

What paperwork do I need with my contracts?

Draft*:

We ask that when possible, we see a copy of the contract while the protocol is being submitted to the appropriate IRB for approval. Our goal is to have negotiations completed by the time IRB approval is obtained so that there is no delay in finalizing the contract.

Under revised School of Medicine policies, we now ask that, for contracts requiring such paperwork, the Departments supply us with a goldenrod with all appropriate signatures and a draft budget at the time the draft is received.

Moreover, we need the following information if it applies to your contract:

- Multicenter study?
- Investigator-initiated?
- Phase I, II, III or IV?
- Clinical research?
- Basic research?

** Drafts may be defined here as a copy of a submitted contract of any type, for the sole purpose of reviewing the terms in advance of processing with paperwork needed for execution.*

Confidentiality Agreement:

- Confidentiality Agreement signed by Principal Investigator (two originals)

No other paperwork necessary unless there is no place for the PI to sign. In that case, we request an SP23 or other form for the PI to sign to indicate his or her knowledge and acceptance.

Clinical Trial:

- Proposal Approval Sheet (goldenrod)
 - Principal Investigator signs
 - Department chair signs
 - HIC approval (Form 310)
 - Conflict of Interest Form
 - Protocol (HIC protocol acceptable)
 - Drug study Questionnaire
 - UVA budget – 25% indirect cost rate applies
 - Clinical Trial Agreement signed by Principal Investigator (two originals)
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Consulting Agreement:

- Proposal Approval Sheet (goldenrod)
 - Principal Investigator signs
 - Department chair signs
- Conflict of Interest Form

- Consulting Agreement (two originals)
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Material Transfer Agreement:

- Material Transfer Approval form (incoming or outgoing material)
- HIC approval (Form 310) – if humans are involved (incoming material)
- Animal Care and Use Committee approval – if animals are involved (incoming material)
- Brief statement of work
- MTA signed by Scientist – (two originals)

Our [MTA agreement for outgoing material, incoming form](http://www.healthsystem.virginia.edu/internet/grants/MTAINTRO.cfm) and [outgoing form](http://www.healthsystem.virginia.edu/internet/grants/MTAINTRO.cfm) may be found on the Office of Grants & Contracts MTA page at this address:
<http://www.healthsystem.virginia.edu/internet/grants/MTAINTRO.cfm> .

Research Funding Agreement:

- Proposal Approval Sheet (goldenrod)
 - Principal Investigator signs
 - Department chair signs
 - HIC approval (Form 310) – if humans are involved
 - Animal Care and Use Committee approval – if animals are involved
 - Conflict of Interest Form – if industry sponsored
 - Statement of Work
 - UVA budget – DHHS negotiated rate, as of July 1, 2006 51.5% MTDC
 - Research Funding Agreement signed by Principal Investigator (two originals)
 - Also, Collaboration Agreements and other agreements that involve research other than clinical trials
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Memorandum of Understanding (Intent):

- Proposal Approval Sheet (goldenrod)
 - Principal Investigator signs
 - Department chair signs
- Memorandum Agreement (two originals)

These Agreements are generally preliminary to a contract and act to commit the parties to good faith negotiation of the final contract.