Compliance Considerations Related To Clinical Trials

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Office of Compliance -- Overview

Our charge is to:

✓ Help USC faculty and staff understand and comply with the rules applicable to their work.
✓ Prevent and detect violations of laws or university policy.
✓ Promote ethical conduct as articulated in the USC Code of Ethics.
To accomplish our charge, the Office of Compliance:

- Performs periodic risk assessments
- Assists in the development of policies and procedures
- Provides training and education
- Conducts periodic assessments, monitoring, and auditing
- Investigates allegations of non-compliance and recommends corrective action when appropriate.

The Office of Compliance also oversees USC’s *Help and Hotline*, (213) 740-2500. You can call this number to obtain guidance or report suspected violations of law confidentially.
The HIPAA Privacy Rule

All USC employees, including researchers and research coordinators, have a legal obligation under the Health Insurance and Portability Act ("HIPAA") to safeguard and keep confidential health information they access in the course of performing research.

In practical terms, what does this mean?
The HIPAA Privacy Rule: Legal Requirements

✓ Generally, a written HIPAA Authorization must be obtained when conducting a research study using a subject’s Protected Health Information, or PHI.
✓ In limited circumstances, a HIPAA Authorization is not required, but only in instances where an authorization is not practicable to obtain (i.e. retrospective chart review where contacting former patients is impracticable/impossible. **Waivers require IRB review/approval!**
✓ A partial waiver may also be appropriate if access to PHI is only required to prepare a research protocol, and not to conduct the research itself.
✓ USC’s template HIPAA Authorization and other HIPAA forms may be found on the USC policies page at: [http://policies.usc.edu/p2admOpBus/hipaa.html](http://policies.usc.edu/p2admOpBus/hipaa.html)
✓ Any modifications to these forms require Office of Compliance review and approval.
The HIPAA Privacy Rule: How to Comply

✓ Obtain HIPAA training
✓ Ensure use of most current version of the informed consent and HIPAA Authorization forms as approved by the IRB.
✓ Verify that a research authorization has been signed by each research participant.
✓ If there is no research authorization, determine whether IRB has issued a waiver – if not, an authorization is required.
✓ Remember, a signed informed consent without a signed HIPAA Authorization is NOT sufficient.
Conflict of Interest in Research

✓ USC encourages its faculty, staff, and students to participate in meaningful professional relationships with industrial and other private partners.
✓ However, some of these relationships can create, or appear to create, conflicts of interest.
✓ Conflicts of interest do not imply any wrongdoing, but they must be disclosed promptly so that they can be reviewed and managed by the university in partnership with researchers and research staff.
Conflict of Interest in Research

Several USC policies address conflicts of interest:

- **Conflict of Interest in Research** policy: covers outside relationships by individual researchers related to research.
- **Institutional Conflict of Interest in Research** policy: covers research-related conflicts created by USC’s financial interests.
- **Relationships with Industry** policy: covers physician’s outside relationships with the pharmaceutical or medical device industry.
- **Conflict of Interest in Professional and Business Practices** policy: Covers general business and personal conflicts maintained by any USC employee (i.e., familial hires, USC business relationships with companies in which the USC employee maintains an ownership or consulting role).
Conflict of Interest in Research

With regard to individual research-related conflicts, the following types of outside activity must be disclosed:

- **Payments for service** (e.g., consulting, payments for service on a board or advisory committee) in excess of $5,000 per year.
- **Private equity interests** (e.g., stocks, stock options not publicly traded), regardless of value.
- **Public equity interests** of $5,000, except when held in an investment vehicle like a mutual fund.
- **Management roles** (e.g., director, officer, or similar position of significant decision-making authority).
Conflict of Interest in Research

How must conflicts be disclosed?

- First, the conflict must be noted at the proposal submission stage.
- Second, the conflict must also be noted in i-Star.
- Third, a complete conflict disclosure must be submitted through “diSClose”, (https://disclose.usc.edu), USC’s electronic system designed to allow for researchers to disclose potential conflicts related to their research.
- Your user name and password for diSClose are the same as your USC NetID and password.
- For assistance on how to use diSClose or make a disclosure, contact the Office of Compliance.
Conflict of Interest in Research

What happens after a disclosure is made?

✔ The disclosure automatically is automatically routed to the Office of Compliance.
✔ The Office of Compliance performs an initial assessment, and if a conflict is present, presents the disclosure to USC’s Conflict of Interest Review Committee (CIRC) at a monthly meeting.
✔ The CIRC reviews the disclosure and formulates a recommendation to the VP of Research on how to manage the conflict if appropriate.
✔ The VP of Research makes the final decision, which is communicated to the person with the conflict and the IRB.
✔ The Office of Compliance monitors compliance over time.
Conflict of Interest in Research

How do I follow USC’s policies on conflicts of interest?

If you are a researcher:

- Complete on-line conflict of interest training. ([https://www.citiprogram.org/](https://www.citiprogram.org/))
- Keep up to date records of all your outside relationships.
- Disclose any potential conflict promptly by noting it at proposal submission and in i-Star, and make a complete disclosure in diSClose.
- Cooperate in the Office of Compliance’s assessment.
- Follow any management plan put in place to manage conflicts.
- Seek guidance from the Office of Compliance if you are not certain whether a particular relationship creates a conflict.
Conflict of Interest in Research

If you are a research coordinator:

- Complete on-line conflict of interest training. (https://www.citiprogram.org/)
- Encourage investigators to promptly disclose outside relationships related to research in diSClose.
- Ask the investigator to complete the portion of the i-Star submission addressing conflicts of interest.
- Help ensure management plans are followed (e.g. when a management plan requires that informed consent be obtained by someone other than the conflicted investigator).
- If you have any financial interests that may create a conflict on a study, inform the investigator with whom you work.
Researchers may need to receive confidential or proprietary information from a sponsor/third party, including:

✔ Protocols, investigator’s brochure and written instructions
✔ Information that is not published
✔ Oral disclosures of confidential information
✔ Data from the study
Confidentiality Agreements and Clauses

Many times, this information is provided through via a confidential data agreement (CDA) or non-disclosure agreement (NDA). These agreements may be found within:

- A clinical trial agreement (CTA)
- Technology license
- Data sharing agreement
- Material transfer agreement (MTA)
Confidentiality Agreements and Clauses

CDA’s/NDAS:

✓ Will define the information that is to be protected
✓ May be one-way, or unilateral – for example, the sponsor may want to provide a researcher with information so the researcher can determine whether he/she wants to participate in the research
Technology license
✓ May also be two-way, or mutual – for example, both parties agree to exchange information and keep it confidential
✓ At USC, CTO reviews and signs CDA/NDA agreements related to the provision of confidential information.
Confidentiality Agreements and Clauses

Other confidential information related to clinical trials:

- Sponsor-provided Protected Health Information (PHI)
- Certificates of Confidentiality – NIH issued document to protect identifiable research information in sensitive areas of research (e.g., sexual attitudes or preferences, information related to the use of illegal drugs, genetic information. Certificates of Confidentiality -- OPRS Guidance.
Confidentiality Agreements and Clauses

Roles/responsibilities of research coordinators and researchers:

☑ Review the Guide to Confidentiality
☑ Determine whether confidential/proprietary information is to be provided
☑ Become familiar with all restrictions
☑ Work together to ensure necessary protections are in place
☑ Do not share confidential information outside USC, or inside USC to those not involved in the research
☑ Contact the Office of Compliance for guidance.
Questions?