**Subcontractor Checklist: Safeguarding and Protecting Children**

**Name of Subcontractor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator:** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**IRB Control #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Directions: Use this form as a checklist for subcontractors to indicate that appropriate criteria are met for safeguarding and protecting children. A subcontractor is defined as a non Jefferson-affiliated individual or entity that is being paid via subcontract from a Jefferson account to conduct human research in collaboration with Jefferson researchers. Use an X to indicate that each criterion is met.

The subcontractor has guidelines in place for safeguarding and protecting children involved in research which meets Thomas Jefferson University (TJU) requirements.

The guidelines apply to the children involved in research-related activities for which the subcontractor receives funds from TJU and to those who interact with the children (e.g., students, faculty, employees and contracted personnel, consultants, contractors, and volunteers).

The guidelines are distributed annually to students, faculty, employees and contracted personnel, consultants, contractors, and volunteers who are expected to abide by the guidelines; and the subcontractor incorporates training on the guidelines prior to implementation of research-related activities associated with a subcontract agreement with TJU.

The subcontractor has a Designated Safety Officer (DSO) who fulfills the responsibilities indicated in its guidelines for safeguarding and protecting children.

The subcontractor ensures that standards are met for appropriate consent/assent of children to be involved in research.

The subcontractor has in place and applies a safe, transparent recruitment process for employing and contracting new research personnel sufficient to avoid hiring or otherwise involving an individual that presents a risk to the safety and protection of children involved in research.

The subcontractor accurately records and stores confidential information and abides by relevant national and international standards for the protection of the rights of human participants in research, including children.

Periodic assessments are performed by the subcontractor to ensure that research involving children is being done in an appropriate environment and locations where processes are applied to ensure safe, inclusive environments for children.

The subcontractor appropriately involves the parent(s) of children 7 and under who are enrolled in research and seeks their recommendations about safeguarding and protecting the child during a research study; and when necessary, the subcontractor may determine that independent oversight may be necessary to enable a child-friendly and protective environment during research.

The subcontractor follows procedures for reporting and investigating suspected violations of its guidelines for safeguarding and protecting children; and when the DSO is satisfied that a violation of the guidelines has occurred, the DSO—in collaboration with the subcontractor’s Research Coordinator—assures prompt implementation of appropriate action designed to remove the risk to the well-being of children.

The subcontractor has adequate provisions in place to protect a whistleblower.

The subcontractor has a Code of Conduct for students, faculty, employees and contracted personnel, consultants, contractors, and volunteers engaged in its research; and the subcontractor is able to verify that it has sufficient procedures for ensuring compliance with the expectation of this Code.

The subcontractor agrees to report to the TJU Principal Investigator any violations of its guidelines for safeguarding and protecting children as well as the actions taken to remove risks to children; this is necessary to allow TJU to fulfill any reporting responsibilities that may be required by a sponsor or funding source.

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Signature of Subcontractor Date

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Signature of Principal Investigator Date