Obligations to Protect Confidential Information
Industry-Funded Research

What is confidential information?

The key is the definition in the contract – Industry Standards.

- Written documents – protocol, investigator’s brochure, written instructions.
- Information that is not published and is being given by the company or their agent to you or the research staff.
- Oral disclosures – the content is such a reasonable person would recognize it as being private/confidential.
- It goes beyond scientific or medical information to marketing information, business strategy, software provided, etc.
- It usually includes the data from the study (which you have the right to use for your internal purposes and publication – but not full external disclosure).
What is generally not included in the definition?

- Information that is publicly known or that becomes publicly known without you or your staff being the ones that disclosed the information
- Information you or your staff knew before you received the information from the company
- Information that you developed before receiving the information from the company and you developed without knowing the company’s information
- Information a third party gave you and they had the right to disclose the information.
- The medical records of the patients and the investigator’s personal notebooks.
Types of exchanges of confidential information

**One-way**
- Primarily in company-initiated drug or device studies – the flow of proprietary information is from the company to the research staff
- Investigator-initiated studies – where the only contribution by the company is funding

**Two-way**
- Investigator-initiated studies – where the company is also providing the investigational device or drug. They will be providing proprietary information on their product.
- Company-initiated studies – where the investigator has a particular expertise or maybe a diagnostic technique, etc. that will be used.
Access to confidential information – the need to know

• Access limited to personnel who need the information to:
  – Perform the study (investigators, sub-investigators, data coordinators, etc.
  – Work with the patients
  – Work with ancillary groups (IRB and IACUC)

• DO NOT SHARE CONFIDENTIAL INFORMATION WITH INDIVIDUALS, INSIDE OR OUTSIDE USC, WHO DO NOT HAVE A “NEED TO KNOW”
Obligations of investigator and staff

• Before providing company-owned confidential information – advise the staff of the confidential nature and the obligation to not disclose the information to anyone else
• Make sure that the protocol and other confidential information is maintained in a secure place – similar to the security you would provide USC proprietary information
• Understand the duration of the obligation – generally ranges from 5 to 7 years after end of the study
• Keep a record of who you provided the information to on the staff.
Obligations of investigator and staff continued...

- Do not convey confidential information to others (in conversation, writing, presentation or any other form) inside the University, unless the recipient has a need to know the information.
- When confidential information is conveyed to someone inside the University ensure that person:
  - Has a need to know the confidential information;
  - Understands which information is confidential; and
  - Has read and understands these training materials.
- Never convey confidential information to persons outside of the University in any form.

- For further information, contact clinicaltrials@usc.edu
A Real Case: Michigan Professor

According to the SEC, after learning from Gilman that the results of clinical trial would fail to meet market expectations (but before such information was to be made public at the ICAD), Martoma, the portfolio manager of S.A.C. Capital and S.A.C. Capital’s head trader collaborated to sell (including to sell short) the Elan and Wyeth stock held by the CR Intrinsic and S.A.C. Capital portfolios, which resulted in approximately $275 million in combined profits and avoided losses for the portfolios managed by the advisers.

Based on this conduct, the SEC charged CR Intrinsic, Martoma and Gilman with violating Section 10(b) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 thereunder and Section 17(a) of the Securities Act. Without admitting or denying the SEC’s findings, CR Intrinsic agreed to pay $274,972,541 in disgorgement, $51,802,381.22 in prejudgment interest and a civil penalty of $274,972,541. [Association of Corporate Council, April 29, 2013]

Confidentiality is a critical responsibility of the investigator and study staff.