REQUEST for AMENDMENT/CHANGE TO RESEARCH PROJECT

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| **INSTRUCTIONS for INVESTIGATORS:** | **IRB Office use only**   |  |  |  | | --- | --- | --- | | **Modification Details:** | | | | **AGENDA DATE** | |  | | **Date received** | |  | | **Date approved** | |  | | **Date of IRB Determination email to Investigator** | |  | | **Date of Annual Review** | |  | | Revision to Consent form  **Stamped Consent:**  Yes  No | | **Date:** | | Minor Change | Major Change | | | IRB Action:  Approved  Approved Contingent  Disapproved | | | | Funded:  Yes  No | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Chair, IRB Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of IRB Administrator Date or Designee | | | |
| 1. Complete this form to request approval for an amendment or change to an IRB-approved research project. 2. Submit this completed document via email attachment to the IRB office at [RESEARCHCOMPLIANCE@kent.edu](mailto:RESEARCHCOMPLIANCE@kent.edu). To submit the form with a typed signature, the form must be submitted from the Investigator’s @kent.edu email account. If completed form is signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply. 3. Do NOT implement the amendment or change to research prior to receiving notification from the KSU IRB that the change has been fully approved UNLESS the change is necessary to eliminate apparent immediate hazards to the subjects.In such cases, the investigator must submit a report to the IRB explaining the protocol deviation.   **DEFINITIONS**  ***Minor Changes:*** *Adding non-vulnerable subjects, adding or deleting personnel, etc. such that the risk/benefit is not affected. Typically, these modifications can be reviewed/approved through an expedited procedure (by the IRB Chairperson and Administrator).*  ***Major Changes:*** *Changes in procedures, methods, informed consent, or adding of vulnerable populations such that the risk/benefit ratio might be affected. Typically, these need review/approval at a fully convened IRB meeting.* |

**To complete this form: *Single left-click to complete text fields. To check a box, double left-click on the box, then click “checked”. Click OK.***

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| **Section I – Investigator Information** | |
| Last Name:      First Name: | IRB Log Number: |
| Title of Study (should match Human Subjects Research Application): | |
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| **Section II PROPOSED CHANGE(S)** | | | | | | | |
| 1. Are you requesting to modify or add Kent State University affiliated Co-Investigators or Key Personnel? | | | | | | | |
| List new study personnel (type N/A if none)  *Attached a copy of* [*Appendix Z*](https://www.kent.edu/research/office-research-compliance/appendix-z) *for any personnel that have a conflict of interest,* [*KSU COI Policy*](https://www.kent.edu/policyreg/university-policy-regarding-financial-interest-sponsored-projects) | | | | | | | CITI is current for all personnel |
|  | | | | | | Yes  No | |
| 1. Are you requesting to modify or add External Co-Investigators or Key Personnel? | | | | | Yes **🡪**Complete[**Appendix B**](https://www.kent.edu/research/office-research-compliance/appendix-b)  No | | |
| 1. Are you requesting a change in the Principal Investigator for this study? | | | | | Yes **🡪**Complete[**Appendix S**](https://www.kent.edu/research/office-research-compliance/appendix-s)  No | | |
| 1. Will changes be made to, or include, any of the following? (check all that apply) | | | | | | | | |
|  |  | Blood drawing, injections, surgical procedures (including biopsies) **🡪** Complete [**Appendix Q**](https://www.kent.edu/research/office-research-compliance/appendix-q) |  | Neonates (uncertain viability/nonviable) 🡪 Complete [**Appendix K**](https://www.kent.edu/research/office-research-compliance/appendix-k) | | | | |
|  |  | Adults with decisional impairment 🡪 Complete [**Appendix W**](https://www.kent.edu/research/office-research-compliance/appendix-w) |  | Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) 🡪 Complete [**Appendix V**](https://www.kent.edu/research/office-research-compliance/appendix-v) | | | | |
|  |  | Children**🡪** **Complete** [**Appendix I**](https://www.kent.edu/research/office-research-compliance/appendix-i) |  | Non-English speaking🡪 Complete [**Appendix J**](https://www.kent.edu/research/office-research-compliance/appendix-j) | | | | |
|  |  | Data/Specimen storage/repository **🡪** Complete [**Appendix C**](https://www.kent.edu/research/office-research-compliance/appendix-c)  (future unspecified use, including research databases for purposes of sharing data or specimens collected with other researchers/studies in the future) |  | Pregnant women/fetuses 🡪 Complete [**Appendix K**](https://www.kent.edu/research/office-research-compliance/appendix-k)  *(Only if pregnant women are intentionally recruited and/or studied)* | | | | |
|  |  | Deception **🡪** Complete [**Appendix D**](https://www.kent.edu/research/office-research-compliance/appendix-d)&[**Appendix M1**](https://www.kent.edu/research/office-research-compliance/appendix-m1) |  | Prisoners 🡪 Complete [**Appendix L**](https://www.kent.edu/research/office-research-compliance/appendix-l) | | | | |
|  |  | Devices **🡪** Complete [**Appendix E**](https://www.kent.edu/research/office-research-compliance/appendix-e) |  | Waiver/alteration of any/all of the basic elements of consent Complete [**Appendix M1**](https://www.kent.edu/research/office-research-compliance/appendix-m1) | | | | |
|  |  | Drugs or biologics **🡪** Complete [**Appendix F**](https://www.kent.edu/research/office-research-compliance/appendix-f) |  | Waiver of the requirement for participants to sign a consent document Complete [**Appendix M2**](https://www.kent.edu/research/office-research-compliance/appendix-m2) | | | | |
|  |  | Genetic testing **🡪** Complete [**Appendix G**](https://www.kent.edu/research/office-research-compliance/appendix-g) |  | None Applicable | | | | |

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| 1. Does this request require the revision(s), addition(s), and/or deletion(s) to the following (check all that apply): | |
|  | Consent Form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) including translated documents |
|  | HIPAA Research Authorization Form(s) |
|  | Recruitment Materials (e.g. ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations |
|  | Script(s) or Information Sheet(s), including debriefing materials |
|  | Instruments (e.g., questionnaires or surveys completed by participants) |
|  | Other, Specify: |
|  | Not applicable |
| *For all items checked, provide:*   1. *a copy of the revised materials, with change(s) underlined (or “tracked”) and* 2. *one copy with change(s) incorporated (clean).*   *Re-submission of the IRB Application for Initial Review of Human Subjects Research is not required.* | |

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| **Section III – DETAILS** | | | | | | | | |
| 1. Describe the change(s) to the research and provide a rationale for each change. | | | | | | | | |
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| 1. Are you requesting an increase in the total number of participants? | | | | | | Yes  No | | |
| **If Yes** **🡪** Please answer the questions below. | | | | | | | | |
| Number to be added: | | |  | | | | | |
| Rationale for addition: | | |  | | | | | |
| 1. Will there be any change in the risk(s) to participants? | | | | | | | Yes **🡪** Explain below  No | |
| Explanation: | |  | | | | | | |
| 1. Will there be any change in the benefit(s) to participants? *Compensation is not to be considered a benefit.* | | | | | | | Yes **🡪** Explain below  No | |
| Explanation: | |  | | | | | | |
| 1. Could the proposed change(s) affect participants’ willingness to take part in the research? | | | | | | | Yes  No | |
| **If Yes** **🡪** How will information be communicated to currently enrolled subjects (e.g., revised consent form, letter to participants, etc.)? | | | | | | | | |
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| **SECTION IV - PRINCIPAL INVESTIGATOR’S ASSURANCE** | | | | | | | | | |
| I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.  I verify that the information provided in this Amendment/Changes to Research form is accurate and complete. I will initiate change(s) to this research only after having received notification of final IRB approval (unless necessary to eliminate apparent immediate hazards to participants). | | | | | | | | | |
|  |  | | |  |  | | |
| Signature of Principal Investigator | | | Date | | |
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|  | Printed name of Principal Investigator | | |  |  | | |
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