. description of any direct benefits to the minor
 - e. statement that the minor does not have to participate if he/she does not wish to participate
 - f. statement that the minor is free to withdraw at any time
 - g. statement that the minor should discuss whether or not to participate with his/her parents prior to signing the assent form
 - h. statement that the parents of the minor will be asked to consent on behalf of the minor
 - i. offer to answer all questions,
 - j. simplified concluding assent statement

2. Only the minor and the investigator should sign the Child Assent Form. The parent or legal guardian of the minor should be given a copy of the assent form.

c. **YOUTH ASSENT FORM**

1. If the subject is 13 to 18 years of age, both a Youth Assent Form and a Parental Consent Form is required. The Youth Assent Form must be written at the appropriate age level and contain simplified versions of the same elements present on the Adult Consent Form. In addition, the Youth Assent Form must contain a statement that the minor and the investigator should sign the Youth Assent Form. The parent or legal guardian of the minor should be given a copy of the assent form.

I. ALTERNATIVE TO WRITTEN INFORMED CONSENT

1. Under special circumstances, the IRB may approve an oral consent document that states that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. The investigator must justify in writing a request to use the "oral form" and provide the IRB with a written summary of what is said to the subject or the representative.
2. When the oral form of consent is used, the following three procedures must be followed:
 - a. The subject and an auditor-witness must sign a statement (the oral consent form) that the subject has been orally informed about the research,
 - b. The investigator and auditor-witness must both sign a copy of the summary which includes a statement certifying that all information in the study was presented orally to the subject,
 - c. A copy of both the oral consent form and the summary must be given to the subject.
3. In anthropological or other studies involving non-literate people (e.g., primitive cultures), the IRB may approve a culturally appropriate consent procedure which deviates from the guidelines.

J. ALTERATION AND WAIVER OF INFORMED CONSENT

1. **Under special circumstances, the IRB** may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. The investigator must justify in writing any request to waive the elements of informed consent. Before a waiver can be issued, the IRB must determine that all of the following conditions exist:
 - a. the project involves no more than minimal risk,
 - b. the rights of the subject will not be significantly infringed upon,
 - c. the research could not practically be carried out without the waiver or alteration,
 - d. if possible, the subject will be fully informed after the project has been completed.
2. The IRB may waive the requirement of the investigator to obtain a signed consent form for some or all subjects (or parents/guardians) if it finds
 - a. the only reason 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, OR
 - b. the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

K. STORAGE OF INFORMED CONSENT FORM

1. Signed copies of informed consent forms must be maintained by the principal investigator and be stored in a secure manner. Unless otherwise specified by Federal and/or state regulations, retention shall be for a period of at least three years beyond the termination of the study. If the investigator resigns from Parker University before the end of the designated period, the informed consent forms must be maintained by the department of research unless otherwise specified.

L. SUBMISSION OF ANNUAL UPDATE

1. Non-exempt proposals are approved for a maximum period of one year only. For all projects, it is the responsibility of the principal investigator to submit to the IRB an annual update (Appendix B). The first annual update is due twelve months following the date the proposal was approved and released. Upon receipt of the annual update, the IRB will review and approve, if appropriate, continuation of the project for the next twelve month period.
2. If the IRB determines that a project requires review more often than annually, the investigator will be so notified. The IRB has the authority to directly observe ongoing research projects and the consent process.
3. When a project is terminated/completed, the investigator must immediately notify the IRB in writing.

M. REPORTING PROPOSED CHANGES IN RESEARCH PROTOCOL

1. Any proposed change in a protocol which affects human subjects must be reviewed and approved by the IRB prior to implementation except where an immediate change is necessary to eliminate a hazard to the subject. Investigators should submit a request for change of research protocol (Attachment C) and a revised consent form. Minor changes during the period for which approval is in force will be reviewed by an expedited review procedure.

N. SUBMISSION OF INJURY REPORT

1. If a subject sustains an injury (physical or psychological) which is related to a research procedure, the investigator must submit an injury report (Attachment D) to the IRB within 72 hours.

O. CATEGORIES OF RESEARCH THAT QUALIFY FOR EXPEDITED REVIEW

1. Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedures authorized in 45 CFR 46:110.
2. Collection of hair and nail clippings, in a non-disfiguring manner deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
3. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
4. Recording of data from subjects 18 years of age or older using non-invasive 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 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).

5. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
6. Collection of both supra-and subgingival dental plaque 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.
7. Voice recordings made for research purposes such as investigations of speech defects.
8. Moderate exercise by healthy volunteers.
9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
10. Research on individuals or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subject's behavior and the research will not involve stress to subjects.
11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. *46 FED. REG. 8392 (26 January 1981)

P. CATEGORIES OF RESEARCH THAT QUALIFY FOR EXEMPT STATUS

1. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the requirements of 45 CFR 46 and full IRB Review. However an IRB Protocol Form (see Appendix A) must still be submitted. The exempt categories as specified in 45 CFR 46:101(b) however do not apply to research involving deception of subjects (the research deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study), intervention research (subject behavior is manipulated and the change measured), or to research involving those classified as mentally infirm. When children are involved as subjects in research, only exemptions #1, 2, 5, and 6 are applicable. Exemption #4 is applicable where the investigator does not participate in the activities being observed. Exemption #3 is not applicable in child research. Some exemption categories as determined by the IRB may not apply to research activities involving other subject populations considered vulnerable or to research involving sensitive aspects of the subject's own behavior (e.g. drug and alcohol abuse, sexual activity).

a. Exempt Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular or 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), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 3. Research involving survey or interview procedures, EXCEPT where ALL of the following exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject; (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
 4. Research involving the observation (including observation by participants) of public behavior, EXCEPT where ALL of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
 5. 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.
 6. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service under those 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.
 7. All exempt research involving human subjects must maintain an adequate standard of informed consent and confidentiality of data. In some exempt research projects, standard written informed consent should be obtained. *46 FED. REG. 8386 (26 January 1981)

Q. RESEARCH INVOLVING INVESTIGATIONAL DRUGS

1. Although it is extremely unlikely that research at PARKER UNIVERSITY would involve the use of investigational drugs, this section is included for completeness and to cover any eventuality. An investigational drug may be defined by one of the following:
 - a. A drug in any of the clinical stages of evaluation (Phase I, II, III) which has not been released by the FDA for general use or cleared for sale in interstate commerce.
 - b. Any commercially available drug proposed for a new use.
 - c. Any commercially available drug to be used in a new dosage, form or method of administration.
 - d. Any commercially available drug which contains a new component such as an ex-

- ipient, coating, or menstruum.
- e. A new combination of two or more commercially available drugs.
 - f. A combination of commercially available drugs in new proportions.
 - g. Any commercially available drug involved in a postmarketing surveillance.
2. Good medical practice and patient interests require that physicians be free to use commercially available drugs according to their best knowledge and judgment. If a physician uses a drug for an indication not in the approved labeling, he or she has the responsibility to be well informed about the drug and to base its use on a firm scientific rationale and on sound medical evidence, and to maintain records of the drug's use and effects. Use of a drug in this manner as part of the "practice of medicine" does not require review by the IRB or FDA notification despite the fact that the drug is technically classified as investigational.
 3. The investigational use of an approved, marketed product differs from the situation described above. "Investigational use" suggests the use of an approved, product in the context of a study protocol. When the principal intent of the investigational use of a drug is to develop information about its safety or efficacy. IRB review and approval is required.
 4. When a marketed drug is shipped in interstate commerce for the purpose of conducting a clinical trial on the drug for an unapproved use, at an unapproved dosage, by an unapproved route of administration, or in an altered dosage form, the submission of an Investigational New Drug permit (IND) is required. Even though the law may not require an IND in all investigational situations, the FDA believes that it is in the interests of the investigator and the public for one to be submitted. It is possible that the FDA may have safety data that are not available to the investigator. Furthermore, information obtained from such a clinical trial might expedite either approval of this new use or a decision regarding its abandonment if similar trials showed adverse results or lack of efficacy.
 5. When a marketed drug is shipped in interstate commerce for the purpose of routine clinical use and is subsequently proposed for use in a manner as defined by "investigational drugs", an IND is not legally required, but IRB review and approval must be obtained.

R. RESEARCH INVOLVING MEDICAL DEVICES

1. Investigational devices are medical devices which are the object of clinical research to determine their safety or effectiveness. Studies undertaken to develop safety and effectiveness data for medical devices involving human subjects must be conducted according to the requirement of the Investigational Device Exemption (IDE) regulations (21 CFR 812).
2. Investigational devices are determined to be either significant risk or nonsignificant risk devices. Examples of nonsignificant risk devices are: most daily wear contact lenses, lens solutions, heel cups, antibacterial surgical garments, incontinent devices, oral training splints, ultrasonic tooth cleaners, and Foley catheters. Investigations of nonsignificant risk devices must meet the abbreviated IDE requirements. Unless otherwise notified by FDA, an investigation of a nonsignificant risk device is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements of the IDE regulations. These regulations require, in part, that IRB approval be obtained and maintained throughout the investigation and that informed consent be obtained and documented.

3. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of the subject. Such a device is intended as an implant; is to be used in supporting or sustaining human life; or is of substantial importance in diagnosing, curing, mitigation, or treating disease, or otherwise preventing impairment of human health. Examples of significant risk devices are:
 - a. pacemakers, IUDS,
 - b. Any commercially available drug which contains a new component such as an excipient, coating, or menstruum.
 - c. A new combination of two or more commercially available drugs.
 - d. A combination of commercially available drugs in new proportions.
 - e. Any commercially available drug involved in a postmarketing surveillance.
4. Good medical practice and patient interests require that physicians be free to use commercially available drugs according to their best knowledge and judgment. If a physician uses a drug for an indication not in the approved labeling, he or she has the responsibility to be well informed about the drug and to base its use on a firm scientific rationale and on sound medical evidence, and to maintain records of the drug's use and effects. Use of a drug in this manner as part of the "practice of medicine" does not require review by the IRB or FDA notification despite the fact that the drug is technically classified as investigational.
5. The investigational use of an approved, marketed product differs from the situation described above. "Investigational use" suggests the use of an approved, product in the context of a study protocol. When the principal intent of the investigational use of a drug is to develop information about its safety or efficacy, IRB review and approval is required.
6. When a marketed drug is shipped in interstate commerce for the purpose of conducting a clinical trial on the drug for an unapproved use, at an unapproved dosage, by an unapproved route of administration, or in an altered dosage form, the submission of an Investigational New Drug permit (IND) is required. Even though the law may not require an IND in all investigational situations, the FDA believes that it is in the interests of the investigator and the public for one to be submitted. It is possible that the FDA may have safety data that are not available to the investigator. Furthermore, information obtained from such a clinical trial might expedite either approval of this new use or a decision regarding its abandonment if similar trials showed adverse results or lack of efficacy.
7. When a marketed drug is shipped in interstate commerce for the purpose of routine clinical use and is subsequently proposed for use in a manner as defined by "investigational drugs", an IND is not legally required, but IRB review and approval must be obtained.

S. RESEARCH INVOLVING PROSPECTIVE/RETROSPECTIVE STUDIES OF CONFIDENTIAL RECORDS

1. Research involving the study of confidential records (e.g., school, University or medical records) is exempt providing the investigator records the data in such a manner that subjects cannot be identified directly or through identifiers linked to the subject.
2. Research involving the study of confidential records is not exempt if the investigator records the data in such a manner that subjects can be identified directly or through identifiers linked to the subject. Before the research can be initiated, the investigator must obtain IRB approval and permission to review the records from the custodian of the

records.

3. If the investigator records the data from confidential records using subjects identifiers with the intention of contacting potential subjects to participate in a prospective study, the following procedures for protecting the privacy and confidentiality of the subject must be followed.
 - a. Before the research can be initiated, the investigator must obtain IRB approval and permission to review the records from the custodian of the records.
 - b. Only the name of the subject, specific selection criteria (e.g., class standing, gender, or medical diagnosis), and the name of the attending physician or other appropriate individual (e.g., subject's dentist, pharmacist, nurse, lawyer, social worker, educator) can be recorded.
 - c. Only the attending physician of the subject or other appropriate individual (e.g., subject's dentist, pharmacist, nurse, lawyer, social worker, etc.) with legal/ethical access to the confidential record should contact the potential subject. The purpose of the initial contact is to obtain written permission from the potential subject to solicit informed consent for participation in the research project. If the subject chooses not to grant permission for the release of his/her name, all data concerning the potential subject obtained by the investigator must be destroyed.

T. PARKER UNIVERSITY POLICY REGARDING IRB GUIDELINES AND PROCEDURES

1. WHO MUST FILE FOR IRB REVIEW?
 - a. Any investigator (faculty, staff, student) affiliated with PARKER UNIVERSITY who plans to conduct research involving human subjects MUST file a request for review with the PARKER UNIVERSITY IRB before implementing such research.
2. WHEN MUST SUCH A "Request for Review" BE FILED?
 - a. The investigator should file such a request for review well before the planned research is to begin. It is possible that changes in the protocol may be required for IRB approval, which may delay the start of such research. Investigators are advised not to wait until the "last minute" to obtain IRB approval.
3. NOTIFICATION OF IRB FINDINGS
 - a. Investigators shall be notified in writing, within 10 days of the IRB review, of the findings and actions regarding their protocol.
 - b. If APPROVED, the investigator may begin the proposed research project
 - c. If CONDITIONALLY APPROVED, the investigator shall be notified of the specific changes to the protocol and/or consent form necessary to proceed with IRB approval of the research protocol. The Chairperson of the IRB shall communicate, in writing, the findings of the IRB and the necessary modifications. Until the investigator convincingly demonstrates, in writing, that all required changes have been made to the IRB's satisfaction, the project CANNOT begin.
 - d. If the Investigator does not respond to the IRB's notification of required changes within 30 calendar days of receiving CONDITIONAL APPROVAL, the proposed project must be resubmitted for full review consideration. The letter of notification to the investigator will convey these stipulations and time limit.
 - e. If DEFERRED, the investigator will be notified in writing that the project as described provides insufficient information to reach a decision for approval or disapproval. The investigator will be asked to resubmit. In addition, the findings of the IRB that resulted in such a decision will be conveyed to the investigator.
 - f. If DISAPPROVED, notification and the findings of the IRB resulting in such a decision will be conveyed, in writing, to the investigator.

4. ANNUAL UPDATE

- a. As part of Parker's record keeping requirements in accordance with Federal regulations and directives, ALL research projects involving human subjects must submit an annual report. Details and forms regarding annual update reports will be sent to all investigators within 10 months following initial approval of the research protocol. Complete and acceptable updates must be filed with the IRB no later than 12 months following initial IRB approval.
- b. Occasionally, selected projects will be reviewed more often than annually. Such projects are:
 1. any research involving fetuses,
 2. any research involving human subjects for which there have been reports of injury or unanticipated problems as a consequence of participating in the research,
 3. any research for which the IRB had specifically required "more often than annual" review at the time approval was granted,
 4. any research project the IRB deems appropriate to review on a more-than-annual basis, including projects not in any of the above categories. "More-often-than-annual" reviews shall follow the same reporting and review procedures as indicated for annual reports, with the appropriate changes in reporting intervals and deadlines.
- c. Reporting Procedure
 1. Annual Reports from Investigators are due one year after the project approval date, or as specified by the IRB. Investigators will be informed of impending Annual Review dates with a memorandum distributed ten (10) months after approval date (or previous annual review for longer term projects). At that time reporting forms will be made available to relevant investigators (Attachment B)
 2. Complete reports are to be delivered to the Director of Research within 12 months following approval date, or as designated by the IRB.
- d. Failure to File an Annual Report
 1. If no Annual Report is filed within a thirty (30) day (grace) period from the Annual Report due date, the Investigator will be notified in writing that the approval for the indicated research project has expired. The investigator is prohibited from further experimentation involving human subjects in that research project
 2. This termination notice/memorandum shall be signed by:
 - a. the Chairperson of the IRB and
 - b. the Director of Research
 3. Termination is effective from the date of the written notification.
 4. In order to re-establish that research project, the Investigator must file a new and complete "Request for Review" as indicated above.

5. CHANGES IN PROTOCOL AND/OR CONSENT FORM(S)

- a. Investigators shall file with the IRB via the Research Institute, IRB Staff Officer, ANY substantive changes in protocol or consent forms. [Form: "Request for Review of Change in Protocol"] A copy of the revised protocol and/or consent form, along with a letter of clarification shall be forwarded to the appropriate IRB Staff Officer no less than 14 days prior to the implementation of such change.
6. If the proposed change requires FULL or EXPEDITED review, additional time may be required. In any case, the proposed change(s) cannot go into effect until IRB approval has been obtained.

7. EXCEPTION: A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subject, however, the IRB must be notified IN WRITING of such a change (within 72 hours) and review is still eventually required.
8. Investigators should consult with the Director of Research and/or IRB Chairperson for advice and an initial opinion of the degree of change in their research protocol or consent form. In any case, the Chair of the IRB has final authority regarding the determination of whether any change in protocol or consent form warrants further IRB action.
9. REPORT OF INJURY AND/OR UNANTICIPATED PROBLEMS
 - a. Investigators must report to the IRB within 72 hours of its occurrence, ANY injury or unanticipated problem involving risks to subjects or others as a consequence of the research project. [Form: "Report of Injury and/or Unanticipated Problems"]
 - b. Investigators are encouraged to use their best judgment regarding the nature and degree of a reportable injury or unanticipated problem. In general, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints of subjects in which they proclaim that participation presents substantial discomfort, risk, and/or endangerment beyond that explained to them, or as otherwise stated in the consent form.
 - c. In addition, investigators are strongly encouraged to share such information with the Director of Research.
10. INFORMED CONSENT DOCUMENTATION
 - a. The IRB must have on file a copy of the consent form being used in each research project. It is the investigator's obligation to send a copy of the consent form, including any revised consent forms, to the IRB.
 - b. The IRB does not store participant (signed) consent forms. It is suggested that investigators keep all signed participant consent forms on file (in their respective offices or laboratories) for a period not less than 3 years.
11. PARKER UNIVERSITY FACULTY ON DEVELOPMENTAL LEAVE AND/OR SABBATICAL
 - a. Faculty on developmental leave and/or sabbatical who conduct research involving human subjects on the PARKER UNIVERSITY campus must file for IRB review and approval through the same channels and regulations as do active PARKER UNIVERSITY **faculty**. **If such faculty conduct human subject research** at another institution, it is the obligation of the researcher to obtain review and approval from a legally constituted IRB at the host or research-site institution. Such faculty obtaining non-PARKER UNIVERSITY IRB approval for their research projects must file a copy of that approval with the PARKER UNIVERSITY IRB.
 - b. VISITING FACULTY from another institution who conduct research involving human subjects while at PARKER UNIVERSITY must have PARKER UNIVERSITY IRB review and approval. Note that some institutions also require their personnel to obtain 'parent institution' IRB approval.
12. RESEARCH CONDUCTED OFF-CAMPUS
 - a. Occasionally, an investigator may wish to conduct a research project (either to recruit subjects or perform an experiment off-campus, either at another University, a hospital or other agency or organization. In any event, if the research project is conducted by an PARKER UNIVERSITY-affiliated person, or if anyone associated with PARKER

UNIVERSITY is involved as an investigator in the study (be it a student, faculty or staff member), the project MUST be approved by the PARKER UNIVERSITY IRB. Please note that, in some cases, the “site” of the investigation may also request their own IRB review and approval of the research project. [For example, hospitals often require their own IRB to review a project before it can be conducted on their premises. By the same token, other colleges, universities, or institutions may wish to review the protocol if the research is to be conducted at their facilities]. It is the responsibility of the PARKER UNIVERSITY investigator to seek and obtain any off-campus IRB approvals required. The PARKER UNIVERSITY IRB will not act on behalf of any investigator to obtain approval from another IRB.

IMPORTANT POINT: Non-PARKER UNIVERSITY IRB approval, that is approval from another IRB, does NOT substitute for PARKER UNIVERSITY review and approval. All projects involving PARKER UNIVERSITY personnel must have PARKER UNIVERSITY IRB approval prior to beginning the research project.

13. RESEARCH CONDUCTED AS PART OF “Consultant” STATUS

- a. Some PARKER UNIVERSITY personnel serve as professional consultants or advisors to off-campus agencies or organizations. Occasionally, such participation involves assisting with design or collection of data derived from human subjects, or the direct involvement of human subjects in a research protocol. Research not funded via any PARKER UNIVERSITY organizational unit that is conducted off-campus by non-PARKER UNIVERSITY personnel does not require PARKER UNIVERSITY IRB approval. In this case, a faculty or staff member serving as an advisor or consultant to the research project is responsible for his/her own professional and ethical conduct and is liable as such. Exceptions are:
 1. the research involves funding granted or channeled through any PARKER UNIVERSITY organizational unit,
 2. the protocol was designed by PARKER UNIVERSITY staff, faculty or student members and/or the data will be collected by any PARKER UNIVERSITY affiliated personnel, in which case, prior PARKER UNIVERSITY IRB approval must be obtained.
- b. As a general rule, investigators serving as consultants in research projects involving human subjects should check with the Director of Research and/or the Chairperson of IRB regarding the need for PARKER UNIVERSITY review of the protocol.

14. COMPLIANCE

- a. Persons conducting research involving human subjects have an ethical as well as professional obligation to ensure the safety, protection and rights of participants. It is the intent of PARKER UNIVERSITY, through the IRB and the Director of Research, to assist investigators engaged in human subject research to conduct their research along ethical guidelines, reflecting professional as well as community standards. In addition, Parker has an obligation to ensure that ALL research involving human subjects meets regulations established by the United States Codes of Federal Regulations (CFR). It is not the intent of Parker, the IRB, or the Research Institute to interfere in any way with competent, ethical, and sound research involving human subjects. However, there exists an obligation and a requirement for all parties involved to ensure that Parker and its personnel are in compliance with regulations governing human subject research. It is important for us all to observe the ‘spirit’ as well as the ‘letter’ of these regulations, since how we conduct research involving human subjects reflects on our professional, personal, and community commitments to rigorous ethical and scientific standards of conduct.

- b. Toward these ends, investigators must be in compliance with all PARKER UNIVERSITY and IRB procedures and regulations regarding research involving human subjects. For those instances where compliance is not forthcoming, the following policy applies:
1. All research involving human subjects MUST have IRB review and approval before such research can be initiated.
 2. Research that is conducted without IRB approval must be terminated immediately. Investigator(s) associated with such research must file for IRB review and approval prior to restarting the research project.
 3. Investigators who continue non-approved research should note that such non-compliance will be handled through appropriate administrative procedures initiating from the Research Institute.
 4. Periodic (at least annually) updates and progress reports of all approved projects must be sent to the IRB, as well as any substantive changes in protocols or consent forms.
 5. Failure to comply with IRB directives, regulations and procedures, including annual reports, changes in protocol, consent forms, and other requests for information or compliance emanating from the Chair of the IRB or the Director of Research will result in the following:
 - a. Project Termination: investigators and their staff and assistants are prohibited from involving human subjects in that research project until formal IRB approval/re-initiation is obtained. Such approval may be sought at a special meeting called at the discretion of the IRB Chairperson.
 - b. Interruption of Research Support: An additional consequence of non-compliance can be the interruption of grant funds (internal or external origin) allocated to that research project. Such “freezing of funds” will continue until the project and its investigators are in compliance according to regulations as determined by the IRB Chair and the Director of Research.
 - c. Report to appropriate Federal agencies: in some cases, Parker is required to report to the Office for the Protection of Research Risks (OPRR) any termination of project due to non-compliance with IRB regulations and directives. Further, such noncompliance is reportable to the Federal agency supporting the non-compliant research project/ investigator.

15. INVESTIGATORY AUTHORITY

- a. In order to determine that all substantive and relevant changes in protocol and/or consent documents are being reported, and in order to verify compliance with IRB regulations, the IRB shall have the authority to physically inspect any research premises or review non-confidential research documents relating to the protocol and procedures being used in human subject experimentation. Generally, the investigator will be asked to provide copies of relevant and necessary documents for IRB review. Such document requests are in addition to that generated in an annual review process. In most cases, this will only occur when there is an indication that a substantive change is in effect which has not been reported, or that unforeseen risks to subjects are present or alleged. Failure to comply with such an IRB request for information may result in suspension or termination of IRB approval of research.

16. AUTHORITY TO SUSPEND OR TERMINATE IRB APPROVAL OF RESEARCH

- a. According to 45 CFR **46.113**, “An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects.

Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported to the investigator, appropriate institutional officials, and the Secretary (of OPRR)".

17. APPEAL PROCEDURES

- a. There are no formal appeal procedures associated with IRB review. The IRB is not a judicial body, but a review board embodied to consider and uphold the rights, welfare, and protection of human subjects in research. IRB approval for research which has been suspended or terminated can be reinstated with a demonstration that the protocol/project can secure IRB approval. Similarly, a disapproved project need only be altered such that it can secure approval. An appeal process assumes that the decision of an IRB can be overturned by another group. An IRB ruling is not subject to appeal nor can it be overturned by another group or person(s). Only the IRB can alter its previous determination.

18. ENACTMENT

- a. These procedures and policies are considered to be in effect immediately upon approval by authorized University officials and remain in effect and enforceable until otherwise amended or repealed.

19. OTHER

- a. IRB policies and guidelines are in effect for all University personnel from the moment personnel become officially affiliated with PARKER UNIVERSITY (contractual start date) until they are no longer officially affiliated with PARKER UNIVERSITY in any capacity. Policies, procedures, and guidelines are subject to change through revisions in relevant Federal law (CFR), PARKER UNIVERSITY IRB rulings, and directives from OPRR.
- b. It is likely that not all possible contingencies have been foreseen or considered in these guidelines and procedures. The IRB, a committee of representatives from each University along with non-University members, strives to deliver the best possible service regarding review of research involving human subjects. To assist in the long-term goal of establishing the means and willingness to assure adequate protection of human subjects, the IRB needs the cooperation of the research community of scholars at PARKER UNIVERSITY.
- c. It is the intent of Parker University and the IRB to invite input from investigators and interested parties regarding revisions and updates to these guidelines and procedures. Where possible and appropriate, changes in IRB-related activity will incorporate these recommendations. Working together, we can develop a streamlined effective system of review and assurance regarding an ethical and professional environment for human subject research.