



<b>SOP Title</b>	IRB Member and Consultant Conflict of Interest				
<b>Date Last Revised</b>	01/10/2019	<b>Date Created</b>	08/22/2018	<b>Revision #</b>	
<b>SOP Number</b>	24	<b>Required by:</b>	<input checked="" type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
<b>Applicability</b>	<input type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
<b>Subgroup</b>	<input type="checkbox"/> NKU Compliance	<input checked="" type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

## 1.0 PURPOSE

To describe policies and procedures for identifying and managing Institutional Review Board (IRB) member and ad hoc or cultural consultant conflict of interest in any type of review (e.g., initial, continuation, modification, noncompliance, unanticipated problem/adverse event, protocol violation, exemption certification)

## 2.0 GENERAL INFORMATION AND SCOPE

In the environment of research, openness and honesty are indicators of integrity and responsibility. These are characteristics that promote quality research and can only strengthen the research process. This policy helps ensure that personal and financial interests do not compromise the rights and welfare of human research subjects. The IRB eliminates all IRB members’ and consultants’ (e.g., ad hoc or cultural) conflicts of interest prior to conducting IRB reviews.

## 3.0 PROCEDURES

1. Prior to conducting the review of any project, including exempt, expedited, full board, continuing review and amendments, the reviewer will declare any potential conflict of interest via the appropriate checklist in Mentor IRB. The first question in each checklist asks if there is a potential conflict of interest and instructs reviewers to contact the IRB Administrator should a conflict of interest exist. The definition of conflict of interest is available within the question’s mouse over.
2. No regular or alternate member may participate in review of any research project in which the member has a conflict of interest, except to provide information as requested. Such review includes initial, continuation, exempt, modification, unanticipated problems involving risk to participants or others, protocol violation, and noncompliance reviews using expedited or convened procedures.
3. It is the responsibility of each voting member or alternate member of the IRB to disclose any conflict of interest when conducting a review and to excuse him or herself from deliberations and voting.
4. A consultant may not participate in the review of any research project in which the consultant has a conflict of interest. Such review includes initial, continuation, exempt, modification, unanticipated problems involving risk to participants or others, protocol violation, and noncompliance reviews using expedited or convened procedures.
5. The NKU IRB Administrator will confirm that no conflict of interest exists when contacting an individual to serve as a consultant and document via the appropriate Mentor IRB checklist.

## 4.0 REFERENCES

## 5.0 FORMS OR ATTACHMENTS

## 6.0 DEFINITIONS

*Conflict of Interest:* Involves any situation in which an IRB member or consultant has any significant personal or financial interest in the proposed research or clinical investigation.

*Significant Personal Interest:* Includes but is not limited to:

- An interest that the IRB member or consultant believes conflicts with his/her ability to objectively review a protocol including interests of the individual or immediate family member (spouse and dependent children) involved in the design, conduct, or reporting of the research protocol.

Examples of a conflicting interest are if the IRB member or consultant is any of the following:

- Principal investigator (PI);
- Co-investigator;
- Study personnel receiving funding from the study, as listed in the study budget;
- A supervisory role over the PI of the study (e.g., graduate advisor);
- Family member of PI.

*Significant Financial Interest:* Anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options, or other ownership interests);
- A proprietary interest in the research such as a patent, trademark, copyright, or licensing agreements including royalties from such rights;
- A financial interest in the sponsor, product or service being tested;
- A position as an executive director or director of the agency or company sponsoring the research regardless of the amount of compensation;
- Any compensation that could be affected by the outcome of the research regardless of the amount of compensation.

Significant financial interest does NOT include:

- Salary, royalties, or other remuneration from the University;
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- Income from service on advisory committees or review panels for public or non-profit entities;
- An equity or financial interest that when aggregated for the IRB member or consultant and the IRB member's or consultant's spouse and dependent children meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other

reasonable measures of fair market value and does not represent more than a 5% ownership interest in any single entity;

- Salary, royalties or other payments that when aggregated for IRB member or consultant and the IRB member's or consultant's spouse and dependent children over the next 12 months are not expected to exceed \$5,000.

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Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	01/10/2019	<input type="checkbox"/>
IRB Chair	<input checked="" type="checkbox"/>	01/10/2019	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>

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Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IRB Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	