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Financial Conflict of Interest (FCOI) Policy for NIH-Funded Research

1. Purpose:

The purpose of the **GREENSTONE BIOSCIENCES, INC.** institutional Financial Conflict of Interest (FCOI) Policy for NIH-Funded Research is manifold:

1. **Integrity of Research**: To ensure that the design, conduct, and reporting of research funded by the National Institutes of Health (NIH) is free from bias resulting from investigator financial conflicts of interest.
2. **Public Trust**: To foster public trust in the scientific process and the credibility of NIH research findings. Public belief in the transparency, integrity, and reliability of research results is paramount for the advancing science and its societal implications.
3. **Compliance**: To provide a framework for compliance with federal regulations regarding financial conflicts of interest in NIH-funded research, specifically the requirements outlined in 42 CFR Part 50, Subpart F, and 45 CFR Part 94.
4. **Transparency**: To establish a clear process for investigators to disclose significant financial interests and for the institution to assess, manage, and, as necessary, report financial conflicts of interest.
5. **Risk Management**: To protect the institution and its researchers from potential reputational, legal, and financial risks associated with undisclosed or unmanaged financial conflicts of interest.
6. **Education & Awareness**: To promote the investigator's understanding and awareness of the complexities surrounding financial conflicts of interest, ensuring a culture of proactive disclosure and responsible research conduct.

Through this policy, we aim to create a harmonious balance between fostering innovative research, maintaining the highest standards of integrity, and ensuring public confidence in the outcomes and findings of NIH-funded research endeavors.

2. Scope:

This Financial Conflict of Interest (FCOI) Policy for NIH-Funded Research is broad-reaching and encompasses the following aspects:

- **Personnel**: This policy applies to all personnel, including but not limited to principal investigators, co-investigators, research staff, interns, consultants, and collaborators, who are directly or indirectly involved in the design, conduct, or reporting of NIH-funded research.
- **Research Phases**: The policy covers all stages of NIH-funded research, from the proposal submission, research design, data collection, analysis, and reporting to dissemination of results.
- **Financial Interests**: The policy examines various types of financial interests, including but not limited to equity in startups, stock holdings, royalties, consulting fees, speaking honorariums, paid advisory roles, patent rights, and travel reimbursements that could influence or appear to influence the outcome of the research.
- **Institutional Responsibilities**: Beyond just research tasks, the policy also pertains to teaching, professional practice, institutional committee memberships, and administrative duties if these roles relate to NIH-funded research.
- **Sub-recipients**: This policy applies if the NIH-funded project involves sub-recipients or collaborators from other institutions. Sub-recipients must either abide by this policy or provide assurance that their institution's FCOI policy is compliant with NIH requirements.
- **External Entities**: This policy extends to financial interests held by the investigator's immediate family members (spouse and dependent children) and entities the investigator has a significant relationship with, especially when they might be stakeholders or beneficiaries of the research.
- **Training and Education**: All those falling within the policy's purview are required to undergo training related to financial conflicts of interest, ensuring a thorough understanding of their responsibilities and the institution's expectations.

This scope ensures comprehensive coverage of all potential areas where financial conflicts of interest might arise, ensuring that NIH-funded research remains unbiased, transparent, and adheres to the highest standards of scientific integrity.

3. Definitions:

- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.
- **Significant Financial Interest (SFI):** Anything of monetary value, including but not limited to: salary, royalties, equity interests, entitlements, or fees.

4. Disclosure of Financial Interests:

- **Initial Disclosure**:
    - All investigators and relevant personnel must disclose their significant financial interests (SFIs) related to their institutional responsibilities before initiating any NIH-funded research.
    - Newly hired or affiliated personnel who join an ongoing NIH-funded project must submit their disclosure promptly, ideally within 30 days of their start date.
- **Annual Update**:
    - Investigators and relevant personnel are required to update their disclosures annually throughout the duration of the NIH-funded research project. This ensures the continued transparency of any new or evolving financial interests.
- **Ad Hoc Disclosure**:

    - Disclosures must be updated within 30 days of discovering or acquiring a new SFI, regardless of the annual update timeline.
- **Family and Personal Relations**:
    - Investigators must also disclose SFIs of their immediate family members (spouse, dependent children) that are likely to be related to the investigator's institutional responsibilities.
- **Travel**:
    - Investigators must disclose any sponsored/reimbursed travel related to their institutional responsibilities, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration, in alignment with NIH requirements.
- **Exclusions**:
    - Financial interests in mutual funds or retirement accounts where the investigator does not directly control investment decisions are generally excluded from the disclosure requirements.
    - Salary, royalties, or other remuneration paid by the institution to the investigator, if the investigator is an employee or otherwise appointed by the institution, do not need to be disclosed.
- **Content of Disclosure**:
    - The disclosure should clearly describe the nature and magnitude of the financial interest (e.g., equity, consulting fees, honoraria, patent licensing arrangements) and, when applicable, its relation to the NIH-funded research.
- **Confidentiality**:
    - All financial disclosures will be treated as confidential to the extent law permits. Only personnel involved in the review, management, or reporting of FCOI will access these records.
- **Disclosure Forms and Portal**:
    - The institution will provide standardized electronic disclosure forms to facilitate consistent reporting. Investigators are encouraged to utilize the dedicated portal for submitting and updating their disclosures.
- **Guidance and Assistance**:
    - Investigators seeking clarity or guidance on what constitutes an SFI or related queries can approach the [designated office/committee] for assistance.

5. Review and Determination:

- **Initial Review**:
    - Upon submission or update of disclosure, the [designated office/committee] will promptly initiate a review of the disclosed significant financial interests (SFIs) to determine if they relate to NIH-funded research and if a potential FCOI exists.
- **Criteria for FCOI Determination**:
    - An FCOI is deemed to exist if the [designated office/committee] concludes that an SFI could:
        - Directly and significantly affect NIH-funded research design, conduct, or reporting.
        - Appear to compromise the integrity or objectivity of the research.
- **Contextual Evaluation**:

    - The review will consider the nature and magnitude of the disclosed SFI, its relation to the research, and the potential for the financial interest to compromise or appear to compromise the researcher's objectivity.
- **Case-by-case Review**:
    - Each SFI will be assessed on a case-by-case basis, considering the specifics of the research, the nature of the financial interest, and any other relevant factors.
- **Use of Expertise**:
    - If required, the [designated office/committee] may consult with subject-matter experts or seek external guidance to ensure an accurate and informed determination.
- **Notification of Determination**:
    - Investigators will be notified in writing of the determination within a specified timeframe, ideally within [14 days] of the disclosure submission.
- **Appeal Process**:
    - Investigators may contest a determination of FCOI. The process to appeal will be as follows:
    - Submission of a written appeal to the [designated office/committee] within [30 days] of receiving the determination.
    - A secondary review will be conducted, potentially involving a separate panel or external expert.
    - Investigators will receive written feedback on the outcome of the appeal.
- **Documentation**:
    - The [designated office/committee] will maintain detailed records of all reviews and determinations for a period of at least [3 years or the period stipulated by institutional and NIH regulations].
- **Retrospective Review**:
    - In instances where an SFI was not disclosed or reviewed promptly, a retrospective review will be carried out to determine any bias in the research. The review will be completed within 60 calendar days of identifying the non-compliance.

6. Management and Reporting of FCOI:

- **Development of a Management Plan**:
    - If an FCOI is identified, the [designated office/committee] will collaborate with the affected investigator to develop an appropriate management plan that specifically addresses the identified conflict.
- **Contents of the Management Plan**:
    - The management plan will detail the following:
        - The nature of the FCOI.
        - Actions that have been, and/or will be, taken to manage the FCOI.
        - Monitoring mechanisms in place to ensure compliance with the management plan.
        - Timelines for periodic reviews to assess the ongoing effectiveness of the plan.
        - Designation of an independent monitor, if necessary, to oversee adherence and review the integrity of the research process.
- **Potential Management Strategies**:
    - Depending on the nature and extent of the FCOI, strategies might include:
        - Public disclosure of the FCOI in presentations and publications.
        - Modification of the research plan to mitigate potential bias.

        - Monitoring of research by independent, unbiased reviewers.
        - Divestiture of significant financial interests.
        - Temporary suspension of project activities until the conflict is resolved.
        - Transfer of the research project to another investigator without a related FCOI.
- **Reporting to NIH**:
    - Following the NIH's guidelines, the institution will promptly report identified FCOIs to NIH:
        - Before expenditure of any funds.
        - Within 60 days of identifying a new FCOI.
        - Annually to provide the status of the FCOI and any changes to the management plan until the conclusion of the NIH-funded project.
        - Upon completion of the project, a final report outlining the handling of any FCOI.
- **Updates to Management Plan**:
    - Should any revisions to the management plan be necessary due to the evolution of the FCOI or changes in the research, these must be promptly reported to the NIH and any other concerned entities.
- **Non-Compliance Reporting**:
    - In cases of non-compliance with this policy or with the agreed-upon management plan:
        - The institution will assess any bias introduced into the research.
        - Corrective measures will be implemented and reported to NIH.
        - Mitigation reports, detailing the impact of the non-compliance on the research and actions taken to rectify, will be submitted to the NIH.
- **Collaborator & Sub-recipient Reporting**:
    - For NIH-funded projects involving sub-recipients or collaborators from other institutions, the lead institution will:
        - Establish a written agreement with the sub-recipient institution specifying the FCOI reporting mechanisms.
        - Ensure that either the sub-recipient institution complies with this policy or the sub-recipient institution's own FCOI policy is in accordance with NIH's requirements.
- **Public Reporting**:
    - In alignment with NIH's transparency expectations, information concerning identified FCOIs held by senior/key personnel will be made available to the public upon request, ensuring that proprietary information remains confidential.

7. Training:

- **Mandatory Training**:
    - All investigators and relevant personnel participating in NIH-funded research are required to complete FCOI training:
        - Prior to engaging in the research.
        - At least once every four years thereafter.
        - Immediately if there are any policy changes or or if the institution finds that the investigator is non-compliant with the policy or the management plan.
- **Training Content**:
    - The training will encompass:
        - Overview of financial conflicts of interest: definitions, implications, and risks.
        - Detailed examination of the institution's FCOI policy and procedures.
        - Federal regulations surrounding FCOI, with a focus on NIH requirements.

        - Case studies showcasing potential FCOI scenarios and how to handle them.
        - Disclosure responsibilities and the importance of transparency.
        - Steps to take if a potential FCOI is identified.
- **Training Format**:
    - Training will be offered in a mix of formats to ensure accessibility:
        - Online modules with assessments to verify understanding.
        - In-person workshops and seminars led by experts in the field.
        - Interactive webinars that offer opportunities for Q&A.
- **Training Records**:
    - The institution will maintain a comprehensive record of all trainings attended, including:
        - Date of training.
        - Format and content.
        - Names and roles of attendees.
        - Assessment scores, if applicable.
- **Periodic Updates**:
    - Training materials will be reviewed and updated annually to remain current and aligned with any changes in federal regulations or institutional policies.
- **External Training**:
    - Investigators attending externally provided FCOI training must provide documentation to ensure content alignment with institutional and NIH standards. The [designated office/committee] will review and approve such external training on a case-by-case basis.
- **Awareness Campaigns**:
    - Periodic campaigns will be launched to raise awareness about the importance of understanding and managing FCOI, ensuring that it remains at the forefront of investigators' consciousness.
- **Feedback and Improvement**:
    - Feedback will be actively sought from participants to refine the training continuously. This ensures that it remains relevant, effective and addresses the needs and queries of the research community.

8. Record Keeping:

All FCOI disclosures, determinations, management actions, and related records will be retained for at least three years from the date of the final expenditure report or, where applicable, from other dates specified in 45 CFR 75.361.

- **Duration of Retention**:
    - All FCOI-related records, including disclosure forms, review findings, management plans, and training records, will be retained for a minimum of three years from the date of the submission of the final expenditure report or, in cases where other regulatory requirements specify a longer retention period, for the duration of that period.
- **Storage & Confidentiality**:
    - Records will be stored in a secure and controlled environment, be it digital or physical. Access will be limited to authorized personnel to ensure confidentiality and protect personal and sensitive information.
- **Digital Management Systems**:

    - The institution will invest in reliable digital management systems, ensuring data integrity, backup, and easy retrieval when necessary. All digital records will be stored with appropriate encryption and cybersecurity measures.
- **Consistency in Documentation**:
    - Standardized formats and templates will be used for all FCOI-related records to ensure consistency and comprehensibility.
- **Auditing & Monitoring**:
    - Periodic internal audits will be conducted to ensure:
    - Complete and accurate documentation.
    - Compliance with both institutional and NIH record-keeping requirements.
    - Effective implementation of management plans.
- **Access for External Review**:
    - In cases of audits or reviews by external bodies, such as NIH or any other regulatory authority, records will be made available promptly, ensuring full cooperation while adhering to confidentiality requirements.
- **Review of Record Keeping Procedures**:
    - The institution's record-keeping procedures will be reviewed annually to identify potential improvements and ensure alignment with evolving best practices and regulations.
- **Disposal of Records**:
    - Procedures for the safe and secure disposal of records after their retention period will be in place, ensuring that personal and sensitive data are destroyed in a manner that eliminates the risk of unauthorized access or reconstruction.
- **Backup & Disaster Recovery**:
    - Regular backups of digital records will be scheduled, and a comprehensive disaster recovery plan will be in place to ensure data protection against potential risks like hardware failures, data breaches, or natural disasters.

9. Non-compliance:

Non-compliance with the institution's Financial Conflict of Interest (FCOI) policies can have serious ramifications for the integrity of research and the institution's reputation. When an investigator or relevant personnel fail to accurately disclose significant financial interests, or when identified FCOIs are not adequately managed, it jeopardizes the objectivity and credibility of the associated research. In such cases, the institution will thoroughly investigate the extent and potential impact of the non-compliance. Immediate corrective actions will be implemented, including updated disclosures, revisions to the management plan, or even halting the research. Additionally, the institution must report any non-compliance to the NIH or other funding agencies, potentially affecting future funding opportunities. Continued or egregious non-compliance may also lead to disciplinary actions against the involved parties, emphasizing the institution's commitment to upholding the highest research ethics and integrity standards.

10. Public Accessibility:

Ensuring public accessibility to Financial Conflict of Interest (FCOI) information is paramount in fostering transparency and trust in research endeavors. The institution is committed to providing the public with clear and timely access to disclosed FCOIs related to NIH-funded research, especially for

senior and key personnel. This commitment extends beyond regulatory requirements and is rooted in our belief in the right of the public to be informed about potential influences on research outcomes. All disclosed FCOIs will be made available upon request, with a dedicated mechanism in place for efficient information retrieval, while still maintaining the confidentiality of proprietary or sensitive data.

11. Collaborators/Sub-recipients:

- **Definition & Roles**:
  - Collaborators and sub-recipients refer to any external entities or individuals that participate in the NIH-funded research project under a formalized agreement but are not directly employed or overseen by the primary institution.
- **Obligations & Agreements**:
  - Before initiating research, a written agreement must be established between the primary institution and the collaborator or sub-recipient, detailing the FCOI reporting responsibilities. This agreement serves to ensure that all parties understand and commit to the same standards and procedures.
- **Disclosure Compliance**:
  - Collaborators and sub-recipients must either:
    - Comply with the primary institution's FCOI policy.
    - Provide assurances that their own institutional FCOI policies are compliant with NIH requirements.
- **Timely Reporting**:
  - Any identified FCOIs by collaborators or sub-recipients must be reported to the primary institution in a timely manner, allowing for a comprehensive review and, if necessary, the development of a management plan that encompasses the entire research project.
- **Training Requirements**:
  - Collaborators and sub-recipients are required to undertake FCOI training, either provided by the primary institution or through their own institution, provided it aligns with NIH standards.
- **Management of Identified FCOIs**:
  - If a collaborator or sub-recipient identifies an FCOI, the primary institution will take an active role in ensuring it is appropriately managed, ensuring consistency across the entire research project.
- **Audits & Reviews**:
  - Periodic reviews or audits may be conducted by the primary institution to ensure collaborators and sub-recipients are in full compliance with the agreed-upon FCOI procedures.
- **Communication Channels**:
  - Established and clear communication channels will be maintained with collaborators and sub-recipients for seamless information flow, inquiries, and updates regarding FCOI.