

490 BIOTECH FINANCIAL CONFLICTS OF INTEREST POLICY

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490 BioTech's Conflicts of Interest sets forth policies related to financial conflicts of interest for 490 BioTech personnel and related parties.

Conflicts of interest and commitment, or perceptions of conflicts of interest and commitment, can occur in a variety of forms. 490 BioTech is devoted to the management of situations that can arise when its employees have any external activity, significant financial interest, or management role that has the potential to:

Negatively impact objectivity in the execution of 490 BioTech duties (a "conflict of interest"), or

Reduce the time and attention an employee can devote to his/her 490 BioTech responsibilities, and thus negatively impact his/her performance or assigned 490 BioTech duties (a "conflict of commitment").

The negative impact of unmanaged or inadequately managed conflicts of interest and commitment or perceived conflicts of interest and commitment can include:

1. The use or perception of use of non-490 BioTech resources for personal benefit or the benefit of immediate family members.
2. The use or perception of use of the employee's position to influence 490 BioTech business in a way that benefits one's self or immediate family members.
3. Confusion in the ownership of intellectual property.
4. Questions about the integrity of one's 490 BioTech related research or scholarly activity.
5. Harm to vulnerable populations, such as student interns and research subjects.

Perceived or real conflicts of interest and commitment can be harmful. Disclosure and management are needed whether the non-490 BioTech relationship is with a for-profit entity, a not-for-profit entity, or a charitable foundation. 490 BioTech manages both by the disclosure of the conflict or perceived conflict followed by the creation of a conflict of interest management plan that specifies how the individual will keep his or her non-490 BioTech activities from causing harm.

Training Requirements

Employees of 490 BioTech must complete financial conflicts of interest (FCOI) training at the following website: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

A Certificate of Completion must be provided to the employee's immediate supervisor.

Training must be completed:

- Prior to engaging in research related to any Public Health Service (PHS)-funded grant
- At least every 4 years
- Immediately, if:
 - 490 BioTech revises its FCOI policy that affects requirements of its employees
 - An employee is new to 490 BioTech
 - An employee is not in compliance with the policy or management plan

Disclosure, Review and Monitoring Requirements

Each employee is required to disclose significant financial interests (SFIs) (and those of the employee's spouse and dependent children) related to the employee's institutional responsibilities that meets or exceeds the regulatory definition of SFI:

- No later than at the time of application for PHS-funded research
- At least annually during the period of a PHS-funded award

- Within 30 days of discovering or acquiring a new SFI

SFI disclosures will be distributed and collected by the Secretary of 490 BioTech. Adequate guidelines will be provided consistent with the regulation for the Secretary to determine whether an employee's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI. Prior to the expenditure of funds, the Secretary will:

- Review all Investigator SFI disclosures
- Determine if any SFIs relate to PHS-funded research
- Determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research)
- Develop and implement management plans, as needed to manage FCOIs

The Secretary will additionally:

- Establish a process to review disclosures of SFIs, make determination of FCOIs, and implement a management plan when required for an employee who is new to participating in the research project or for an existing employee who discloses a new SFI.
- Establish a process to review disclosures of SFIs, make determination of FCOIs, and implement a management plan within sixty days whenever 490 BioTech identifies an SFI that was not disclosed timely by an employee or not previously reviewed by 490 BioTech.
- Establish a process to take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor employee compliance with management plans until completion of the project.

Reporting Requirements Specific to the National Institutes of Health (NIH)

490 BioTech will send initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulation:

- Prior to the expenditure of funds
- Within 60 days of identification for an employee who is newly participating in the project
- Within 60 days for new, or newly identified, FCOIs for existing employees
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.

490 BioTech will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and will submit a Mitigation Report in accordance with regulation 42 CFR 50.605(a)(3)(iii).

490 BioTech will notify NIH promptly if an employee fails to comply with the its FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

Maintenance of Records

490 BioTech will maintain all FCOI-related records to meet or exceed the regulatory requirements:

- For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).
- From other dates specified in 45 CFR 75.361, where applicable.

Enforcement Mechanisms and Remedies and Noncompliance

490 BioTech will provide adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure employee compliance.

490 BioTech will complete and document retrospective reviews within 120 days of a determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified

or managed in a timely manner and to document the reviews consistent with regulation 42 CFR 50.605(a)(3).

490 BioTech will ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research 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 employee with an FCOI that was not managed or reported by 490 BioTech as required by the regulation, 490 BioTech will require the employee involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- To request an addendum to previously published presentations.

Subrecipient Requirements

Where applicable, 490 BioTech will establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.

- If applicable, 490 BioTech will obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
- If applicable, 490 BioTech will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.
- Alternatively, if applicable, 490 BioTech will include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

Public Accessibility Requirements

490 BioTech will make its FCOI policy publicly accessible by posting the FCOI policy on its website.

490 BioTech will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. This information will:

- Include the minimum elements as provided in the regulation
- Be posted on a Public Website or made available within 5 calendar days of a written request
- Be updated, at least annually (web site only but any response to a written request will include the updated information)
- Be updated, within 60 days of a newly identified FCOI (web site only but any response to a written request will include the updated information)
- Remain available for three years from the date the information was most recently updated.