

Guidance for UW-Madison Financial Disclosure Process

The purpose of this guidance document is to describe the UW-Madison policies and procedures to obtain and document financial disclosure information for members of the study team involved in the conduct of FDA regulated, investigator-initiated clinical trials.

Per 21 CFR 54, 21 CFR 312 and 21 CFR 812, Sponsor-Investigators are expected to document financial disclosure information and obtain the financial disclosures from all members of the study team that will make a direct and significant contribution to the data¹ (i.e. sponsor-investigator, Principal Investigator, co-investigators, sub-investigators, other applicable members of the study team). Sponsor-Investigators are expected to obtain the financial disclosure information before permitting an investigator to participate in a clinical study because the sponsor is in the best position to inquire as to financial interests and arrangements, and to become aware of any potentially problematic financial interests or arrangements as early as possible in the product development process to minimize study bias.

According to the University of Wisconsin-Madison (UW-Madison) “Policy on Financial Conflicts of Interest in Federally Funded or Human Subjects Research” (<https://kb.wisc.edu/gsadminkb/page.php?id=32993>), all members of the study team engaged in human subjects research (Engagement in Human Participants Research at UW-Madison Policy: <https://kb.wisc.edu/hsirbs/page.php?id=22206>) must annually disclose all outside activities and significant financial interests held by themselves or their immediate family members via an Outside Activities Report (OAR) and update the OAR within 30 days of acquiring or discovering a new significant financial interest during and following the completion of the study², per applicable regulations. The thresholds used by UW-Madison meet or exceed the standards for reporting financial interests to a sponsor/sponsor-investigator per 21 CFR 54 Financial Disclosure by Clinical Investigators. Therefore, the UW-Madison OARs and disclosures can be used to fulfill the requirements of 21 CFR Parts 312.53, 312.57, 312.64 and 812.43 for sufficient, accurate financial disclosure information.

In the event that the UW-Madison Conflict of Interest Committee determines that a UW-Madison faculty or academic staff study team member has a perceived financial conflict of interest that necessitates the individual follow a management plan, the existence of the management plan will be identified to the sponsor-investigator through the UW-Madison IRB application process along with documentation whether the management plan applies to the specific study (e.g., a managed entity sponsors the study). If no management plan is issued to a study team member or if a management plan is determined not to apply, the sponsor-investigator can use this information to confirm that there are no known financial conflicts that exist for the specific study.

¹ Examples of roles that make a direct and significant contribution to the data include but are not limited to treatment or evaluation of research subjects, performing critical trial related procedures such as a full physical to qualify subjects for the study, and/or collecting and evaluating study data.

These roles may be performed by co-investigator(s), sub-investigator(s) and/or other study team members. (See [Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions: Statement of Investigator](#) for further information.)

² According to the [FDA Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators](#), completion of the study means that all study subjects have been enrolled and follow-up of primary endpoint data on all subjects has been completed in accordance with the protocol.

Recommendations:

Financial disclosure information must be collected for all members of the study team that will make a direct and significant contribution to the data¹. The format for documenting financial disclosure is determined by the sponsor-investigator.

When all members of the study team are UW-Madison faculty or academic staff, the sponsor-investigator may use the process described above to confirm whether a financial conflict of interest exists for the study. If no conflict of interest exists, the sponsor-investigator is encouraged to print and maintain a copy of this document with the study regulatory file(s) in lieu of obtaining a separate financial disclosure agreement from each study team member.

When a clinical trial includes the involvement of study team members from other institutions or organizations or the review of such study has been ceded to a non-UW-Madison IRB of record, sponsor-investigators must obtain a separate financial disclosure agreement from each applicable study team member.

A Financial Disclosure Agreement template for non-UW-Madison investigators and studies ceded to a non-UW Madison IRB is available in the Study Initiation tab of the [Clinical Research Toolkit](#).

References:

- [Policy on Financial Conflicts of Interest in Federally Funded or Human Subjects Research](#)
- [Financial Conflict of Interest Policy and Procedures: Guidance Document](#)
- For a full index of UW-Madison Conflict of Interest (COI) and Outside Activities Reporting (OAR) Policies, refer to <https://kb.wisc.edu/gradsch/topics.php?c=2901&l=4&a=d>
- FDA Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators: <https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf>
- Federal Regulation references:
 - 42 CFR 50, Subpart F
 - 45 CFR 94
 - 21 CFR 54
 - 21 CFR 312.53, 312.57, 312.64
 - 21 CFR 812.43

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These roles may be performed by co-investigator(s), sub-investigator(s) and/or other study team members. (See [Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions: Statement of Investigator](#) for further information.)