**Research Committee – Panel on Research Ethics**

**Sub-Panel on Biomedical Science & Engineering Research Ethics (Human Participants)**

Research Ethics Protocol Modification Form

**Instructions to applicants**

1. Please complete the Modification Form, and do not modify its format.
2. Enter the information required and do not refer to other document(s).
3. Submit completed Modification Form via email to rskto.ethics@um.edu.mo.
4. For information on research ethics and methodology, please refer to the Guidelines & Procedures for the Sub-Panel on BSERE, and the World Medical Declaration of Helsinki posted on our website at: <http://www.um.edu.mo/research/ethic.html.>

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| **SECTION 1 - BASIC STUDY INFORMATION** |
| 1.0 Name of Principal Investigator (PI): |  |
| 1.1 Approved Protocol Reference no.: |  |
| 1.2 Associated Grant Reference no.: | (1) |
| (2) |
| 1.3Source of Funding (External/Internal): |  |
|  |
| **FOR RESEARCH ETHICS SUB-PANEL USE ONLY** |
| **Amendment ID** |  |
| **Chair / Delegate** |  | **Decision** |  |
| **Signature** |  | **Date** |  |

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| **SECTION 2 – CONTACT INFORMATION** |
| 2.0 PI Faculty/Department: |  |
| 2.1 Contact no.: |  |
| 2.2 Email address:  |  |
| SECTION 3 - PROPOSED MODIFICATIONS |
| 3.0 Place an X after the category(ies) that describes the proposed changes.

|  |  |  |
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| Category of Modification |  | Additional Instructions |
| Administrative  |   | Complete section 4 if requesting change to enrollment(s) for an interventional study |
| Clinical with no increased risk to subjects |  | Must complete section 4 |
| Clinical with increased risk to subjects. |  | Must complete section 4 |

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| 3.1 Place an X after the box(es) that describes the type of addendum/modification being requested

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Modification |  | Type of Modification  |  |
| Change in informed consent form |  | Change in UM enrollment |  |
| Change in protocol |  | Change in sponsor/funding source |  |
| Change to or new recruitment material |  | Changes to study team personnel |  |
| Requested as the result of an adverse event |  | Changes to study title |  |
|  |  | Others  |  |

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| * 1. Provide a brief overview of your project including a description of the hypothesis, aims, and objectives.
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| 3.3 If applicable, provide the revised version of the consent document for which approval has to be sought |
| 3.4 If applicable, provide the revised version of the protocol for which approval has to be sought |
| 3.5 Describe any proposed changes to currently approved investigators, research personnel and/or individuals authorized to obtain consent in detail.  *(Insert more rows if needed.)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Add, Change or Remove | Last Name, First Name  | Role in Study (LIMIT to PI, co-investigator, coordinator, contact person, and consenter) | Institutional Affiliation (If not UM) | Degrees Held | Licenses/Certifications | Function(s) in Study (e.g. consent, exams etc.) |
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| 3.6Describe the proposed changes noted in 3.1 in detail, if necessary add details to changes in staff noted in 3.5. *(If the modification chosen in 3.1 is about a change/add in new recruitment material, please provide a copy of the currently approved consent form.)*  |
| 3.7 Describe any implications for increased risks to study participants due to the proposed changes.   |
| 3.8 If there is an increase in risk that may affect human participants’ willingness to continue to participate, describe how subjects will be informed.  |
| **SECTION 4 – ENROLLMENT DATA***(required for clinical changes or increasing enrollment #s for interventional studies)* |
| 4.0 Provide the number of subjects currently approved for enrollment at or by UM.  |
| 4.1 Provide the number of subjects enrolled at or by UM since the last continuation or initial review if continuing review has not yet occurred.  |
| 4.2 Provide the number of subjects enrolled at or by UM since initiation of the trial. |
| 4.3 Is this study open for new enrollment? *(if yes, please proceed to 4.6, if no, please proceed to 4.4)* |
| 4.4 Did the study close to enrollment prior to reaching recruitment goals? |
| 4.5 If the study closed early to recruitment, explain why and how it impacts the study design.  |
| 4.6 If it is still opened for enrollment, place an X after any vulnerable populations that are likely to be recruited for this study.

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| --- | --- | --- | --- | --- | --- |
| Pregnant Women (B) |  | Children/Adolescents (D) |  | Economically Disadvantaged (S) |  |
| Fetuses (B) |  | Children Who are Wards (D) |  | Educationally Disadvantaged (S) |  |
| Neonates of uncertain viability or non-viable (B) |  | Decisionally Impaired (D) |  | Terminally Ill (S) |  |
| Abortuses (B) |  | UM Students (S) |  | Prisoners (C) |  |
| Viable Neonates (D) |  | UM Employees (S) |  |  |  |

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| 4.7 Provide any additional comments to describe subject populations. *(e.g. terminally ill with average life expectancy of less than one year, or only involvement of subjects is via data collected from chart review*s)***[Note: UM student and employees are considered vulnerable when a direct relationship exists between the PI and the participant, e.g. professor-student or supervisor-employee and the student or employee is a recruitment focus, e.g., studies examining a new method of instruction for which student input is needed. If the requested modification bears on the additional protections for vulnerable populations the PI must complete the appropriate corresponding worksheet.]*** |
| 4.8 Are currently enrolled subjects still on active study treatment?  |
| 4.9 Provide the number of participants withdrawn since the initiation of the trial. |
| 4.10 Provide explanations for withdrawals. |
| 4.11 Provide a summary of [adverse events](http://resadm.uchc.edu/hspo/raec/policy/adversereporting_policy.doc) that have been deemed to be unanticipated problems involving risk to participants or others. |
| 4.12 Provide a summary of outcome available to date for all participants. |
| SECTION 5 - ADDITIONAL INFORMATION |
| 5.0 If this study involves an Investigational New Drug (IND) or Investigational Device Exemption (IDE) provide the following:

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| --- | --- | --- | --- |
| Drug/Device Name | IND/IDE # | Manufacturer Name | Sponsor Name |
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| 5.1 For clinical modifications involving INDs or IDEs, provide the date of correspondence with the CFDA clinical reviewer and attach the correspondence.  |
| SECTION 6 – COMMENTS FROM PI |
| 6.0 Provide any additional comments that may be helpful to the Sub Panel in evaluating this request for addendum/modification.  |
| SECTION 7 – SIGNATURE AND DATE |
| 7.0 I certify that, as applicable to this study, the approved protocol, forms and approved methods for recruitment and obtaining consent have been used and that unanticipated problems, adverse events and issues of non-compliance (e.g., major protocol deviations) have been reported according to policy. Based on the information provided, I believe approval of this request for addendum/modification to this study is justified.Signature: Date: |