Lifespan System-wide Policy	**Subject:** Lifespan Research Policy	**File under:** CCPM-23
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I. Purpose:

To affirm Lifespan's intention to seek and receive grants and contracts from various sponsors, including, but not limited to the federal government, and to abide by sponsors' requirements. Lifespan will manage the grant and contract activities under applicable federal, state and local laws.

II. Eligibility:

This policy applies to all Lifespan Employees and all employed members of physician corporations with Administrative, Supervisory and Teaching Services Agreements (AS & T) which agree to research governance, conducting research on-site or off-site with the approval of various compliance committees. Exceptions to this eligibility criterion will be made through the use of a separate research governance agreement, approved by the Administrative Director, Office of Research Administration (ORA).

The Principal Investigator (PI) has the ultimate scientific responsibility for the design, conduct and oversight of the research project as well as judicious management of study funds.

Safeguarding the rights and welfare of participants in research and other research activities is the responsibility of the CEO of Lifespan and the Presidents of the affiliate hospitals and, by way of delegation in writing by each of them, is assigned to the Senior Vice President of Research/Chief Research Officer and the Administrative Director of the Office of Research Administration (ORA) who are charged with the responsibility to exercise appropriate administrative oversight to assure that Lifespan's policies and procedures are effectively applied in compliance with its affiliate hospitals' federal assurances.

With regard to research subject programs, the Senior Vice President of Research/Chief Research Officer will serve as the Institutional Official for the affiliated hospitals.

III. Policy:

3.1 Introduction

The Chair or Chief of the department initiating the research will determine the scientific merit of the research proposals and will indicate his/her approval on the standard forms which will be submitted to the ORA. Upon submission of the completed application, the ORA will review the application to assure that it meets with the appropriate sponsor guidelines and that the proposal includes the appropriate institutional assurances. Submission of a research application for review by the ORA (both financial and regulatory committee aspects) commits the PI to all institution, regulatory and sponsor regulations. Appropriate signature(s) of the authorized representative(s) will be obtained. Proposals submitted by PIs to outside granting institutions without such approval and signature, may be rendered invalid, and the grant, if awarded, may be refused by Lifespan. Research may only begin upon PI's receipt of an activation notice from the Office of Research Administration.

3.2

Various non-federal sponsors will have specific requirements for the management of their awards. These may be found in the award notice or contract with the individual proposal in the ORA.

3.3

Federal regulations impose duties and obligations upon the recipients of Federal grants and contracts. As a recipient, Lifespan expects all Lifespan Employees and PIs and all others subject to this policy to abide by all applicable federal and state regulations and all Lifespan policies whether at a system or site-specific level. The following refer to the requirements and cost principles employed to manage federal research both programmatically and financially:

2 CFR 200 (Uniform Guidance), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards:

45 CFR Part 74, App E: Cost Principles for Hospitals

3.4

For the purpose of overseeing research activities involving human participants, the affiliate hospitals have established Institutional Review Boards (IRB), in accordance with federal and state rules, regulations and applicable laws.

All research involving human participants must be submitted to the ORA by the investigator and will be reviewed by the appropriate Human Subjects Committee (IRB), under the Department of Health and Human Services (DHHS) regulations, 45 CFR 46, and/or Federal Drug Administration (FDA) regulations, the Belmont Report, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The regulations provide a systematic means based on established ethical principles, for protecting the rights and welfare of individuals who may be exposed to the possibility of physical, psychological, or social injury while they are participating as subjects in research, education, or related activities. Researchers at Lifespan affiliated hospitals will adhere to the governing procedures for the conduct and review of all human research as found in “Lifespan Human Research Protection Program Policy and Procedure Manual”, Policy Number ORA RRC 001.

In addition, Lifespan and its’ investigators will follow the State of Rhode Island “Rules and Regulations for Licensing Hospitals” (R23-17-HOSP), Section 16, “Research Involving Human Subjects".

3.5

All research involving animal research subjects must be submitted to the ORA by the investigator and will be reviewed by the appropriate Institutional Animal Care and Use

Committee (IACUC) under the standards established by the Animal Welfare Act 9 CFR 9, Chapter 1, Subchapter A, Parts 1, 2 and 3, and by the current editions of documents entitled, "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and "Guide for the Care and Use of Laboratory Animals".

3.6

All research involving radioactive drugs must be submitted to the ORA by the investigator and will be reviewed by the appropriate Radioactive Drug Research Committee in accordance with federal regulations 21 CFR part 361.1.

3.7

In order to ensure that all regulations are observed, questions relating to matters concerning federal grants and all other research related matters should be directed to the Administrative Director, Lifespan Office of Research Administration, or the Senior Vice President of Research/Chief Research Officer

Further guidance and information may be found in the policies located at http://www.lifespan.org/research/administration/policies.html

IV. Procedure:

If a Lifespan Employee or a Lifespan Professional Staff member has a *question concerning* the *interpretation or applicability* to a particular circumstance of any of the laws or regulations referred to in this Policy, such Lifespan Employee or Lifespan Professional Staff member should first consult with his/her supervisor(s) and if his/her supervisor(s) is unable to answer the question or provide any guidance or, if, because of the circumstances, it would be inappropriate to discuss the matter with his/her supervisor(s), then such Lifespan Employee or Lifespan Professional Staff member should contact the Lifespan Senior Vice President/Chief Research Officer; in any case, the Lifespan Employee or Lifespan Professional Staff member may contact the Office of the General Counsel or the Corporate Compliance Officer for advice. If any Lifespan Employee or Lifespan Professional Staff member is aware of any violation or threatened or potential violation of this Policy, or *suspects* a violation of this Policy has occurred, such Lifespan Employee or Professional Staff member must refer to the Policy on Code of Conduct for instruction as to what action to take. No adverse action will be taken against any party who reports, in good faith, any violation or apparent or threatened violation.