

Item 21.

**Form F Testing Agreement or Form G
Lab Study Agreement**

**FORM F TESTING AGREEMENT
OR
FORM G LAB STUDY AGREEMENT?**

Run the Lab Study Checklist to determine which intellectual property clause is appropriate for the study.

<http://www.utsystem.edu/ogc/intellectualproperty/labcheck3.htm>

**USE THE FOLLOWING IP SECTION FOR A LAB STUDY
AGREEMENT (FORM F)**

A. “Ideas, know-how, data (including study results), and other intellectual property generated under this Agreement shall be the sole and exclusive property of the employer of the author or inventing party and inventorship shall be determined in accordance with U.S. Patent laws.”

OR

If after performing the Lab Study Checklist you determine that your agreement is a true Testing Agreement, the following IP section can be used.

B. “All rights to any invention conceived and reduced to practice as a direct result of the performance of the work conducted under this Agreement [using the study drug -- delete if not applicable] in accordance with the protocol provided by Sponsor to Institution shall belong to Sponsor. Institution agrees to assign to Sponsor, at the request of Sponsor, the sole and exclusive ownership thereto, upon payment of costs by Sponsor, if any, incurred by Institution in the filing, prosecution, issuance and/or maintenance of any patent application or patent issuing thereon. Further prosecution and costs, if any, shall thereafter be borne by Sponsor.”

NOTE: USE OF THE CLAUSE INTENDED FOR TESTING AGREEMENTS IN A LAB STUDY AGREEMENT WILL NECESSITATE PROCESSING ON FORM G.

FORM F TESTING AGREEMENT OR FORM G LAB STUDY AGREEMENT?

- ❖ If PI is even slightly involved in creating the protocol, then the checklist will conclude that there is “a likelihood of invention.”
- ❖ It is a clear Testing Agreement with the default answers in the checklist, e.g., :
 - (a) the PI is NOT involved in developing the protocol; and
 - (b) there is NO flexibility in the protocol such that the PI will not be involved in an inventive way; and
 - (c) the PI will only be providing data to the Sponsor (not analysis of the data).
- ❖ With anything but a clear Testing Agreement, you may have a situation where :
 - (a) the PI is involved in developing the protocol; AND/OR
 - (b) the flexibility of the protocol opens up the possibility that PI could be involved in an inventive way; AND/OR
 - (c) the PI will be providing analysis of the data.

Transmittal Forms:

- i. A clear Testing Agreement – Form F (Paragraph “B” above)
- ii. A Non- Conforming Lab Study Agreement – Form G (Paragraph “B” above)
- iii. A Conforming Lab Study Agreement – Form F (Paragraph “A” above)

Possible Scenarios for a Form G Lab Study Agreement:

Scenario #1

- (a) the PI is involved in developing the protocol; AND
- (b) the flexibility of the protocol opens up the possibility that PI could be involved in an inventive way; AND
- (c) the PI will be providing analysis of the data.

Scenario #2

- (a) the PI is involved in developing the protocol; AND
- (b) the flexibility of the protocol opens up the possibility that PI could be involved in an inventive way.

Scenario #3

- (a) the PI is involved in developing the protocol; AND
- (c) the PI will be providing analysis of the data.

Scenario #4

- (b) the flexibility of the protocol opens up the possibility that PI could be involved in an inventive way; AND
- (c) the PI will be providing analysis of the data.

Scenario #5

(a) the PI is involved in developing the protocol.

Scenario #6

(b) the flexibility of the protocol opens up the possibility that PI could be involved in an inventive way.

Scenario #7

(c) the PI will be providing analysis of the data.

Lab Study or Testing Agreement --Red Flags to Help Identify A Contract That Suggests We May Be Functioning as a Commercial Lab

- ❖ Contract is very long (9 to 15 pages versus 3 pages)
- ❖ “Services” appears in title
- ❖ Recitals or equivalent provisions describe a Lab Service Agreement or a “work for hire” agreement ---> raises issues of relationship to our mission and Unrelated Business Income Tax (UBIT)
- ❖ Includes lengthy Compensation and Invoice Section – compare with our standard “Awards” paragraph
- ❖ Requires Lab Visits and stringent Right to Inspect
- ❖ Includes lengthy Quality Assurance Section
- ❖ Includes Retention Schedule for retaining data and samples at the component (basically forever) – too burdensome
- ❖ Identifies us as a Storage/Archival Facility
- ❖ Patents and Inventions Section gives all inventions to Sponsor – when the checklist would suggest that we probably need what’s ours is ours, what’s yours is yours and what’s joint is joint
- ❖ Includes lengthy University Indemnification Section
- ❖ Publication Section may be missing or may give Sponsor the right to ‘approve’ publication
- ❖ Includes lengthy force majeure section
- ❖ Includes stringent FDA Review and Reporting Section or Information and Support Section – obligates us to provide testimony, services, reports, etc.
- ❖ Includes long Statement of Work
- ❖ Includes Retest Criteria or Performance Standard or Warranty of Results Sections
- ❖ Includes provision where we refund their \$\$\$ if . . .
- ❖ Includes an Insurance Section

work/RedFlag