

	Standard Operating Procedures
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Procedure Category:	Pre-Study Activities
Procedure CLN-02-02:	Study Contract Creation/Negotiations

Procedure Overview

This procedure describes the basic steps in creating a contract and negotiating the terms of the contract with the sponsor.

Responsible Individuals

Investigator; Qualified MICHHR personnel, and DRDA as applicable

Procedure

The following steps outline the contract creation process:

1. When a contract needs to be created, the investigator assembles all relevant information to be included in the contract. If a master contract exists, the new work is prepared as a task order under the existing master contract. If no master contract exists but the investigator has executed a contract with the sponsor in the past, the previous contract is used as a template for the new contract.
2. If the investigator has not executed a previous contract with the sponsor, a search is conducted to see if a previous contract has been executed with the sponsor by any other investigator. If so, the previous contract is used as a template for the new contract.
3. If no previous contract exists, a new contract is created. If the contract is to be developed by MICHHR, the standard study contract template is used as a guide and all appropriate sponsor and investigator information is inserted in the draft contract.
4. The DRDA reviews and approves the contract before it is forwarded to the sponsor. Any modifications requested by the investigator must be approved internally.
5. Any other modifications to the contract (other than names and addresses) need to be approved internally by MICHHR management prior to forwarding the contract to the sponsor for review.
6. Once a study contract is fully executed, original, signed copies are retained by the investigator, the MICHHR and the sponsor.

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Contract negotiations can occur on both internally-created contracts and externally-created contracts. The following steps outline the contract negotiation process:

1. If there's a need for negotiations on a proposed contract, the investigator and the MICHHR work together to negotiate with the sponsor.
2. All modifications to the contract need to be reviewed internally by the investigator, the MICHHR, and DRDA. If the modifications are acceptable to all, a revised copy is sent to the sponsor for review and signature.
3. If the modifications requested by the sponsor are unacceptable to the MICHHR, the investigator, or DRDA, the sponsor is notified that their requested changes are not acceptable. At this point an effort is made to reach a compromise that is acceptable to all parties. If the sponsor is unwilling to reach an acceptable compromise, the investigator, the MICHHR and legal counsel must assess the implications of the proposed contract and reconsider whether or not the contract is acceptable.

Documentation

The contract and supporting information serve as documentation for this procedure.

Deviation Approval

The Director, MICHHR or designee, must approve deviation from this procedure. The Director, MICHHR or designee, must store documentation of the deviation approval.

Procedure Author

Manager, Research Support Core

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