**Institutional Review Board (IRB)**

**Application**

**Rev 09-27-2018**

 **Please type your responses in the box provided. Use as much space**

 **as necessary (the boxes will expand). Please answer each question.**

 **If a question is not applicable, put ‘N/A’ in the box.**

|  |  |
| --- | --- |
| **1. Research Study Title**           | **IRB Assurance Number:** |

|  |
| --- |
| **2. Principal Investigator and Contact Information** |
| **a. Principal Investigator (including degrees)** | **b. Academic Title**      | **c. Affiliation**      |
| **d. Responsible Department** | **e. Email Address**           |
| **f. Phone number**      | **g. Mailing Address**         |
| **h. Fax number**      |
| **i. Project Manager Name**          | **j. Email Address**      |
| **k. Phone number**      | **l. Fax number**      |
| **3. Study Personnel** |
|  **In addition to the Principal Investigator, are there other individuals working on this study?**   Yes\*    No |
|  \*If yes, please complete a PersoHYPERLINK "file:///C:/Users/MOlden/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/Documents/Human%20Protections%20Administrator/Forms.htm"nHYPERLINK "file:///C:/Users/MOlden/AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/Documents/Human%20Protections%20Administrator/Forms.htm"nel Roster listing all individuals working on this study and attach relevant documentation (such as CV/Biosketches and Protecting Human Research Participants certificates) with application. |
| **4. Additional Institutional Review Board(s) Reviewing this Study***Please note: current IRB approvals must accompany this application.* |
| **a. Institution Name**        | **b. Study Number**      | **c. Current Approval Date**      | **d. Research Activity**      |
| **a.2. Institution Name**        | **b.2. Study Number**      | **c.2. Current Approval Date**      | **d.2. Research Activity**      |

|  |
| --- |
| **5. Study Summary** *Please provide a summary (in lay terms) for each section. If there is a study protocol, please provide a copy of the protocol with this application; otherwise all pertinent study information must be provided in the boxes below.* |
| **a. Hypothesis and Goals**       |
| **b. Study Procedures and Methodologies**           |
| **c. Participant Selection**        |
| **d. Statistical Design**       |
| **e. Randomization to Control/Intervention Groups:**           |
| **f. Expected duration of the study (include timeline and duration of participant involvement)**       |
| **g. Plan for Confidentiality of Data:**           |
| **h. Plan for monitoring of data for the safety of participants:***Include the individuals reviewing the data [such as a Data and Safety Monitoring Board (DSMB)], the data being reviewed, the frequency of review, and the rules for interim analysis for safety (such as statistical considerations and stopping rules), and reporting of adverse findings to the Parker University IRB.*     |
| **i. Use of Study Results**        |

|  |
| --- |
| **6. Funding Information** |
| **a. Funding source**           | **b. Type\*** | **c. Grant Number**           |
| **d. Title of Grant or Funding Application**            |
| **e. Period of support**           | **f. Amount of support, per year**           | **g. Awardee Institution**           | **h. PU is the recipient of:**  prime    subcontract   none |
| **Second Funding Source Information** |
| a. Funding Source           | b. Type\* | c. Grant Number           |
| d. Title of Grant or Funding Application           |
| e. Period of Support           | f. Amount of support, per year           | g. Awardee Institution           | h. PU is the recipient of:  prime    subcontract   none |
| **Third Funding Source Information** |
| a. Funding Source           | b. Type\* | c. Grant Number           |
| d. Title of Grant or Funding Application           |
| e. Period of Support           | f. Amount of support, per year           | g. Awardee Institution           | h. PU is the recipient of:   prime    subcontract   none |
| **Please note that a complete copy of the grant application must be submitted with this application in order to receive IRB approval.** |

|  |
| --- |
| **7. Study Site(s)**  |
| **a. Name of Institution**            |
| **c. Is this an International site?**    Yes    No | **d. Does this site require IRB review?\***    Yes    No\*\* |
| **e. Status of IRB Review**       | **f. Site FWA**           *If this study is supported by DHHS funds, and the site is engaged in research, a FWA is required.* |
| **g. Is the PI the lead investigator of a multi-site study?**  Yes [ ]  No [ ]  |
| **h. If yes, describe the management and communication among sites for unanticipated problems involving risks to participants or others, interim results, protocol modifications, reports to regulatory agencies:**           |
| a.2. Name of Institution            |
| b.2. Location of Institution *(including country)*            |
| c.2. Is this an International site? Yes [ ]  No\*\* [ ]  | d.2. Does this site require IRB review?\* Yes [ ]  No\*\*[ ]  |
| e.2. Status of IRB Review      | f.2. Site FWA          *If this study is supported by DHHS funds, and the site is engaged in research, a FWA is required.* |
| a.3. Name of Institution            |
| b.3. Location of Institution *(including country)*            |
| c.3. Is this an International site? Yes [ ]  No\*\*[ ]  | d.3. Does this site require IRB review?\* Yes [ ]  No\*\*[ ]  |
| e.3. Status of IRB Review      | f.3. Site FWA          *If this study is supported by DHHS funds, and the site is engaged in research, a FWA is required.* |

|  |
| --- |
| \*If unsure, please review the federal guidelines on “Engagement of Institutions in Research”: <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>\*\*If no, please provide the IRB with a letter of support from the institution where the research will take place. |

|  |
| --- |
| **8. Participant/Case Information** |
| **a. Inclusion Criteria** *(age, gender, health condition, etc.)*           |
| **b. Exclusion Criteria** *(age, gender, health condition, etc.)*           |
| **c. Expected number of individuals to be screened for enrollment (if applicable):**            |
| **d. Expected number of individuals to be enrolled:**            |
| **e. Age Range:**            |
| **f. Gender:**             |
| **g. Ethnicity:**             |
| **h. Participants are:** *(Please mark all that apply)* |
|  🞏 Minors (under 18 in US) 🞏 Pregnant women 🞏 Fetuses 🞏 Low literate 🞏 Decisionally impaired 🞏 Economically disadvantaged 🞏 Prisoners or detainees |  🞏 Persons at high risk of becoming detained or imprisoned 🞏 Employees 🞏 Students, fellows, or faculty 🞏 International study 🞏 Persons with a stigmatized health condition 🞏 Non-English speakers\* |  🞏 Inpatients 🞏 Outpatients 🞏 If inpatients or outpatients, what is the status of their health?            |
| \*If **participants’ first language is not English,** please provide all research materials to be used with participants (such as recruitment, consent, and educational materials) in the language best understood by the participant for the PU IRB’s review and approval, before implementation. *Please note that back-translations may be required for non-English documents.* |
| 1. If the participants are **LOW-LITERATE,** please describe how investigators will ensure participants’ understanding of the research

            |
| **j.** If the participants are **STUDENTS, FELLOWS, or FACULTY** of PCC, indicate your (and other study personnel, if applicable) involvement in the participant’s education/employment:           |
| **k.** If this is an **INTERNATIONAL** study, please indicate the following: |
| (i) The investigator’s familiarity with the culture in which the study is taking place.           |
| (ii) The cultural norms and how this study may affect a participant’s standing in their community.           |
| (iii) The standard of care in the community, how it differs from the proposed research procedures, and a plan for the continuation of care once the research is complete.           |
| **l. Describe how the rights, welfare and privacy of participants will be protected:**           |
| **m. List any potential risks to participants:**           |
| **n. List any potential benefits to participants:**           |
| **o. Describe the significance to the health and welfare of the general public:**           |
| **p. Describe the remuneration for participants (including amount, schedule, and type):**           |
| **q. Describe and list any costs to participants:**           |
| **r. List the procedures that are being performed already for diagnostic or treatment purposes:**           |
| **s. List any medical or psychological resources available to participants (should they need them as a consequence of participation in this study) :**           |

|  |
| --- |
| **9. Data Source Information** |
| **a. Please indicate the source(s) of data for this study** *(mark all that apply)* |
|  🞎 Interviews 🞏Questionnaires/surveys | 🞏 Focus groups🞏 Public records | 🞏 Medical records🞏 Biological specimens | 🞏 Photos/Videos🞏 Voice recordings | 🞏 Registries🞏 Other-*Please explain:*       |
| **b. Will these data be linked to participants/cases or contain any personal identifiers?**    Yes   No |
| c. If the data are **de-identified,** will the study personnel have any links/keys to identifiers? If Yes, please describe who will have access to identifiable information and how you will protect identifiable information from accidental disclosure.            |
| d. If the data are **not de-identified,** when will identifiers be removed and how will you protect identifiable information from accidental disclosure?            |
| **e. Are any of the data coming from covered entities under Health Insurance and Portability and Accountability Act (HIPAA)?\*** Yes    No    |
| f. If yes, describe the data use agreement between the researchers and the clinical entity\*\*            |

|  |
| --- |
| \* If unsure of HIPAA applicability, please review the federal guidelines: <http://privacyruleandresearch.nih.gov/>; or call the PU IRB office.\*\* Please provide HIPAA authorizations from the covered entity and waiver requests with this application. |

|  |
| --- |
| **10. Website Information** |
| **a. Does this study have a website?**     Yes     No |
| **b. What is the website address?**            |
| **c. What is the purpose of the website (e.g. recruitment, questionnaire, informational, etc.)?**           |

|  |
| --- |
| **11. Informed Consent** Full disclosure of the study and participants’ rights should be given verbally to the participants including all the information in the informed consent document. ***A copy of the recruitment materials (if applicable), and informed consent and/or assent document must be included with this application.*** |
| **a. Describe the recruitment process in detail.** *Include information on who will be recruiting participants, their relationship to the research and to the participants.*            |
| **b. Describe the informed consent process in detail.** *Please include information on who will be consenting these individuals.*      |
| **c. How will consent be obtained?** *Documentation must be provided*   Written Verbal |
| **d. Is a waiver of any required element of informed consent being requested?\***    Yes    No |
| e. If yes, please specify       |
| **f. Does this study involve children (under 18 years of age in Iowa)?\*\***    Yes\*\*    No |

|  |
| --- |
| \* For information on the required elements of informed consent, please see [HHS Guidelines](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html):\*\* If yes, please include a copy of the minor’s assent form with this application. |

|  |
| --- |
| **g. Describe the assent process in detail.**           |
| **h. How will assent be obtained?** *Documentation must be provided*  Written    Verbal |
| **i. Are you requesting a waiver of assent?**   Yes\*    No If yes, please specify and provide a justification for this request:       |
| **j. Describe the process for obtaining parental permission for the children to participate in the research:**           |
| **k. How will permission be obtained?** *Documentation must be provided*    Written    Verbal |
| **l. Are you requesting a waiver of parental permission?**    Yes\*    No If yes, please specify and provide a justification for this request:            |

|  |
| --- |
| **12. Radiation to be Used** |
| **a. Will ionizing radiation (e.g. x-rays) be used?**    Yes\*    No |
|  \*If yes, complete sections 12.a.1 – 12.a.7 |
| a.1 Please state the x-ray procedure(s) to be performed:            |
| a.2 Please state the number of x-ray studies:            | a.3 How frequently will each participant be studied?            |
| a.4 Department(s) where procedure(s) will be performed::            | a.5 Participant Group(s):            |
| a.6 Physician(s) responsible for performing the x-ray procedures:            | a.7 What is the radiation exposure to the participant?            |
| **b. Will non-ionizing radiation (e.g. MRI, ultrasound, or lasers) be used?**    Yes\*    No |
|  \*If yes, complete sections 12.b.1-12.b.7 |
| b.1 Please state the source of the non-ionizing radiation:            |
| b.2 Manufacturer and model of the instrument:           |
| b.3 Exposure parameters:\*       |
| \**Please include (as applicable):** **MRI:** Static magnetic field strength (Gauss), SAR: average and peak RF heating, rate of magnetic field strength change with time (dB/dt) relative to gradient, and acoustic noise (decibels)
* **Ultrasound:** Frequency (Hz) and intensity (W/cm2)
* **Lasers or Ultraviolet:** Power output (W/cm2), wavelength (nm) and tissue exposure (J/cm2)
 |
| b.4 Part of body exposed:            | b.5 Number of studies:            | b.6 Length of time each participant will be exposed:             |
| b.7 Is the exposure considered to be routine?    Yes    No\* |
|  \*If no, please explain the reasons for the investigative exposure:       |

|  |
| --- |
| **13. Drugs, Biologics, and Devices** |
| **a. Will drugs, biologics, dietary supplements or food additives be used in the research?**    Yes\*    No |
|  If yes, please describe:            |
| **b. Will non-ionizing radiation (e.g. MRI, ultrasound, or lasers) be used?**    Yes\*    No |
|  If yes, please describe:            |

|  |
| --- |
| **14. Biological Materials** |
| **a. Material Description:** *(blood, tissue, vectors, antibodies, etc.)*       |
| **b. Will any of the material being used in the study come from a third party?**    Yes\*    No |
|  \*If yes, please describe:            |

|  |
| --- |
| **15. Genetic Analysis** |
|  **Does the study involve genetic analysis?**    Yes\*    No |
|  \*If yes, please describe:       |

|  |
| --- |
| **16. Investigator Interest** |
| **a. Does the investigator or investigator’s family member have a financial interest in a business which owns a technology to be studied and/or is sponsoring the research?**    Yes\*    No |
| b. \*If yes, please describe:             |
| **c. Are there any plans for commercial development related to the findings of this study?**   Yes\*    No |
| d. \*If yes, please describe:             |
| **e. Will the investigator financially benefit if the findings are commercialized?**   Yes\*    No |
| f. \*If yes, please describe:            |
| **g. Will participants financially benefit if the findings are commercialized?**   Yes\*   No |
| h. \*If yes, please describe:             |
| ***\*Please note that these issues must be disclosed in the informed consent document.*** |

|  |
| --- |
| **Research Study Title:**           |

By signing this application form:

* I agree to accept responsibility for the rights and welfare of the research participants involved with this study.
* I agree that the benefits outweigh the risks to the participants in this study.
* I agree to comply with the Parker University Institutional Review Board policies and procedures.
* I certify that, to the best of my knowledge, I am in compliance with the Department of Health and Human Services and Federal Drug Administration
* policies and procedures regarding the protection of human participants.

 Principal Investigator Signature Date

By signing this application form:

* I certify that the research proposed in this human studies application is of sound design, which is able to address the scientific question or questions posed. Furthermore, I certify that the Principal Investigator has adequate time and resources to meet the study design requirements and complete the study as proposed in this application form.

 Department or Center Chair Signature Date

 Print Department Chair Name Date

**Additional Required Signatures**

**For projects involving education/curriculum:**

 Departmental Supervisor or Associate Provost Date

**For all Student projects:**

 Student Investigator Date

 \*Mentor Signature Date

 Print Mentor Name Mentor Phone Number Print Mentor Email Address

\*Please note, in addition to your mentor’s signature, we require a letter of support from your mentor, their CV or Biosketch, and Protecting Human Research Participants Certificate.

|  |
| --- |
| PU Institutional Review Board • 2550 Walnut Hill Lane • Dallas, Texas 75224 USA voice: 214.902.7365 • fax: 214.902.2482 • email: dlawrence@parker.edu |