1. SPR Therapeutics Financial Conflict of Interest (FCOI) policy for Public Health Service (PHS) funded Research
   1.1 SPR Therapeutics is adopting this policy to promote objectivity in research by establishing standards to ensure that research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator FCOI.

2. Applicability
   2.1 This FCOI policy is applicable to each Investigator who is planning to participate in, or is participating in research funded by PHS by means of a grant or cooperative agreement; provided, however, that this part (42 CFR 50) does not apply to SBIR Program Phase I applications.

3. Definitions
   3.1 **"Disclosure of Significant Financial Interest"** means an Investigator's disclosure of significant financial interest to an Institution.
   3.2 **"Financial Conflict of Interest," or "FCOI,"** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
   3.3 **"FCOI Report"** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
   3.4 **"Financial Interest"** means anything of monetary value, whether or not the value is readily ascertainable.
   3.5 **"HHS"** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
   3.6 **"Institution"** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding. SPR Therapeutics is considered an "Institution" for purposes of this policy.
   3.7 **"Institutional Responsibilities"** means an Investigator's professional responsibilities on behalf of SPR Therapeutics, and as defined by SPR Therapeutics in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Data and Safety Monitoring Boards
   3.8 **"Investigator"** means the project director or principle investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
   3.9 **"Manage"** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
   3.10 **"PD/PI"** means a project director or principle investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this part.
   3.11 **"PHS"** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
   3.12 **"PHS Awarding Component"** means the organizational unit of the PHS that funds the research that is subject to this part.

3.13 **"Research"** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this part, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

3.14 **"Senior/Key Personnel"** means the PD/PI and any other person identified as a senior/key personnel by SPR Therapeutics in the grant application, progress report, or any other report submitted to the PHS by SPR Therapeutics under this part.

3.15 **"Significant Financial Interest"** means:

3.15.1 A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's responsibilities on behalf of SPR Therapeutics:

3.15.1.1 With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary, compensation, and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

3.15.1.2 With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3.15.1.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.15.2 Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. WI-7.2.2 f will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with SPR Therapeutics' FCOI policy, the clinical department head or designee will determine if further information is needed, including a

determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

3.15.3 The term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by SPR Therapeutics to the Investigator if the Investigator is currently employed or otherwise appointed by SPR Therapeutics, including intellectual property rights assigned to SPR Therapeutics and agreements to share in royalties related to such rights; any ownership interest in SPR Therapeutics held by the Investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3.16 **"Small Business Innovation Research"** (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

4. SPR Therapeutics Responsibilities regarding Financial Conflicts of Interest

4.1 Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If SPR Therapeutics maintains a policy on financial conflicts of interest that includes standards that are more stringent than the NIH policy (42 CFR 50) (e.g., that require a more extensive disclosure of financial interests), SPR Therapeutics shall adhere to its policy and shall provide FCOI Reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with SPR Therapeutics' own standards and within the timeframe prescribed by this part.

4.2 Inform each Investigator of SPR Therapeutics' policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

4.2.1 SPR Therapeutics revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

4.2.2 An Investigator is new to SPR Therapeutics; or

4.2.3 SPR Therapeutics finds that an Investigator is not in compliance with SPR Therapeutics' financial conflict of interest policy or management plan.

4.3 If SPR Therapeutics carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), SPR Therapeutics (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by:

4.3.1 Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of SPR Therapeutics or that of the subrecipient will apply to the subrecipient's Investigators.

4.3.1.1 If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of SPR Therapeutics for disclosing significant financial interests that are directly related to the subrecipient's work for SPR Therapeutics;

4.3.1.2 Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to SPR Therapeutics. Such time period(s) shall be sufficient to enable SPR Therapeutics to provide timely FCOI reports, as necessary, to the PHS as required by this part;

4.3.1.3 Alternatively, if the subrecipient's Investigators must comply with SPR Therapeutics' financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to SPR Therapeutics. Such time period(s) shall be sufficient to enable SPR Therapeutics to comply timely with its review, management, and reporting obligations under this part.

4.3.2 Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, *i.e.,* prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

4.4 Designate a SPR Therapeutics official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

4.5 Requirements

4.5.1 Require that each Investigator who is planning to participate in the PHS-funded research disclose to the clinical depart head or designee the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

4.5.2 Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by SPR Therapeutics, during the period of the award. Such disclosure shall include any information that was not disclosed initially to SPR Therapeutics pursuant to paragraph 4.5.1 of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

4.5.3 Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of Significant Financial Interests within thirty

days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

4.6 Provide guidelines consistent with this part for the clinical department head or designee to determine whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether the Significant Financial Interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when SPR Therapeutics, through the clinical department head or designee, reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. SPR Therapeutics may involve the Investigator in the clinical department head's or designee's determination of whether a Significant Financial Interest is related to the PHS-funded research. A financial conflict of interest exists when SPR Therapeutics, through its clinical department head or designee, reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

4.7 Take such actions as necessary to Manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph 4.3 of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to section 5.1.

4.8 Provide initial and ongoing FCOI Reports to the PHS as required pursuant to section 5.2.

4.9 Maintain records relating to all Investigator disclosures of financial interests and SPR Therapeutics' review of, and response to, such disclosures (whether or not a disclosure resulted in SPR Therapeutics' determination of a financial conflict of interest) and all actions under SPR Therapeutics' policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

4.10 Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

4.11 Certify, in each application for funding to which this part applies, that SPR Therapeutics:

4.11.1 Has in effect, an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

4.11.2 Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of Significant Financial Interests;

4.11.3 Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this part;

4.11.4 Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and SPR Therapeutics' review of, and response to, such disclosure, whether or not the disclosure resulted in SPR Therapeutics' determination of a financial conflict of interest; and

4.11.5 Shall fully comply with the requirements of this part.

5. SPR Therapeutics Management of Financial Conflicts of Interest

5.1 Management of financial conflicts of interest.

5.1.1 Prior to SPR Therapeutics' expenditure of any funds under a PHS-funded research project, the clinical department head or designee shall, consistent with section 4.6: review all Investigator disclosures of Significant Financial Interests; determine whether any Significant Financial Interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

5.1.1.1 Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

5.1.1.2 For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

5.1.1.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

5.1.1.4 Modification of the research plan;

5.1.1.5 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

5.1.1.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

5.1.1.7 Severance of relationships that create financial conflicts.

5.1.2 Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to SPR Therapeutics, the clinical department head or designee of SPR Therapeutics shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, SPR Therapeutics may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of SPR Therapeutics' review.

5.1.3 Whenever SPR Therapeutics identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by SPR Therapeutics during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the clinical department head or designee shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

5.1.3.1 Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

5.1.3.2

5.1.3.2.1 In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator

to disclose a significant financial interest that is determined by SPR Therapeutics to constitute a financial conflict of interest; failure by SPR Therapeutics to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, SPR Therapeutics shall, within 120 days of SPR Therapeutics' determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

5.1.3.2.2 SPR Therapeutics is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

5.1.3.2.2.1 Project number;

5.1.3.2.2.2 Project title;

5.1.3.2.2.3 PD/PI or contact PD/PI if a multiple PD/PI model is used;

5.1.3.2.2.4 Name of the Investigator with the FCOI;

5.1.3.2.2.5 Name of the entity with which the Investigator has a financial conflict of interest;

5.1.3.2.2.6 Reason(s) for the retrospective review;

5.1.3.2.2.7 Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

5.1.3.2.2.8 Finding of the review; and

5.1.3.2.2.9 Conclusions of the review.

5.1.3.3 Based on the results of the retrospective review, if appropriate, SPR Therapeutics shall update the previously submitted FCOI Report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, SPR Therapeutics is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and SPR Therapeutics' plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, SPR Therapeutics will submit FCOI reports annually, as specified elsewhere in this part. Depending on the nature of the financial conflict of interest, SPR Therapeutics may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of SPR Therapeutics' retrospective review.

5.1.4 Whenever SPR Therapeutics implements a management plan pursuant to this part, SPR Therapeutics shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

5.1.5

5.1.5.1 Prior to SPR Therapeutics' expenditure of any funds under a PHS-funded research project, SPR Therapeutics shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to SPR Therapeutics that meets the following three criteria:

5.1.5.1.1 The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this part;

5.1.5.1.2 SPR Therapeutics determines that the significant financial interest is related to the PHS-funded research; and

5.1.5.1.3 SPR Therapeutics determines that the significant financial interest is a financial conflict of interest.

5.1.5.2 The information that SPR Therapeutics makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

5.1.5.3 If SPR Therapeutics uses a publicly accessible Web site for the purposes of this subsection, the information that SPR Therapeutics posts shall be updated at least annually. In addition, SPR Therapeutics shall update the Web site within sixty days of SPR Therapeutics' receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if SPR Therapeutics determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of SPR Therapeutics' identification of a new financial conflict of interest. If SPR Therapeutics responds to written requests for the purposes of this subsection, SPR Therapeutics will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of SPR Therapeutics' identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

5.1.5.4 Information concerning the significant financial interests of an individual subject to paragraph 5.1.5.1 of this section shall remain available, for responses to written requests or for posting via SPR

Therapeutics' publicly accessible Web site for at least three years from the date that the information was most recently updated.

5.1.6 In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, SPR Therapeutics may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as SPR Therapeutics deems appropriate.

5.2 Reporting of financial conflicts of interest.

5.2.1 Prior to SPR Therapeutics' expenditure of any funds under a PHS-funded research project, SPR Therapeutics shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by SPR Therapeutics to be conflicting and ensure that SPR Therapeutics has implemented a management plan in accordance with this part. In cases in which SPR Therapeutics identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, SPR Therapeutics shall not submit an FCOI report to the PHS Awarding Component.

5.2.2 For any significant financial interest that SPR Therapeutics identifies as conflicting subsequent to SPR Therapeutics' initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), SPR Therapeutics shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that SPR Therapeutics has implemented a management plan in accordance with this part. Pursuant to paragraph 5.1.3.2 of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by SPR Therapeutics (e.g., was not timely reviewed or reported by a subrecipient), SPR Therapeutics also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph 5.1.3.3 of this section, if bias is found, SPR Therapeutics is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

5.2.3 Any FCOI report required under paragraphs 5.2.1or 5.2.2 of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of SPR Therapeutics' management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

5.2.3.1 Project number;

5.2.3.2 PD/PI or Contact PD/PI if a multiple PD/PI model is used;

5.2.3.3 Name of the Investigator with the financial conflict of interest;

5.2.3.4 Name of the entity with which the Investigator has a financial conflict of interest;

5.2.3.5 Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

5.2.3.6 Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose

value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

5.2.3.7 A description of how the financial interest relates to the PHS-funded research and the basis for SPR Therapeutics' determination that the financial interest conflicts with such research; and

5.2.3.8 A description of the key elements of SPR Therapeutics' management plan, including:

5.2.3.8.1 Role and principal duties of the conflicted Investigator in the research project;

5.2.3.8.2 Conditions of the management plan;

5.2.3.8.3 How the management plan is designed to safeguard objectivity in the research project;

5.2.3.8.4 Confirmation of the Investigator's agreement to the management plan;

5.2.3.8.5 How the management plan will be monitored to ensure Investigator compliance; and

5.2.3.8.6 Other information as needed.

5.2.4 For any financial conflict of interest previously reported by SPR Therapeutics with regard to an ongoing PHS-funded research project, SPR Therapeutics shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. SPR Therapeutics shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

5.2.5 In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, SPR Therapeutics may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as SPR Therapeutics deems appropriate.

6. Remedies.

6.1 If the failure of an Investigator to comply with SPR Therapeutics' financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, SPR Therapeutics shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to SPR Therapeutics for further action, which may include directions to SPR Therapeutics on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require SPR Therapeutics employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

6.2 The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and SPR Therapeutics' review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in SPR Therapeutics' determination of a financial conflict of interest. SPR Therapeutics is required to

submit, or permit on site review of, all records pertinent to compliance with this part. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that SPR Therapeutics has not managed the financial conflict of interest in accordance with this part. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

6.3 In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by SPR Therapeutics as required by this part, SPR Therapeutics shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

7. Other HHS regulations that apply.

7.1 Several other regulations and policies apply to this part. They include, but are not necessarily limited to:

7.1.1 2 CFR part 376—Nonprocurement debarment and suspension (HHS)

7.1.2 42 CFR part 50, part D—Public Health Service grant appeals procedure

7.1.3 45 CFR part 16—Procedures of the Departmental Grant Appeals Board

7.1.4 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations

7.1.5 45 CFR part 79—Program fraud civil remedies

7.1.6 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments

8. Revision History

Document Number	Author	Change Order	Description of Changes
SPR-FRM-7.2.2ad	Lechman	0012868	-Initial Document based upon NDI document FRM-7.2.2ad. Only changes made include SPR logo and removing references to NDI and portfolio companies