Saint Louis University Institutional Review Board

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| Additional Criteria for Department of Energy (DOE) Research  (*Check if “Yes” or “N/A.” Note: all must be checked for final approval.)* | |
|  | The researchers have submitted the DOE Checklist to Verify Compliance with Requirements to the IRB for use in verifying compliance with DOE requirements. |
|  | The protocol describes clear reporting processes, in which the DOE Human Subjects Protection Program Manager will be notified of the following within 48 hours (MUST check all):  Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.  Any suspension or termination of IRB approval of research.  Any significant non-compliance with HRPP procedures or other requirements. |
|  | The protocol describes the processes by which the DOE-Cyber Incident Response Capability will be immediately notified of any finding of a suspected or confirmed data breach involving personally identifiable information in printed or electronic form and the methods of providing a description of corrective actions to be taken within 48 hours for concurrence by the appropriate DOE Human Subjects Protection Program Manager. |
|  | Contractors will comply with the [Contractor Requirements Document (CRD)](https://www.directives.doe.gov/directives/0443.1-BOrder-b/at_download/file) and will periodically conduct self-assessments to ensure compliance with the Human Subject Research Program procedures. |

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