Guidance to Yale Principal Investigators on Reviewing Confidentiality Clauses

GCA asks you to review confidentiality clauses in order to determine whether you can accept the conditions imposed. GCA handles technical review, but you need to determine what you can accept operationally; whether you would be able to comply. You should use the following criteria in making the decision:

1. Make sure you clearly understand what will be confidential and what will not be. You don't want to promise confidentiality and then breach the contract because you didn't realize what information was confidential.

   Usually the clause says that all confidential information will be clearly marked. But sometimes the clause describes the confidential information, with phrases such as "the protein homologues" or "information told to you by the sponsor," and then you are expected to know what the sponsor wants kept confidential. Accept these only if they are truly unambiguous.

   a. Example of an acceptable clause: "*Confidential documents are those that are provided by the Company and labeled confidential, or information communicated verbally by the Company and followed up within 30 days with a written statement stating it is confidential.*"
   b. Example of a clause that you need to assess: "*The molecular structures of the precursor molecules are confidential."*
   c. Example of a vague clause: "*Your work relating to the second phase of work under this contract is confidential."* What is the "second phase"? What work "relates" to it. What information linked to that work is confidential?
   d. Example of a vague clause: "*The Materials are confidential.*" It is unclear what is confidential: the fact that you have the materials? something about the materials, such as a chemical formula?

2. Make sure that the confidentiality will not make it difficult to publish the results of your research. Watch out especially for any impact on student work. You can't risk a student losing the ability to complete and publish a dissertation (or other important academic work).
   a. Example: *If the structure of a molecule provided by the company is confidential, will you be able to publish your research without discussing that structure? If a clinical trial protocol is confidential, can you publish without discussing the protocol?*

3. Make sure you can actually keep the confidential information confidential. When you agree to confidentiality, you must segregate the covered data and documents. This may mean that you would need to keep even your own notes and print-outs confidential to the extent they contain confidential information. You would not be able to reveal the confidential information when you talk about your research with colleagues, students, or at departmental meetings.

a. Consider your notes: *Can you document your work without placing confidential information in places where it would be seen? Would it be reflected in the way you write up your data? Would you need the confidential information in your lab notebook?*
b. Consider your lab and office: *If you share laboratory facilities, you would need to develop protocols that ensure that confidential material is kept in a secure location, not accessible to other people in the facility. If a student works in your office, but not on this research, you would need to ensure the student has no access to any confidential notes, records, data printouts, protocol, etc.*
c. Consider your computer: *Would the confidential information appear on a computer screen? If so, are there others in the room who might see it (other than on a need to know basis)? How would you prevent that?*
d. Consider your IT system: *If the confidential information is stored electronically, how would segregate the files from access by others who use that computer system? If you use confidentiality and security measures for any of your information, you must use it for your confidential information, such as encryption or FISMA security.*
e. Consider other offices with which you work: *If you need to share confidential information with administrative offices, such as GCA, or EHS, do so only on a need-to-know basis. Mark the information as confidential, or tell them it is. Make sure you can comply with any additional steps required by the clause, such as obtaining written assurances from the person who gets the information.*
f. Consider the timelines: Can you maintain the confidentiality for as long as the other side is requesting?

4. Make sure you can maintain confidentiality on behalf of others, and after the research is concluded.
   a. Example: *Most confidentiality clauses require that the PI ensure confidentiality on behalf of everyone working on the project for years after the project is concluded. Make sure you have a written plan to make that happen.*

5. Does the confidential information have some conceivable military or national security use such that it might be export controlled? If so, notify the Director of International Agreements. You may need an export control compliance plan in order to be sure you are not violating criminal law. (Nonconfidential information at Yale is generally not subject to export controls).
   a. Example: *Testing a drug for efficacy against a potential biological weapon disease such as anthrax or polio might count as export controlled activity. Allowing foreign national students access to the research could constitute a criminal act.*

6. Review the provisions for what happens when your use of the confidential information terminates. If destruction of the information is required, would that harm your research record? Do you need to preserve copies for future uses, such as validation/verification?

last revised 3/22/2010

Guidance to PIs on Reviewing Confidentiality Clauses