Parker University
Institutional Review Board for the Protection of Human Subjects in Research

Request for Review Coversheet

All research involving the use of human subjects must be submitted to the Parker University Institutional Review Board (IRB) for approval before the initiation of research. A minimum of 2 weeks must be allowed for the review procedure. For detailed information regarding IRB procedures and regulations, consult the Parker University ***Guide for the Protection of Human Subjects in Research.***

Principal Investigator:
☐ Faculty ☐ Student ☐ Other:
Secondary Investigators(s):

Attach a list of all Investigators associated with the research project. Include their institutional affiliations, Academic Degrees, and levels of involvement in the project (i.e., P1, student, co-investigator, consultant, physician, etc.).

Department: Phone:
Title of Project:

Proposed Starting Date: Projected Completion Date:
☐ Exempt or Expedited Approval Requested (attach appropriate form)

For IRB Use Only

❒ NOT APPROVED (Recommendation attached)

❒ APPROVED Date:

❒ Exempt ❒ Expedited ❒ Full

Type or print name _____ Position: _____
IRB Chairperson

_____ _____
Signature Date:

Type or print name _____ Position: _____
Institutional Approval

_____ _____
Signature Date:

IRB Request for Review
Overview Checklist
ATTACH BEHIND COVERSHEET

I. SUBJECTS: The proposed protocol would involve human subjects who are: (check all that apply)

☐ none of the following
☐ institutionalized persons (wards, mentally disabled)
☐ minors (persons under age 18)
☐ prisoners
☐ pregnant women
☐ fetal material/placenta
☐ in utero fetuses
☐ ex utero fetuses (including nonviable fetuses)
☐ persons under the care/supervision of another institution (hospital, nursing home, group home, convalescent home, etc.)

☐ Yes ☐ No The protocol involves human subjects who will receive drugs, food, beverages, or other internally administered substances.

☐ Yes ☐ No The protocol involves human subjects who will receive or be exposed to radioactive materials.

II. FUNDING:

☐ ☐ No
☐ The protocol is being submitted for federal funding
☐ Other external funding
☐ Internal funding
☐ No external or internal funding is being sought

III. OTHER INSTITUTIONAL CONSIDERATIONS:

Is this project a continuation of a project which was/is being conducted at another institution?

☐ Yes ☐ No Name of institution:

This project ☐ is being ☐ will be ☐has been ☐ will not be reviewed by an IRB at another institution.

Name of institution:

Exempt or Expedited Status

Tentative determination of exempt or expedited status may be possible by referring to IRB policy statement and/or 45 CFR which both list and explain the following categories.

This project qualifies for ***exemption*** from 45 CFR 46 because the only involvement of human subjects will be in one or more the following categories (as listed In Subpart A, Part 46.101 of the code, ***Guidelines):***

☐ (1) ☐ (2) ☐ (3) ☐ (4) ☐ (5) ☐ (6)

This project qualifies for ***expedited review*** procedures authorized in 46.110 of 45 CFR 46 Part 46 because it involves no more than minimal risk and the only involvement of human subjects will be in one or more of the following categories as detailed 46 FR 8392 of January 26, 1981, and on page 14 of the ***Guidelines:***

☐ (1) ☐ (2) ☐ (3) ☐ (4) ☐ (5)
☐ (6) ☐ (7) ☐ (8) ☐ (9) ☐ (10)

IRB Request for Review
New Project Outline Form

All investigators must provide a detailed protocol addressing the following points of information, using numbered paragraphs that correlate with the list. Incomplete information may result in delay of the review process.

A. Project Identification

PARKER UNIVERISTY IRB

Number: (for IRB use only)

Current Date:

Title of Project:

Principal Investigator's Name, Academic Degree(s), University Title and Department:

Signature: _____

B. Description of the Research Project

1. What are the goals, hypotheses, and specific aims of this research (append the research protocol

2. What is the significance of this research?

3. Has the scientific merit of this project been peer-reviewed, or will it be before the project starts? ☐ Yes ☐ No
Indicate the means of review:

4. Where will the human subjects undergo the experiments or procedures (PARKER UNIVERISTY, other PARKER UNIVERISTY clinic, off-campus location, etc.)?

C. Description of the Human Subjects of the Research, Consent and Recruitment Procedures

1. How many groups of human subjects are involved? For each group, indicate (a) anticipated number: (b) age range: (c) sex: (d) ethnic
background: and (e) health status (e.g. healthy subjects, patients with certain disorders):

2. What are the criteria for inclusion and exclusion of human subjects?.

3. Do subjects belong to any of the following special classes: (a) children (age 8 years) ☐ Yes ☐ No, (b) pregnant women, ☐ Yes ☐ No (c) mentally incompetent, ☐ Yes ☐ No (d) questionable state of mental competence or consciousness, ☐ Yes ☐ No (g) prisoners or other institutionalized persons, ☐ Yes ☐ No and (h) others who are likely to be vulnerable ☐ Yes ☐ No? If yes, provide rationale for and justify their involvement:

4. How will the human subjects be recruited? Please indicate (a) the source (clinics, hospitals, general public.) and (b) method of recruitment: posters, flyers, public advertisement ***(append text of the advertisement):***

5. How will the consent of the human subjects be obtained? ☐ in writing ☐orally ***(append the texts of written consent documents and/or the verbatim account of the orally given information),*** (b) what measures will be taken to ascertain that legally and morally adequate informed consent will be obtained if the subjects are children, mentally incompetent, of questionable state of competence or consciousness, prisoners or institutionalized (e.g. involvement of parents, guardians, or next of kin in the consent process), (c) the circumstances under which consent will be sought and obtained, and (d) the method of documenting consent.

D. Method and Materials of the Research on Human Subjects

1. Will the human subjects undergo any treatments or other interventions (e.g. manipulation, soft tissue treatment, ultrasound, electrical stimulation, acupuncture, imaging...) solely for the purposes of this research? ☐ Yes ☐ No

If yes, for each procedure specify (a) the nature, (b) duration, (c) frequency, and (d) whether the procedure will require a hospital day or overnight admission:

2. Will any treatments or interventions which the human subjects will undergo as standard or customary health care be modified for the purposes of this research? ☐ Yes ☐ No

If yes, for each procedure specify (a) the nature and (b) the extent of the modification (e.g. detuned ultrasound), (c) any resulting increase in the length or frequency of the procedure, and (d) any increase in the number of clinic visits:

3. Will the investigators carry out the planned treatments or other interventions themselves? ☐ Yes ☐ No

If yes, for each treatment or intervention that requires special skills (e.g. manipulation, venipuncture, imaging...), please identify the responsible qualified investigator:

If no, please specify arrangements for qualified implementation:

4. Will investigational test articles such as drugs, biologicals, substances (including placebo) or devices, be administered or applied to the human subjects? ☐ Yes ☐ No

If yes, for each test article indicate (a) name or code number, (b) type or chemical nature, (c) source, (d) presumed function or mechanism of action, (e) dosage, (f) frequency, (g) route of administration or application, (h) total duration of use, and (i) whether the 30-day interval has elapsed or been waived and/or whether its use has been withheld or restricted by the US Food and Drug Administration (FDA); *(please provide any investigational drug/device exemption (ICE) number and append manufacturer's information on each test article):*

5. Will non-investigational (marketed) test articles be administered or applied to the human subjects for the purposes of this research? ☐ Yes ☐ No

If yes, for each test article indicate (a) generic and trade names, (b) source, (c) dosage, (d) frequency, (e) route of administration or application, (f) total duration of use, and (g) if it is to be used for a purpose which is not authorized by the FDA:

6. Will radioisotopes be administered to the human subjects? ☐ Yes ☐ No

If yes, for each radioactive compound indicate (a) chemical nature, (b) amount of radioactivity to be administered, (c) frequency, (d) route, (e) total duration of administration, and (f) status of approval by the Texas Department of Nuclear Safety.

7. Will the human subjects be exposed to external sources of radiation? ☐ Yes ☐ No

If yes, indicate (a) type of exposure, and (b) total dosage to be delivered for the purposes of this research:

8. Will the human subjects complete questionnaires? ☐ Yes ☐ No

If yes, specify their nature, duration and frequency of their administration (append text of each questionnaire)

9. Will blood be removed from the human subjects for the purposes of this research? ☐ Yes ☐ No

If yes, indicate (a) route, (b) method, (c) frequency of removal, (d) total volume to be removed in milliliters or, for children, as percentage of total blood volume, and (e) total time span involved:

10. What is the total duration of involvement of a human subject in the project?

11. THERAPEUTC ALTERNATIVES: Describe any therapeutic alternatives that may be advantageous to subjects.

12. INFORMATION PURPOSELY WITHHELD: ☐ Yes ☐ No
State any information purposely withheld from the subject and justify this non-disclosure or deception.

E. Risks and Benefits of the Research

1. Are there potential physical, psychological, social, legal or other risks or inconveniences to the human subjects (e.g. injury, discomfort, extensive clinic visits, deprivation of a treatment of established efficacy, risks to confidentiality...) of any aspects of this research? ☐ Yes ☐ No

If yes, (a) itemize and describe the risks or inconveniences, (b) assess the likelihood or seriousness of the risks, and c) assess the risks in comparison to any alternative treatments or interventions:

2. For each risk or inconvenience indicated above, (a) specify the measures to be taken to protect the subjects from it, or to minimize its impact or occurrence, (b) if women of childbearing age are among the subjects, specify measures to be taken to avoid harm to fertility potential, undetected fetus, or breast-fed newborn, (c) assess the likely effectiveness of the protective measures, (d) specify any provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects and (e) whether there will be any provisions for monitoring the data to be collected to ensure the safety of subject:

3. Explain why are the risks and inconveniences to the subjects indicated above reasonable in relation to the anticipated benefits to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result from the research:

F. Costs of the Research

1. Please indicate the source of funds to cover the costs of this research: Internal research budget will cover the costs of the project.

2. Will patients or their health insurance carriers incur any expenses related to this research? ☐ Yes ☐ No

If yes, identify each cost item, and for each indicate amounts, whether the written consent form discloses this potential liability, and justify the assignment of the burden:

3. WIII the subjects receive payments or other compensation for participating? ☐ Yes ☐ No

If yes, indicate amounts:

G. ADDITIONAL COMMENTS:

Attach any separate statement or summary of your research project that you may have prepared for another purpose if you believe it is relevant and would be helpful for this review.

IRB Request for Review PI Compliance Form and Checklist

If the PARKER UNIVERISTY Institutional Review Board (IRB) approves this protocol, I agree to:

1) Execute the research plan as described in this application.

2) Report to the IRB, prior to implementation, any change in the research plan which may affect the use of human subjects.

3) Report to the IRB any problems which arise in connection with the use of human subjects.

4) File progress reports with the IRB at least annually.

5) Notify the PARKER UNIVERISTY RB if, for any reason, the project is terminated prior to its expected termination date.

In all instances, original signatures only will be accepted. ('Per' or name stamp signatures unacceptable).

SIGNATURE OF PRINCIPAL INVESTIGATOR* DATE

POSITION DEPARTMENT

SIGNATURE OF FACULTY DEAN / STUDENT SUPERVISOR DATE

POSITION DEPARTMENT

Signature certifies the investigator, to the best of his/her knowledge, in full compliance with the Parker University Regulations governing Human Subject Research as stated in the IRB Guidelines for the Protection of Human Subjects in Research.

Supervisor is required to closely supervise student research to ensure continued protection of human subjects.

RESEARCH DEPARTMENT REVIEW: The Dean, or authorized delegate, is responsible for an initial review of the proposed investigation. Signature testifies that the proposed investigation has been reviewed, and it is the *opinion of* the Director of Research that the investigator is in compliance with the Parker University regulations governing human subject research as stated In the IRB Guidelines for the Protection of Human Subjects. This review is primarily intended for information and is *not* a substitution for IRB consideration or review.

SIGNATURE OF DIRECTOR OF RESEARCH/AUTHORIZED DELEGATE DATE

INVESTIGATOR CHECK LIST. Submit the original with signatures as well as electronically to hndetan@parker.edu. Each of the following should be submitted in the sequence listed:

1. Request for Review Forms (please complete all sections).
2. Informed consent Form (s) (include all relevant versions).
3. Detailed Research Protocol (include detailed and complete information to allow review). Send to:

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

Attention: A complete copy of the "Request for Review" must be sent to the Provost