



Risk & Compliance Questionnaire

PI Name:	
Organization Name:	
Title of Proposed Research:	

1. Ethics and Research/Data Integrity

- **Prior Violations.** Indicate whether the Principal Investigator (PI), or any person proposed to work on the grant, has been accused of or found to have engaged in any ethics violations, or research or data integrity violations, including any instances of fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. If “yes,” provide information concerning the circumstances on a separate document.

Yes No

- **Research Misconduct and Integrity Policies.** Indicate whether the PI or proposing institution has established policies concerning scientific or research misconduct, such as those required by 42 C.F.R. part 93, “Public Health Service Policies on Research Misconduct.” If “yes,” please provide a copy.

Yes No

2. Regulatory Compliance

- **Non-Delinquency on Federal Debt.** The Federal Debt Collection Procedure Act, 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the U.S., and has a judgment lien filed against it, is ineligible to receive a Federal grant. Indicate whether the proposing institution is delinquent in repaying any Federal debt.

Yes No

- **Prior Regulatory Violations.** Indicate whether the PI or the proposing institution has, in the past 5 years, been accused of or found to have engaged in any violation of regulation or statute in connection with the award or performance of any federal grant, cooperative agreement, subaward, or federal contract or subcontract. If “yes,” provide information concerning the circumstances on a separate document.

Yes No



- **Regulatory Compliance Programs.** Indicate whether the proposing institution has established programs and procedures to (a) identify regulatory requirements applicable to the work to be performed under a grant, and (b) ensure compliance with such regulatory requirements. If “no,” provide information concerning the circumstances on a separate document.

Yes

No

3. **Conflicts of Interest**

- **FCOI Regulations.** Indicate whether the proposing institution is subject to, and in compliance with, the financial Conflict of Interest (FCOI) standards and requirements set forth in 42 C.F.R. 50.601-50.606, applicable to Public Health Service (PHS) grants or cooperative agreements.

Yes

No

- Answer the following questions concerning financial interests of the PI or any person proposed to work on the grant (“Grant Workers”) or their spouses or immediate family members (“Family Members”) that could cause an actual or potential personal conflict of interest, using attachments.

A. **Compensation.** Identify all entities, other than the proposer, that provide Grant Workers or Family Members with compensation or income, including wages, salaries, commissions, Board fees, professional fees, fees for business referrals, licensing fees or royalties, or other payments derived from intellectual property interests, that might be directly or indirectly benefited by the grant activities.

B. **Board Memberships.** Identify all entities, other than the proposer, for which any Grant Worker or Family Member serves as a Board member that might be directly or indirectly benefited by the grant activities.

C. **Consulting Relationships.** Identify all entities, other than the proposer, with which Grant Workers or Family Members have a paid or non-paid consulting relationship, including commercial and professional consulting and service arrangements, scientific and technical advisory board relationships, or expert witness relationships, that might be directly or indirectly benefited by the grant activities.



- D. Other Reimbursements. Identify all entities, other than the proposer, that in the past 12 months have provided Grant Workers or Family Members with honoraria or reimbursements for travel expenses, or that you have reason to believe might do so in the next 12 months, that might be directly or indirectly benefited by the grant activities.

- E. Research Support. Identify all entities, other than the proposer, that in the past 12 months have provided Grant Workers or Family Members with research funding or other forms of research support, or that you have reason to believe might do so in the next 12 months, that might be directly or indirectly benefited by the grant activities.

- F. Business ownership. Identify all entities, other than the proposer, in which Grant Workers or Family Members have an ownership interest, and that might be directly or indirectly benefited by the grant activities.

- G. Investments. Complete the table below or submit a bank or other statement that discloses the requested information concerning financial holdings and interests in entities, other than the proposer, that might be directly or indirectly benefited by the grant activities. Provide information for Grant Workers and Family Members. Do not disclose information concerning diversified mutual funds. Do not disclose the amount or value of the financial holding or interest. Use additional pages as necessary. The financial and other information provided in this Disclosure Statement will be held by CASIS in confidence and disseminated within CASIS only on a need-to-know basis.

<i>Name of Holding or Entity (Company or Entity Name)</i>	<i>Type of Holding or Interest (E.g., stock, bond, etc.)</i>	<i>Owner of Holding or Interest and Relationship (E.g., PI, spouse, etc.)</i>

- H. Other. Other than the financial interests disclosed above, identify any other financial interests or relationships of any Grant Worker or Family Member that might pose a potential or actual conflict of interest as a result of the grant activities.



4. **Other Risks**

- **Prior Terminations.** Indicate whether the PI or proposing institution has, in the past 5 years, had any federal grant, cooperative agreement, subaward, or federal contract or subcontract terminated for cause or default. If “yes,” provide information concerning the circumstances on a separate document.

Yes

No

- **Miscellaneous.** Indicate whether the PI or proposing institution is aware of any fact or circumstance not otherwise disclosed in its grant request or in response to this questionnaire that might pose a risk to its ability to successfully perform a grant. If “yes,” provide information concerning the circumstances on a separate document.

Yes

No

I certify that the information set forth in this Questionnaire, is true and correct to the best of my knowledge and belief. I understand that the financial and other information provided in this Statement will be held by CASIS in confidence and disseminated within CASIS only on a need- to-know basis.

Principal Investigator

Signature

Printed Name

Title

Date