**PURPOSE:** This Standard Operating Procedure (SOP) describes the methods for using the KSU Institutional Review Board (IRB) or a KSU-relied upon IRB for a research protocol involving human subjects.

**SCOPE:** This SOP applies to all research submitted to the KSU IRB or relied upon IRB.

**RESPONSIBILITY:** The Investigator is responsible for *not* conducting any human subjects research without obtaining prior IRB review and approval.

**DEFINITIONS:**

**Collaborative Institutional Training Initiative (CITI) Program:** The Division of Research and Sponsored Programs, in conjunction with the CITI Program, has made available online courses in Human Subject Protections, Responsible Conduct of Research, Laboratory Animal Welfare and Good Clinical Practice.

**The following types of research studies are reviewed by the KSU IRB:**

* Principal Investigator-initiated trials where KSU faculty/staff hold the Investigational New Drug (IND) or Investigational Device Exemption (IDE) for the test article and KSU Principal Investigator-initiated trials which have been determined by the FDA to be IND exempt;
* Research which involves rDNA or other biological agents which must be reviewed and approved by the KSU Biosafety Committee; and
* Studies that are sponsored by or conducted at Kent State campuses
* Studies that are exempt from review or that meet the criteria for expedited review

**KSU relied-upon IRBs:**

The KSU IRB relies upon the review and approval of certain research products by external IRBs including, but not limited to, Western Institutional Review Board (WIRB), Cleveland Clinic, University Hospital, and Case Western Reserve University. While KSU relied-upon IRBs serve as the IRB of record for certain research, the KSU IRB performs an administrative review of the applications to ensure they meet the criteria for external review. The KSU IRB is also responsible for the local conduct of the research and would be involved in issues related to subjects participating at the KSU site.

The following types of studies are eligible for external IRBs review:

* All industry sponsored Phase 1, 2, 3 & 4 multicenter clinical trials regardless of funding source (i.e., federal, foundation, non-profit or industry) involving drugs and devices, registry studies or observational trials.
* All clinical research projects in which there is an institutional conflict of interest must be reviewed by one of these external IRBs, regardless of funding source.

**PROCEDURE:**

1. Investigators who submit studies for KSU IRB review and approval are required to do the following:
   1. All KSU and KSU affiliate faculty, staff, and students involved in human subjects research projects must complete a KSU IRB approved education program for human subjects protection. Investigators and research staff may complete the CITI program to meet this requirement [www.citiprogram.org](http://www.citiprogram.org). .
   2. Research staff should include a copy of their training certificates (which are valid for three years), to the submission email.
   3. All research personnel are required to submit a current curriculum vitae (CV) or resume with the IRB application submission.
   4. Research staff proposing to recruit human subjects is required to submit an application to the IRB for review and approval prior to initiating each project.
   5. IRB submission materials must be sent via email from their kent.edu account.
   6. Research staff complete the applicable pages of the IRB application and send all appropriate supporting documentation (e.g., protocol, informed consent form, etc.) to the discipline specific IRB reviewer for initial evaluation.
2. Investigators who submit studies for KSU relied-upon IRBs review and approval are required to do the following:
   1. Investigators and/or designated research personnel seeking external IRB review and approval must submit an IRB Authorization Request form to the Office of Research Compliance at Researchcompliance@kent.edu. Copies of the external IRB application and research protocol should accompany this completed form.
   2. The KSU IRB will conduct an administrative review of the research materials.
   3. The ORC will initiate contact with external IRB and facilitate IRB authorization agreement or review by KSU IRB (if required).
   4. Investigators and designated research personnel will follow external IRBs guidelines for the submission and review.

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| **REFERENCES:** | 45 CFR 46.115  21 CFR 56.108 (a)  21 CFR 312, 812  KSU Human Research Protections Program (HRPP) Guidance for Investigators |
| **RELATED POLICIES:** | SOP 201: Regulatory Documentation  SOP 202: Privacy and Confidentiality  SOP 204: Adverse Event Reporting  SOP 205: Institutional Conflicts of Interests |
| **APPENDICES:** |  |
| **REVISION HISTORY:** Keep a running history of all revision dates. | |

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| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |
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