



III. PROCEDURE/INFORMATION

a. Research Disclosure Review Committee

- i. **Establishment of a Committee** – The VP for the Health Sciences shall appoint a committee to review and make recommendations related to Required Disclosures made by Researchers and/or the Institution. The committee shall be named the Conflict of Interest in Research Committee (“CIRC”) and may consist of the following members:
 1. Director, Research Compliance and Safety (Chair)
 2. Senior Associate Dean, Research (*ex officio*)
 3. Chair, Institutional Review Board or Director of Human Research Protections Program
 4. Assistant Dean for Clinical and Translational Research
 5. Assistant Dean for Basic Science Research and Postdoctoral Affairs
 6. Staff Attorney, Research Administration
 7. Director of Neiswanger Institute for Bioethics and Health Policy
 8. Associate Vice President, Corporate Compliance & Internal Audit
 9. Associate Dean of Research, Marcella Niehoff School of Nursing
 10. Two (2) clinical research faculty
 11. One basic science research faculty
 12. One community member(s)

Other qualified persons (QP) may be selected by the VP for Health Sciences Research in lieu of or in addition to the above members. However, at all times, the membership shall consist of individuals who conduct research, the institutional conflicts of interest officer and individuals with experience in administrative oversight and conflict resolution. The CIRC shall meet when necessary to discuss and make recommendations to the Institution regarding Required Disclosures.

ii. CIRC Responsibilities

1. Develop/oversee processes for required disclosures relevant to research including interface with other institutional disclosures. (see Appendix [1] Tables 1-3 Algorithms).
2. Review Required Disclosures that may pose a conflict or the appearance of a conflict and determine whether the disclosure, management, elimination or another course of action is appropriate (see Appendix [2] HHS guidelines for the disclosure of significant financial interest).
3. Document the CIRC’s decisions.
4. Establish monitoring procedures and conditions surrounding research involving a financially interested individual.
5. Communicate as appropriate with the IRB and IACUC.
6. Develop a process by which CIRC decisions may be appealed.



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- iii. **CIRC Review Criteria** –The CIRC shall consider the following factors when analyzing a Required Disclosure and recommending actions to be taken:
1. Nature and extent of the Financial Relationship;
 2. Appearance of impropriety;
 3. Risks to subjects and/or to the integrity of the study;
 4. Appropriateness of recruitment techniques;
 5. Whether disclosure of the Financial Relationship to prospective subjects is warranted;
 6. If there should be a separation of responsibilities for financial decisions and research decisions;
 7. Whether additional oversight or monitoring of the research is in order;
 8. If an independent data and safety monitoring committee or similar monitoring body should perform additional oversight of the study;
 9. Whether reduction or elimination of the Researcher’s Financial Relationship is needed to avoid a conflict of interest; and
 10. If a modification of the roles of the particular research staff or changes in the location for research activities would mitigate the risk.
- b. **Disclosure and Review Procedures** –
- i. **Reporting** - If a Researcher and/or the Institution has a Financial Relationship that constitutes a Required Disclosure, the Researcher and/or the Institution shall promptly report such disclosure to the CIRC through the mechanisms established for applying for protocol approval. If the Required Disclosure arises during the course of a study, the Researcher and/or the Institution should promptly notify the appropriate compliance oversight body of the Required Disclosure (IRB or IACUC, or if neither is applicable disclosure should be made to the Senior Associate Dean of Research). Irrespective of these study-reporting requirements, the Researcher should describe the Required Disclosure on his/her Annual Disclosure Statement. See Policy P-17.
 - ii. **Review Process** - Once reported, the CIRC Chair shall contact the Researcher and/or the Institutional official, conduct an interview and gather necessary information so the CIRC can perform its evaluation. The Chair shall then schedule a CIRC meeting. The CIRC shall meet to discuss the Required Disclosure. Minutes of the meeting will be recorded. The Chair shall communicate recommendations made by the CIRC to the Researcher and/or the Institution and the appropriate oversight board.
 - iii. **Decision-making** - The CIRC makes recommendations to the Senior Associate Dean for Research which may include the reduction, management or elimination of any actual or perceived research conflict of interest. The final decision is made by the Senior Associate Dean for Research.
 - iv. **Appeals** – Researchers and/or Institutional officials may direct their appeals of decisions made regarding a Financial Relationship to the Dean of Primary Appointment, Loyola University Chicago at 2160 South First Avenue, Maywood, Illinois 60153.

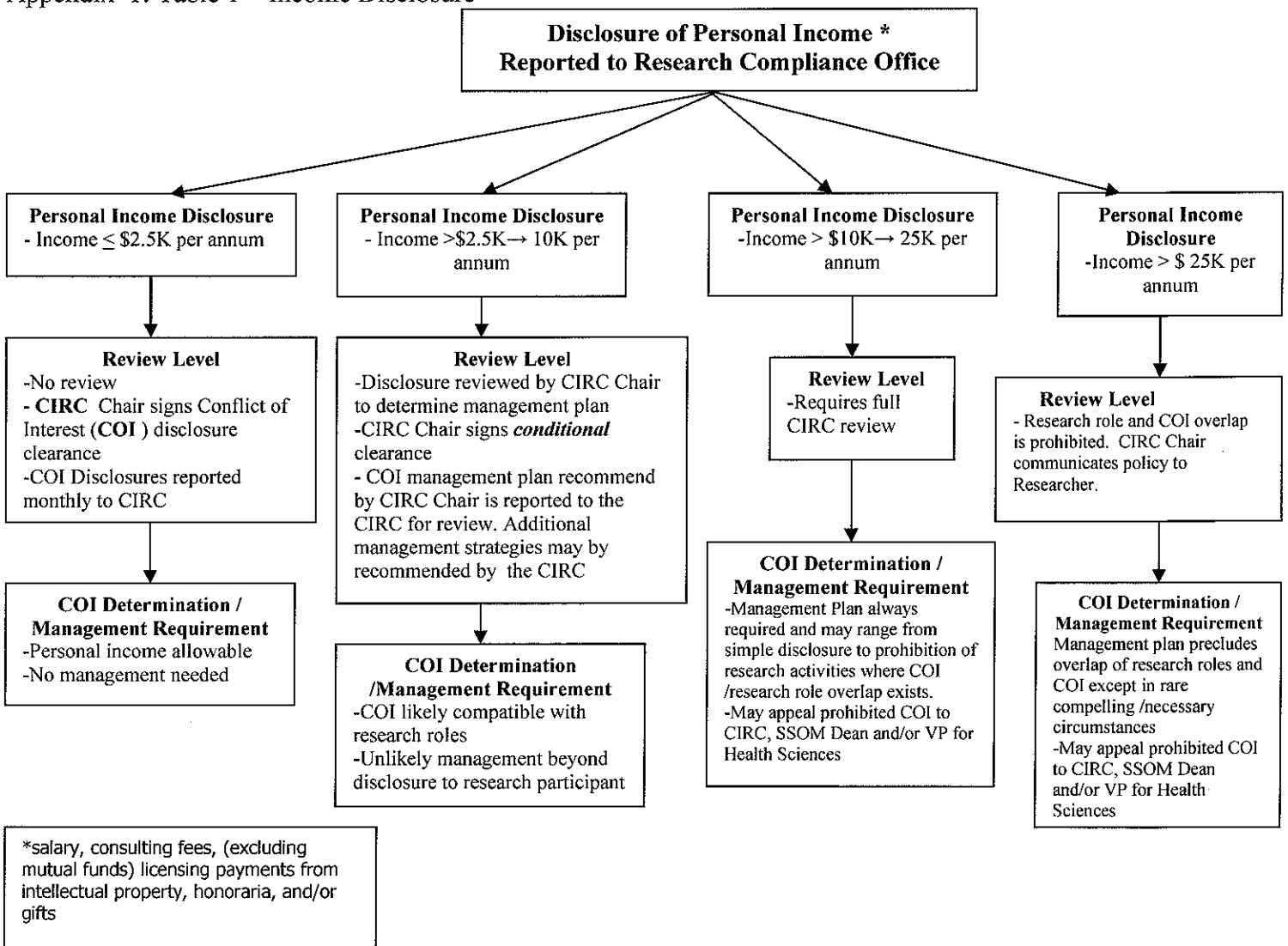


- c. **Sanctions** – Any Researcher who fails to adhere to this policy will be subject to disciplinary action as outlined in the faculty or employee handbook, as applicable.
- d. **Institutional Conflicts of Interest**; identified Institutional conflicts of interest shall be appropriately managed and/ or ameliorated.

IV. RESPONSIBLE PARTY

Questions about this policy may be directed to the Director of Research Compliance and Safety.

Appendix 1: Table 1 – Income Disclosure



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Table 2 – Equity Publicly Traded

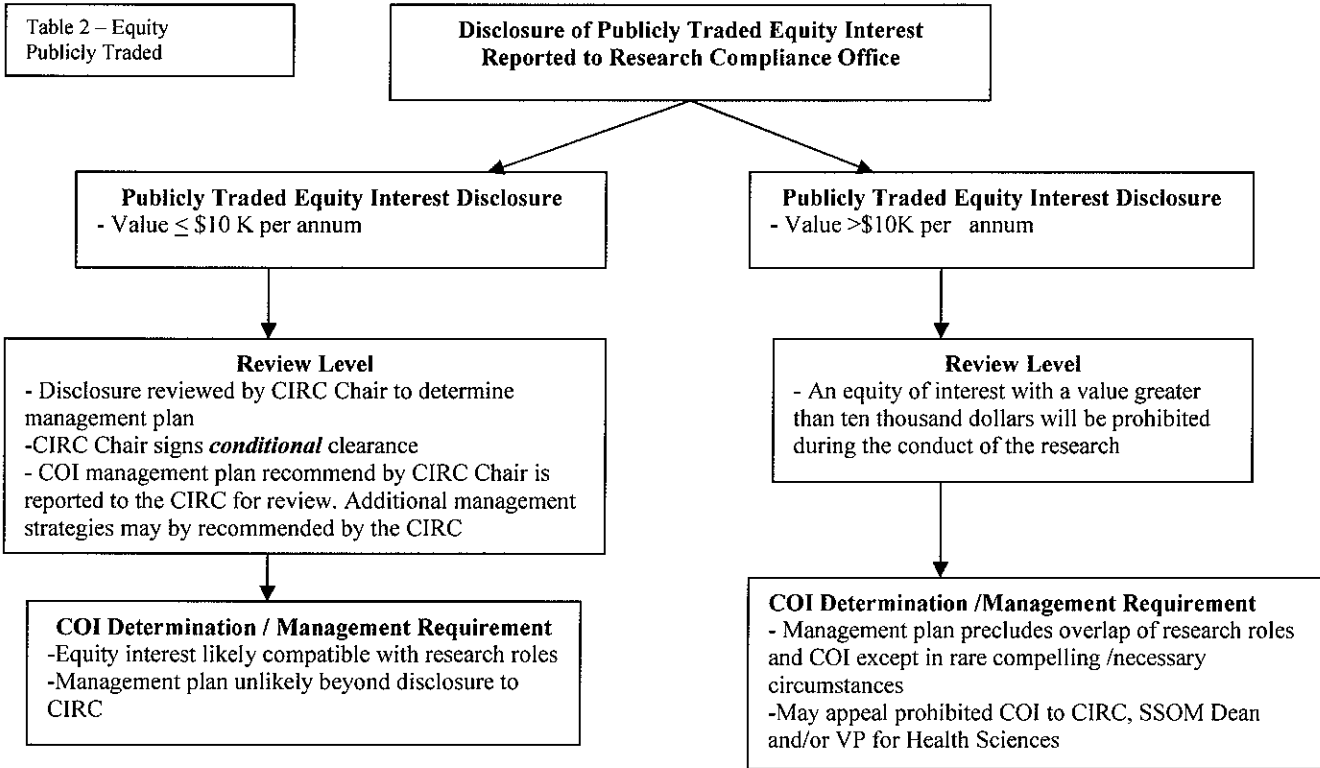
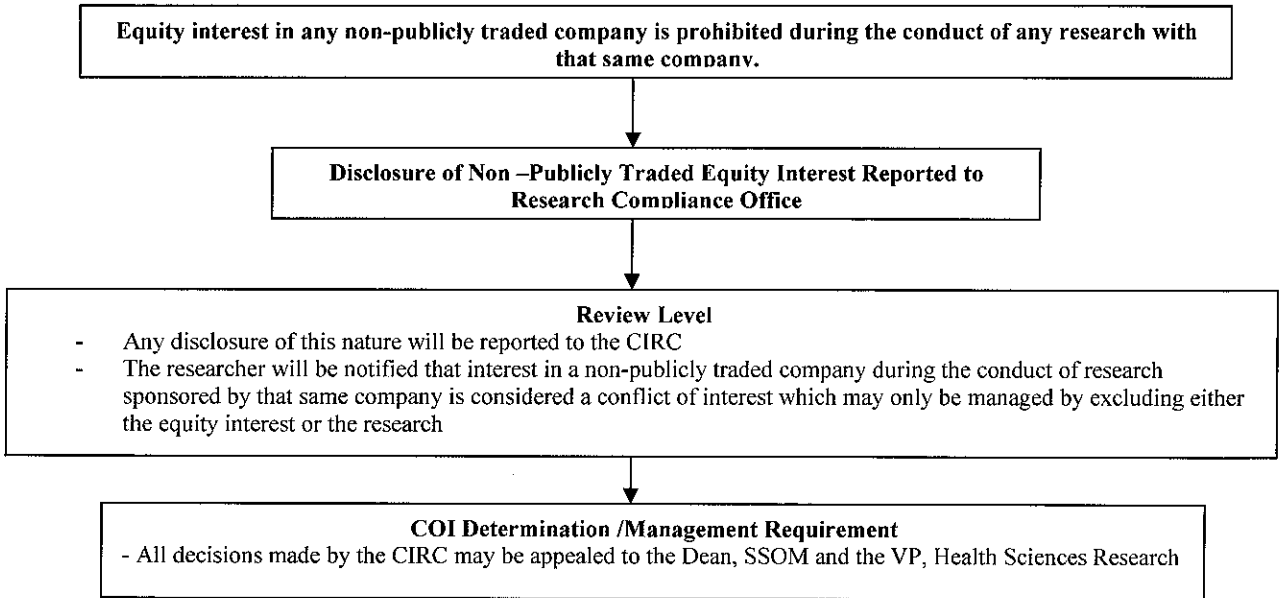


Table 3 – Equity Non-Publicly Traded



Appendix 2:

United States Department of Health and Human Service (HHS) Public Health Service regulatory requirements cover Institutional management of the financial interests of individual investigators who conduct Public Health Service supported research (42 CFR Part 50, Subpart F and 45 CFR Part 94). For more information you may go directly to the HHS final guidance document on financial relationship and interests involving human subjects @ <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>.

Examples for managing conflicts are located at 42 CFR 50.605(a), 45 CFR 94.5(a).

- a. PHS regulations require grantee institutions and contractors to designate one or more persons to review investigators' financial disclosure statement (45 CFR 50.604(b), 45 CFR 94.4(b). The PHS threshold for significant financial interest:
 - i. \$10,000/year income;
 - ii. Equity interests over \$10,000;
 - iii. 5% ownership in a company (42 CFR 50.603, 45 CFR)

Website references;

1. <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>
2. <http://www.fda.gov/oc/guidance/financialdis.html>