



Procedure Name: Legal Documents Routing Procedure
Effective Date: March 29, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: OCT-012
Application: Legal Documents Routing
Page: 1 of 3

OBJECTIVE:

The objective of this procedure is to define the process for routing Confidential Disclosure Agreements and sponsor contracts.

SCOPE:

This procedure applies to all proposed clinical trials governed by OCT

BACKGROUND:

There are two basic documents germane to every clinical trial agreement. The first document is the Confidential Disclosure Agreement, or CDA, and the second document is the contract with the sponsor.

The routing policies for both types of documents are essentially the same.

Prior to a Principal Investigator (PI) or anyone else examining a protocol for the first time, a CDA must be executed. Execution of a CDA legally binds the PI and other UNTHSC personnel not to disclose the contents of a protocol except on a need to know basis and forbids disclosure to any competitor of the sponsor. Since the consequences of violating this agreement can be severe to the HSC, the Legal Department must give prior approval to all language of the CDA.

Consequently, if a PI is interested in doing a trial based on the preliminary description provided by the sponsor, Legal must first approve and have Regulatory Affairs (RA) of the Office of Clinical Trials (OCT) negotiate the language of the CDA with the sponsor. Under no circumstances is a PI to independently initiate the execution of said agreement.

After CDA language is agreed upon with the sponsor and after the CDA itself is signed by both parties, then the PI is furnished with a copy of the protocol and the contract, with its proposed budget.

CONTROLLED COPY, Do Not Duplicate

**CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE**

UNT-HSC OFFICE OF CLINICAL TRIALS
Legal Documents Routing Procedure

OCT-012

Page 2 of 3

PROCEDURE – ROUTING CONFIDENTIAL DISCLOSURE AGREEMENTS:

1. The Clinical Research Coordinator (CRC) and/or the Clinical Study Administrative Coordinator (CSAC) will obtain an electronic copy of the sponsor's CDA and will send a copy of it to RA of OCT.
2. RA of OCT then emails the CDA to the Legal Department for approval. Should Legal require changes in the language, the CDA is sent back to RA so it can be returned to the sponsor with a request for the needed changes.
3. Once the sponsor has agreed to and signed off on any changes and sent the final version to RA, RA will prepare the Routing Sheet, route the document for signatures and then send the partially-executed, HSC-signed CDA back to the sponsor.
4. After the HSC-signed CDA is received by the sponsor, the sponsor will return a fully executed CDA to RA, who in turn will make copies for their files, for the PI/CRC/CSAC, and have the fully executed original delivered to Legal.

PROCEDURE – ROUTING CONTRACTS:

1. Once the CDA has been processed and fully executed, the sponsor will send a copy of the protocol and proposed contract to the RA Projects Manager.¹ If protocol and/or proposed contract are sent to the PI, the PI or his/her CRC and/or CSAC will forward it to the RA Projects Manager.
2. The RA Projects Manager emails the proposed contract to the Legal Department who inserts any needed language changes. Legal then returns the contract to RA, who in turn sends it to the sponsor to have the changes ratified.
3. When the sponsor reconciles the contract with HSC Legal's requirements and the budget with the Director's, the sponsor will send the contract to RA. RA will attach a routing sheet, notify the coordinator the contract is on its way, and deliver said contract to the coordinator and to no one else.
4. The coordinator is responsible for obtaining the signatures of both the PI and Department Chair. Once done, RA is notified to pick up the contract to deliver it to the remaining signatories.
5. All required signatures for the contract shall be obtained within one week of its receipt from the sponsor (unless one or more signatories are absent). If one or more signatory/signatories be absent for more than one week, then that signatory's/signatories' delegate(s) shall sign. If no delegate(s) has been named then the contract will be brought to the Director for further routing.

¹ Some sponsors may simply post their contracts on a website known as Interlink and expect research organizations such as the Health Science Center to download the contract.

CONTROLLED COPY, Do Not Duplicate

**CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE**

UNT-HSC OFFICE OF CLINICAL TRIALS
Legal Documents Routing Procedure

OCT-012

Page 3 of 3

6. After all required signatures are obtained, the contract is returned to RA.
7. RA makes a copy of the partially executed contract for its records and returns the original to the sponsor who then signs it, making the contract fully executed.
8. The fully executed contract is then returned to RA, who makes copies for the OCT Financial Manager, the coordinator, and for the file. The original is then delivered to Legal.

NOTES:

1. In shipping documents back and forth to the sponsor, overnight mail will always be used unless otherwise specified by the sponsor.
2. During Step (2) of above, the Director of Clinical will be negotiating the project budget with the sponsor. The agreed upon budget becomes an exhibit attached to the sponsor-ratified contract. Both the contract and the exhibit will then be routed for signatures.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-112	Replacement of “policy” with “procedure”; update of procedures and addition of change history.	MVWB

CONTROLLED COPY, Do Not Duplicate

**CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE**