OSP Preclinical Trial CDA Guidance

OSP understands that there are situations where there is an urgent need to execute a confidential disclosure agreement (CDA) with a potential clinical trial sponsor. CDA’s are sometimes also referred to as Nondisclosure Agreements or Proprietary Information Agreements and sometimes company Visitor’s Agreements are actually CDA’s with a different name. While only OSP has legal authority to sign a CDA on behalf of the UW, there is no policy prohibiting our faculty from signing a CDA in a strictly personal capacity.

A faculty member who signs a CDA is exposed to potential personal liabilities and if something goes wrong, the UW will not be obligated to provide representation. While OSP cannot recommend that faculty members personally sign CDA’s and OSP cannot provide personal legal advice for this purpose, below is some guidance on this topic, including a list of issues OSP commonly deals with in preclinical trial CDA’s. In addition, attached to this guidance is a reprint of information on this subject found in the UW Clinical Trials Handbook that is accessible through the School of Medicine’s Office of Research and Graduate Education website.

- A UW faculty member has no authority to enter into a CDA on behalf of the UW. If a faculty member desires to enter into a CDA personally, all references to the UW or anyone other than the faculty member must be deleted or stricken through.
- The length of the confidentiality obligation should be reasonable. A 3 to 7 year secrecy period is typical, but occasionally companies may insist on something longer.
- The scope and stated purpose of the CDA should be limited. A CDA should cover only a single named clinical trial, protocol or drug rather than possible additional future studies or other matters. If other study opportunities arise in the future, the faculty member can sign a new CDA for an additional study.
- The term of the agreement should be short (it usually does not need to be longer than 6 months to a year and can be shorter). The CDA term is different than the confidentiality period. Because the CDA should only cover a single trial or drug, there is no reason to have an open-ended or longer term agreement as the activity will occur over a short period of time.
- The sponsor should be required to mark or otherwise clearly designate what is considered confidential. Generally, this is not an issue with protocols, but there may be other product information that the sponsor should be required to mark if it wants it treated as confidential.
- CDA’s must have the usual and customary exceptions to confidentiality, including no confidentiality obligation with respect to information already known by the faculty member, information that is publicly known, or information that is independently developed by the faculty member without use of the information.
- The CDA will probably be clear that the company is not transferring any rights in its intellectual property (IP) under the agreement, but be sure that the CDA does not appear to transfer IP rights from the faculty member or UW to the company.
- The CDA should not contain any provisions indicating any kind of exclusive relationship with the company, any prohibition against working with another company, or any obligation to participate in the study.
- All restrictions must be carefully followed. Some sponsors may have requirements for use of encrypted email or sponsor systems for access, so strict adherence to the CDA is essential.
Best Practices for Handling the Confidentiality Agreement

When an industry sponsor first approaches you about a new clinical trial, ask whether the sponsor will require a confidentiality agreement.

If the sponsor requires a confidentiality agreement that includes the UW as a party to the agreement, encourage the sponsor to accept the standard UW pre-approved "Pre-Clinical Trial Nondisclosure Agreement" (NDA). Emphasize to the sponsor that this will minimize turn-around time and that the UW standard agreement contains typical provisions for the protection of both parties. Give the sponsor a copy of the standard UW agreement and follow these steps:

1. Ask the sponsor to complete the "Protocol" section on page three of the agreement, sign the agreement, and return it to you. Note that the terms of this standard UW agreement cannot be changed in any way. If changed, the agreement must be negotiated and signed by OSP.
2. Print your name and title, then date the agreement and sign on page three. Send or fax the agreement to your department chair (or division head, as appropriate), who has been authorized by memorandum to sign this standard agreement on behalf of the UW.
3. Make three copies of the signed, executed agreement. Deliver the original to the sponsor, keep one copy for your files, and send one copy to the clinical trials group at OSP.

The UW may have a pre-approved NDA. Check with OSP or your administrator to see if this sponsor has a pre-negotiated agreement. If the sponsor requires a confidentiality agreement that includes the UW as a party to the agreement but declines to use the standard UW pre-approved agreement, you and the sponsor have two choices:

1. Ask the sponsor to mail or fax its own standard agreement to you. Then, send the sponsor's agreement for institutional review, negotiation, and signature to the clinical trials group at OSP, or
2. Sign the sponsor's agreement on your own behalf only, making it very clear to the sponsor that you are not authorized to sign any agreements on behalf of the UW. Sign on your own behalf only if you feel that there is a strong reason to conclude an agreement on-the-spot and do so only after you have crossed out all references in the agreement to the UW, substituting your own name instead. Note the potential pitfalls discussed in the paragraph below, and remember that by signing such an agreement on your own behalf, you may incur personal liabilities that the UW will not cover.

Usually confidentiality agreements are straightforward; however, there are some potential pitfalls. For example, the agreement may be overly broad, going beyond the purpose of protecting against disclosure the sponsor's protocol and other confidential information. An overly broad confidentiality agreement may extend into matters such as:

- requiring confidentiality of the trial results,
- restricting your freedom to publish or gain access to data,
- requiring that you disclose your own confidential information to the sponsor,
- result in a loss of intellectual property rights,
- or may bind you for an excessive period of time.

Such provisions may also be inconsistent with the UW's policies and may expose you to legal risks contrary to your best interests. If you see such provisions in the sponsor's proposed confidentiality agreement, you should either decline to sign the agreement or you should revise or delete the provisions and then require that your revisions/deletions be initialed by the sponsor's authorized representative.