

_____, effective date September 24,
2013, and are supported by the UWOFA Collective Agreement 2018-2022, Article

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and of FCOI processes, including some relevant obligations of Western

Operational Procedures and the Investigator Procedures

Significant Financial Interest (SFI): A Financial Interest that reasonably appears to be related to the Investigator's Professional Responsibilities and:

1. with regard to a publicly traded entity, the aggregate value of any salary or other payments for services received from the entity during the 12 month period preceding the disclosure plus the value of any equity interest in the entity as of the date of disclosure exceeds \$5,000 USD;
2. with regard to a non-publicly traded entity:
 - a) the aggregate value of any salary or other payments for services received

III. UNIVERSITY OBLIGATIONS:

The institutional obligations of Western

- c) how the management plan is designed to safeguard objectivity in the research project;
 - d) confirmation of the Investigator's agreement to the management plan;
 - e) how the management plan will be monitored to ensure Investigator compliance; and
 - f) other information as needed.
- 3) Impose appropriate conditions or restrictions to manage the FCOI(s); these could include, but are not limited to, the following:
- a) public disclosure of the FCOI (e.g., when presenting or publishing the research);
 - b) for research projects involving human participant research, disclosure of the FCOI directly to participants;
 - c) appointing a research ethics committee.

complete (within 120 days of determining non-compliance) a retrospective review of the Investigator's activities and the research project in order to determine whether any of the research conducted during the time of non-compliance was biased in its design, conduct or reporting.

- 2) During the retrospective review, impose, if necessary (depending on the nature of the FCOI), additional interim measures regarding the Investigator's participation in the research project pending completion of the review.
- 3) Document the retrospective review, including, at minimum, the following key elements:
 - a) project number and title;
 - b) PD/PI (or contact PD/PI if a multiple PD/PI model is used);
 - c) name of the Investigator with the FCOI;
 - d) name of the entity with which the Investigator has an FCOI;
 - e) reason(s) for the retrospective review;
 - f)

- i. within 60 days of identification (by a Western review as per section C above) of an FCOI for an Investigator who is newly participating in the project;
 - ii. within 60 days for a new, or newly identified (by a Western review as per section C above), FCOI for an existing Investigator ;
 - iii. at least annually (in the time and manner specified by the PHS awarding component), to provide the status of any previously reported FCOI and any changes to the management plan (if applicable), until the completion of the project. The report must explain how the FCOI is being managed or why it no longer exists; and
 - iv. following a retrospective review (as per section E above), to update a previously submitted report, if appropriate.
- 2) Include in any FCOI report sufficient information to enable the PHS awarding component to understand the nature and extent

- b) a description of the impact of the bias on the research project (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm, and analysis of whether the research project is salvageable); and
 - c) Western's plan of action (or actions taken) to eliminate or mitigate the effect of the bias.
- 4) Notify the PHS awarding component promptly if a retrospective review results in a finding of bias, including the corrective action taken or to be taken.
 - 5) Make information relating to disclosures of SFIs, and Western's review, determination and action taken, available to the PHS or HHS promptly on request, whether or not an FCOI was found to exist.

G. Compliance, Enforcement Mechanisms and Remedies

- iii. name of the entity in which the SFI is held;
- iv. nature of the SFI; and
- v. approximate dollar value of the SFI (dollar ranges are permissible: \$US0-\$4,999 USD; \$5,000 USD-\$9,999 USD; \$10,000 USD-\$19,999 USD; amounts between \$20,000 USD-\$100,000 USD by increments of \$20,000 USD; amounts above \$100,000 USD by increments of \$50,000 USD), 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.

b) be provided by a written response within 5 business days of a written request, and include up-to-date information;

c) state in the written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least (a) 316-3.2 () 10. ndat atina

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