**IRB PROJECT SPECIFIC DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS (SFI)**

**Instructions – Form - Template**

**Purpose:**

This form serves to aid compliance with both the institutional policy for individual conflict of interest disclosures and the IRB policy for project specific disclosures. When a SFI is disclosed, sign-off by an individual within the Office of the Vice President for Research (OVPR) serves to document that that office is aware of the individual’s engagement in the specific research study.

**Directions:**

**All projects (i.e. exempt, expedited, full board):** The PI, or designee, is responsible for soliciting information regarding SFIs from all investigators, study coordinators, data managers, and persons authorized to obtain consent as applicable to a study (i.e. key personnel to be designated on the IRB application). The term investigator is inclusive of the Principal Investigator and any other person who is responsible for the design, conduct or reporting of research. The information is to be solicited from key personnel when initial approval is sought and when continuing approval is sought. Information must also be solicited from individuals being added as key personnel through a request for modification. Records of such communications are to be kept with the study documents (e.g. in the regulatory binder). While the task of soliciting such information may be delegated, it is ultimately the responsibility of the Principal Investigator (PI) to obtain information from key personnel regarding SFIs.

**When Key Personnel Do Disclose a SFI:** If any member of the key personnel indicates that a **SFI does exist**, the following form must be completed, routed for sign-off, and incorporated into the IRB submission packet (i.e. for initial review, continuing review, or when an individual is being added as a key personnel through a request for modification).

**Instructions:**

**Step 1:** Using the template provided at the end of this document, solicit and obtain project specific SFI disclosures from **each i**ndividual to be listed in the study application as key study personnel. **The individual responses from key study personnel are to be maintained with the study records (e.g. in a regulatory binder). The individual responses should not be submitted to the IRB or to the Office of the Vice President for Research**.

**Step 2:** Ensure all key study personnel have responded and review the individual responses. If all responses are “no”, no further action is required. The Project Specific Disclosure form is not required for the IRB submission. (*Note*: the response to the question within the IRB application that asks if a SFI exists will be No.) If any responses are “yes”, CONTINUE to Step 3.

**Step 3:** If a SFI is disclosed by any Key Personnel, complete the Project Specific Disclosure form provided below.

* Provide study specific information at the top of the form.
* List in the table **only key personnel who indicated that “Yes” a SFI does exist**.
* **For modification** requests, list only the new person(s) being added to the study who indicated that a SFI does exist.

**Step 4:** Submit **the completed form**, to the Office of Vice President for Research (OVPR) for review and sign-off by **emailing it to** [**fcoi@uchc.edu**](mailto:fcoi@uchc.edu) If you have questions regarding the form contact either Gus Fernandez-Wolff ([gfernandez@uchc.edu](mailto:gfernandez@uchc.edu) )or Kristen Tremblay ([ktremblay@uchc.edu](mailto:ktremblay@uchc.edu)).

The OVPR staff will return a signed copy of the form, and if applicable the management plan, to the designated contact person.

**Step 5:** Attach the signed form and any associated management plan or communication indicating that a management plan is not required to the IRB submission packet in the IRIS system. .

**For non-UConn Health employees who disclose having a significant financial interest related to the project,** attach any available information from the investigator’s institution; the IRB may request additional information, as necessary.

**IRB PROJECT SPECIFIC DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS (SFI) FORM**

**IRB Submission Type:  New  Continuation  Modification (adding new Personnel)**

**Study Title**:

**IRB # (if known)**:

**Anticipated Submission Date if known:**

**Sponsor / Funding Source(S)**:

**Product(s), Service(s) or Technolgy(ies) Being Tested or evaluated**:

**Contact Person to return form to (name and email)**:

**For Initial and Continuation submissions** list only the persons responsible for the design, conduct and reporting of the research (i.e. PI, Co-I, Study Coordinator, Data Manager, Persons Obtaining Consent) **who are on the IRB application and** **who have indicated that a SFI does exist.**

**For modifications** list only the person(s) being added to the study who have indicated that a SFI does exist.

Maintain this OVPR-signed form **and supporting documents** (e.g. e-mail response from each individual member of the study team, or person being added to the study team) in the regulatory binder.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **List of Personnel who answered Yes (affirming an SFI Related to this Research Exists)** | | | | |
| **Name,**  **LAST** | **Name, First** | **Role on Study  (PI, Co-I, Consenter, Coordinator)** | **Primary\***  **Institutional Affiliation if Other than UConn Health** | **FOR OVPR USE ONLY**  **Comments from OVPR  (e.g., scheduled for review on\_\_, plan attached, not a conflict etc. )** |
|  |  |  |  |  |
|  |  |  |  |  |

**Note**: tabbing out of the last cell on the right will insert additional rows.

\*If a SFI is disclosed for someone whose primary institutional affiliation is not UConn Health, include documentation from the primary institution regarding their review/determination of the SFI when submission is sent to the IRB.

**E-mail completed form to** [**fcoi@uchc.edu**](mailto:fcoi@uchc.edu)**. Contact Gustavo-Fernandez-Wolff or Kristen Tremblay if you have questions pertaining to this form.**

***Additional Comments from Research Team:***

**FOR OVPR USE ONLY:**

**Individual from Office of Vice President for Research – Signature and Date**

**TEMPLATE FOR COMMUNICATION WITH STUDY TEAM TO DETERMINE STATUS OF SFI**

Instructions: Copy and paste the information below into an email, or print for signature, filling in blanks and deleting instructional language where applicable, to obtain written assurance of information regarding Significant Financial Interests of study team personnel.

REMINDER: **The email requesting information and the return email from each study team member, with their responses, must be kept with the study documents (e.g. in the study regulatory binder)**. The email communication serves as their signed response. If the information below is printed and signed in hard copy, keep the signed form with the study documents**. If providing in hard copy – you must print and attach the definition of SFI to the form.**

As a member of the research team for the study noted below, you must be compliant with the institutional conflict of interest policy for individuals involved in research (e.g. annual disclosure, training) as well as the IRB project specific disclosure requirements.

Please respond to this email by **[DATE]** and indicate whether or not you or a member of your immediate family (spouse, dependent children) have any significant financial interests (SFIs) **related to this research project**. The definition of Significant Financial Interest is found in [Policy 2006-01](http://health.uconn.edu/policies/wp-content/uploads/sites/28/2015/07/policy_2006_01.pdf) ( http://health.uconn.edu/policies/wp-content/uploads/sites/28/2015/07/policy\_2006\_01.pdf). Please review this definition before responding.

**[PI or designee to complete the following fields before soliciting information]**

**Study Title**:

**Sponsor / Funding Entity**:

**Product, Service or Technology being tested or evaluated in the Research**:

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**[Respondent must complete the following section]**

**Respondent Name:**

I have reviewed the definition of SFI, and am aware of my obligation to inform the IRB and the Office of Research Compliance of any changes to my current status. My current status is as follows:

**\_\_\_\_\_Yes I (or a member of my immediate family) DO** have a Significant Financial Interest related to this research (select all that apply):

\_\_\_\_\_SFI in the Sponsor/Funding Entity;

\_\_\_\_\_SFI related to the Product/Service/Technology involved in this research.

Note for UConn Health employees: If yes and not previously disclosed to the Office of the Vice President for Research, you must also complete the Individual Financial Disclosure Form available at <http://research.uchc.edu/rcs/fcoi> Follow the directions available at that site.

For non-UConn Health employees:  Provide **any available** information from your institution regarding the SFI (e.g., current management plan, determination that plan is not required, etc.)

\_\_\_\_ **I DO NOT, nor does any member of my immediate family**, have a Significant Financial Interest related to this research project.

**Signature and Date** if disclosure not provided through email