

(Assurances Incorporated by Reference in Subagreements Awarded by Wright State University)

ARTICLE VII - ASSURANCES

Subcontractor in executing the agreement is certifying that:

A. Research Subjects, Patients or Recipients of Services

1. **Human Subjects** - If the Subcontractor uses human subjects in its performance of the project, it shall comply with HHS policies and regulations on the protection of human subjects (45 CFR Part 46, as amended). Prior to any use of human subjects pursuant to this Agreement, the Subcontractor shall certify to University the following:

(a) That it has an approved Federalwide Assurance ("FWA") on file with the Department of Health and Human Services ("HHS") Office for Human Research Protections ("OHRP"); and

(b) That the appropriate Institutional Review Board ("IRB") authorized under the Subcontractor's FWA has reviewed and approved the research protocol, within 12 months of the budget period start date and before any research is conducted on human subjects. The Subcontractor shall provide University with copies of the IRB's approval action upon University's request.

2. **Inclusion of Children as Subjects in Clinical Research** – If this Subcontract is funded by an NIH grant, Subcontractor shall comply with National Institutes of Health policies and regulations regarding the inclusion of children as subject in clinical research (45 CFR Part 46).

3. **Inclusion of Women/Minorities as Subjects in Clinical Research** - If this Subcontract is funded by an NIH grant, Subcontractor shall comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" (*NIH Guide for Grants and Contracts*, Vol. 23, No. 11, March 18, 1994, as revised; *Federal Register*, 59 FR 14508-14513, March 28, 1994), implementing section 492B of the PHS Act.

B. Care and Treatment of Laboratory Animals - If the Subcontractor uses live, vertebrate animals in its performance of the Project, it shall file or have on file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare, NIH. It shall also comply with the applicable portions of the Animal Welfare Act of 1966 (as amended), and follow the guidelines described in U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, *NIH Guide for the Care and Use of Laboratory Animals*, and the Public Health Service ("PHS") policy on Human Care and Use of Laboratory Animals, and such other requirements as are established by the Prime Sponsor. The Subcontractor shall certify to WSU that it has obtained a valid and current Institutional Animal Care and Use Committee ("IACUC") approval, and shall provide University with a copy of the IACUC approval upon University's request.

C. Recombinant DNA Molecules - If the work to be performed under this subcontract involves recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules, it agrees to follow the most recent guidelines concerning recombinant DNA research in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

D. Lobbying - It shall comply with all policies and procedures as issued by the Prime Sponsor under Section 319 of Public Law 101-121, 31 U.S.C. 1352, and 45 CFR Part 93. Further it warrants it neither has used nor will use any appropriated federal funds to lobby for or otherwise influence the awarding or amending of this agreement, and that it will disclose the use of any non-federal funds used for these purposes on the appropriate federal form. The substance of this clause shall be incorporated in all subcontracts under this agreement at any tier.

E. Nondiscrimination - It will comply with applicable provisions of Title VI of the Civil Rights Act of 1964, as amended; Executive Orders 11246 and 11375; the Age Discrimination Act of 1975, as amended; Title IX of the Education Amendments of 1972, as amended; and Section 504 of the Rehabilitation Act of 1973, as amended. The Subcontractor shall file an Assurance of Compliance, Form HHS-690, with the Office of Civil Rights of HHS, and furnish University with copies of its assurances of compliance with the above upon request.

F. Debarred or Suspended Parties - Neither it nor any of its employees or principals:

1. Is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this Agreement by any federal governmental department or agency.
2. Has not, within the three-(3) year period preceding the application, been convicted of, or had a civil judgment rendered against it, for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; for violation of a Federal or State antitrust statute; for commission of embezzlement, theft, forgery, bribery, falsification or destruction of records; or for making false statements or receiving stolen property;
3. Is not currently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated above; and
4. Has not, within a three-(3) year period preceding the application, had any public transaction (Federal, State or local) terminated for cause of default.

If, during the term of this Agreement, the Subcontractor or any of its employees or principals become debarred, suspended, proposed for debarment, declared ineligible, voluntarily excluded from participation by any federal governmental department or agency, or is under investigation for any of the activities listed in F (2), above, the Subcontractor shall promptly notify University of such fact in writing.

G. Clean Air Act - It will comply with all applicable standards, orders, or regulations issued pursuant to the Clean Air Act and the Federal Water Pollution Control Act. (applicable to agreements in excess of \$100,000)

H. Drug-Free Workplace - It will comply with the Drug-Free Workplace Act of 1988.

I. Audit Reports - It will submit one of the following within ninety (90) days after signature of this agreement:

- A copy of its latest A-133 audit or,

- A letter signed by an authorized official of Subcontractor stating that its latest A-133 audit disclosed no material weaknesses.

J. Financial Conflict of Interest - It shall comply with the requirements of 42 CFR Part 50, subpart F regarding financial conflicts of interest in research. Subcontractor further warrants that:

1. It has, in effect, a written and enforced administrative process to identify, manage, reduce, or eliminate conflicting financial interests with respect to research projects;
2. It will inform University of the existence of any conflicting financial interests covered by 42 CFR 50.605 prior to the expenditure of any federal funds;
3. It will continue to make similar reports on subsequently identified conflicts; and
4. It will make additional information available to the University, upon request, as to how identified conflicting interests have been handled in accordance with the regulations.

K. Research Misconduct - It has established administrative policies as required by 42 CFR Part 50, Subpart A, and that it will comply with those policies and the requirements as published at 54 FR 32446 regarding Procedures for Dealing with and Reporting Possible Misconduct in Science.

L. Salary Limitations - If this Subcontract is funded by a DHHS grant, Subcontractor will comply with applicable salary limitations. None of the funds awarded under this agreement shall be used to pay the annual salary of an individual at a rate in excess of the Executive Level I of the Federal Executive Pay scale (**NIH and SAMHSA**), excluding benefits. This limitation applies to subcontracts at any tier under this agreement.

M. Acknowledgment of Federal Funding, Freedom of Information Act, and Privacy Act - It will comply with the applicable provisions of the Freedom of Information Act, the Privacy Act of 1974, and, if this Subcontract is funded by an NIH grant, the most recent NIH guidelines concerning the acknowledgment of federal funding and availability of information.

N. Human Pluripotent Stem Cell Research - If the work to be performed under this subcontract involves human pluripotent stem cell research, it agrees to follow the most recent guidelines from NIH concerning this type of research and the informed consent requirements of section 498A of the PHS Act.

O. Investigational New Drug Applications/Investigational Device Exceptions - If the work to be performed under this subcontract involves clinical research involving investigational new drugs (IND), drugs approved for a different indication, or experimental combinations of drugs, it must meet the Food and Drug Administration's (FDA) IND regulations (21 CFR 50 and 312), FDA's human subjects protection requirements, and the HHS human subjects' requirements.

P. Restrictions on Controlled Substances and Sterile Needles - If this Subcontract is funded by an NIH grant, Subcontractor will follow the NIH guidelines for the ethical and safe conduct in science and organizational operations in the following areas:

- Limitation of use of funds for promotion or legalization of controlled substances (Section 202 of the Controlled Substance Act, 21 U.S.C. 812).

- Restriction on distribution of sterile needles unless approved by the Secretary of HHS.

Q. Metric System - It will comply with Executive Order 12770, Metric Usage in Federal Government Programs.

R. Military Recruiting and ROTC Program Access to Institutions of Higher Education - It will comply with section 588 of the National Defense Authorization Act of 1995, as implemented in 32 CFR Parts 23 and 216, that precludes grant awards to schools that the Department of Defense (DoD) determines have an anti-ROTC (Reserve Officer Training Corps) policy or practice.

S. Nondelinquency on Federal Debt - It is not delinquent on the repayment of any federal debt and is otherwise in compliance with the applicable provisions of the Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e).

T. Protection of Research Subjects Identity - If this Subcontract is funded by an NIH grant, Subcontractor will comply with Section 301(d) of the PHS Act and 42 CFR 2a regarding the protection of research subjects' identities.

U. Research on Transplantation of Fetal Tissue - If this Subcontract is funded by an NIH grant, Subcontractor the work to be performed under this subcontract involves research on transplantation of fetal tissue, it will make available the statements and consents required by subsections 498A (b)(2) and (c) of the PHS Act or will ensure HHS access to those records if maintained by an entity other than the subcontractor.

V. Pro-Children Act - If the work to be performed under this subcontract will be done in facilities where federally funded children's services are provided, it will comply with Public Law 103-227, Title X, Part C--Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994.

W. Program Fraud Civil Remedies and False Claim Acts - It shall comply with the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801, 45 CFR Part 79, and the False Claims Act, 31 U.S.C. 3729, 45 CFR Parts 74 and 92.

X. Health and Safety Guidelines - If this Subcontract is funded by an NIH grant, Subcontractor will comply with the regulations in 29 CFR 1910.1030, *Bloodborne Pathogens*; 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*; 42 CFR Part 72, *Interstate Shipment of Etiological Agents*; and all Federal, State, and local health and safety standards as applicable for establishing and implementing necessary measures to minimize its employees' risk of injury or illness in activities related to NIH grants.

Y. Controlled Substances - If the work to be performed under this subcontract involves the use of controlled substances, it will ensure that the requirements of the Drug Enforcement Administration (DEA), including registration, inspection, and certification, as applicable, are met. Further information is available from the National Institute on Drug Abuse at (301) 443-6300.

Z. Data and Safety Monitoring - If the subcontractor uses human subjects in its performance of the project, it warrants that it will take appropriate actions to protect the privacy and confidentiality of those subjects, that it has policies and procedures in place that protect identifying information, and that it oversees compliance with those policies and procedures.

AA. Confidentiality of Patient Records - Pursuant to Section 543 of the PHS Act, as implemented at 42 CFR Parts 2 and 2a, the Subcontractor shall keep confidential records of substance abuse patients except under specified circumstances and purposes.

BB. Ban on Human Embryo Research and Cloning - It shall not use any funds for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208 (a)(2) and section 498 (b) of the PHS Act. The Subcontractor also shall not use funds for the cloning of human beings or other purposes set forth in a Presidential memorandum dated March 4, 1997.

CC. Limitation on Payments to Consultants - If this Subcontract is funded by an NSF grant, Subcontractor agrees that payments to individuals for consultant services under this Subcontract shall not exceed the daily equivalent of the then current maximum rate paid to an Executive Schedule Level IV Federal employee (exclusive of indirect cost, travel, per diem, clerical services, fringe benefits and supplies).

DD. Training in Responsible Conduct of Research (RCR) – If this Subcontract is funded by an NSF grant, the Subrecipient Organization/Institution hereby certifies that it will ensure that all undergraduates, graduate students, and postdoctoral researchers supported by the NSF grant will be trained on oversight in the responsible and ethical conduct of research.