

The TJU Human Research Protection Program (HRPP) Part II, Conflict of Interest and IRB Noncompliance

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Conflict of Interest – Employees

- All employees must complete electronic disclosure yearly or more often if potential conflict arises
- The COI Committee decides if a conflict exists and determines required actions (management plan)
- In case of human subjects research possibilities are
 - Severance of relationship, divestiture or reduction of financial interest, or put \$ in escrow account
 - Public disclosure (publications, lectures, consent forms)
 - Modification of research plan
 - Disqualification from participation in all or a portion of the research
- COI Committee discloses investigator conflicts and management plan to IRB and IRB may accept/agree or may make requirements more but not less stringent
- Research conducted under provisions of the management plan is subject to ongoing monitoring for compliance

Conflict of Interest (continued)

- IRB members and consultants must declare actual or potential COI.
 - Current level for financial COI is \$5,000.00
 - Non-financial COI may result from personal beliefs, personal or institutional relationships, or career advancement
- If there is a COI, member or consultant must not be in the meeting room for the discussion of the project or the vote.

Noncompliance with human subjects regulations

- Noncompliance is a violation of any federal, state, or local regulation, or any university or IRB policy that governs human research
- Serious noncompliance may
 - Affect subject safety, increase risks to subjects, compromise the integrity of data, violate the rights and welfare of subjects, affect a subjects' willingness to continue in a study.
- Continuing noncompliance
 - Pattern of noncompliance that indicates a lack of understanding of regulations or ethical requirements – may be repeated similar incidents or series of different events.
- Reporting suspected noncompliance may be done by an employee or a research subject or subjects' family, caregiver, etc.
 - Director or Associate Director of OHR in writing or telephone
 - TJU Compliance hotline
 - Department Chair or University Ombudsman
 - May be initiated by the IRB or from findings of a QI/QA audit, or may be self-reported.

Noncompliance with human subjects research regulations (cont.)

- Possible noncompliance reports are assessed by the Director or Associate Director as to whether the allegation may represent serious or continuing noncompliance.
- If not serious or continuing the OHR leadership meets with the investigator and research team to devise and implement a corrective action plan. If the noncompliance is associated with a HIPAA infraction, a representative from Office of University Counsel attends the meeting.
- If Serious or continuing
 - The Director, DHSP appoints a Noncompliance Subcommittee consisting of the chair of the IRB that originally approved the protocol, a member of that IRB, the Director and/or Associate Director, DHSP, and a member of the Office of University Counsel.
 - An audit of the study file is performed by the DHSP Quality Assurance Team.
 - The Director sends written notice of the allegation to the researcher and requests a written response within ten (10) business days. The Subcommittee reviews the allegation of noncompliance, the response of the researcher, and any other pertinent information.
 - The Subcommittee may retain outside expertise for assistance.

- The investigation should be completed if possible within sixty (60) days after the allegation is received. At the conclusion of the investigation, the Subcommittee will make a recommendation to the appropriate IRB.

Possible recommendations include

- Dismissal of the allegation as unjustified or non-substantive,
- Due diligence where the violation of human subjects' regulations is administrative in nature,
- Corrective actions including increased oversight/monitoring, modification of the informed consent process, modification of the continuing review schedule, suspension of research or termination of research,
- Notification of current participants if information may affect their willingness to continue in the study or requirement that current participants re-consent to participation,

- Referral to the University Integrity Officer (Assoc. Provost for Research Support Services) for situations falling within the definition of scientific misconduct to be addressed under TJU Policy 110.02, "Responding to Alleged Misconduct in Research." In this event, the Vice President will notify the Dean of the appropriate College.
- The IRB will deliberate the recommendation(s) of the Subcommittee at its next convened meeting and votes to approve or disapprove the Subcommittee's recommendations or ask for further information or investigation. The researcher will be notified in writing of the outcome of the investigation as well as the IRB's requirements within (10) working days of the convened meeting.