

Item 7.

Publication Concerns & Pitfalls

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How to Correct Publication Problems ~ Use Your Hierarchy of Options

First Option ~

Delete the entire clause and replace with a UT standard clause.

Second Option ~

Carefully review and edit Sponsor's clause to bring it into conformance.

Potential Problem	How to Fix the Problem
Clause gives Sponsor the right to approve our publication	Replace 'approve' with 'review and comment'
Clause gives Sponsor unlimited or unreasonably long time to review publication	Add time limits to the clause ~ 30-60 days (if Sponsor insists on a longer review period, discuss this your PI)
Clause gives Sponsor the right to delay publication to protect IP rights BUT does not specify length of delay	Specify length of delay ~ 30-90 days is okay – agree to longer times for delay only under special situations
Clause gives Sponsor the right to publish a joint publication before Institution can publish	Add time limit that Sponsor can delay our right to publish results (12–24 months is acceptable from the completion of UT's part of the study (first choice) or from the end of the entire study (second choice))
Clause, ANYWHERE in the agreement, gives Sponsor ownership of the study results	Insert a cross-reference to UT's right to publish the results at the place in the agreement ~ "Subject to Institution's right to publish ..."
Clause in Confidentiality Section makes study results confidential	First Choice – delete the sentence that makes the results confidential. Second Choice – cross-reference UT's right to publish the results.

PUBLICATION

By Susan E. Ramsey, UT Health Science Center at Houston

How to identify and deal with potential publication problems.

I. Check Sponsor's Publication Clause for Potential Problems:

- A. Provision giving Sponsor a right to approve University's publication. (B.1)
- B. Provision giving Sponsor unreasonable amount of time to review publication. (B.2)
- C. Provision giving Sponsor a right to further delay publication to protect Intellectual Property without a specified time limit. (B.3)
- D. Provision giving Sponsor a right to publish a joint publication before University may publish Study results. (B.4)
- E. Provision, any where in the agreement, that gives Sponsor ownership of Study data or results. (B.5)
- F. Provision, in Confidentiality Section, that makes Study data or results confidential.(B.6)

II. Two Ways to Correct Publication Problems:

- A. Delete the whole clause and replace with UT standard publication clause.
- B. Carefully review and edit Sponsor's clause:
 - 1. Strike all provisions that give Sponsor a right to approve publication.
 - 2. Limit Sponsor's time for review of publication, (30 – 60 days delay is generally acceptable, any thing beyond that you should check with PI).
 - 3. Add time limit to Sponsor's right to delay publication to protect patentable inventions, (30 – 90 days delay is general acceptable, any thing beyond that you should check with PI).
 - 4. Add time limit to Sponsor's right to delay UT's publication until joint publication is publish, (18 to 24 months is generally acceptable, from the finish of UT's part of the study (preferred) or from the end of the entire study).
 - 5. Insert a cross-reference to UT's right to publish the Study results, "Subject to Institution's right to publish the results of the Study as set forth in Section ___.
 - 6. Strike all provisions that reference Study data and results as confidential. If you can not strike Study data and results, cross reference UT's right to publish the Study results.

PUBLICATION DRAFTING TIPS

I. Publication

- Preserve inviolate the absolute right of the Institution (PI) to publish the results of the study.
- There are UBIT implications if we are just performing laboratory work for commercial entities.
- Keep delays for review to a reasonable limit.
- If the study is multi-site, try to preserve the right of the Institution (PI) to publish separately if, after a reasonable time, multi-site publications have not been forthcoming.
- Make sure that the right to publish is properly cross-referenced in confidentiality provisions and in any provisions establishing ownership of data.
- Remember that the owner of the copyright in publications pursuant to UT System Policy will be the PI, so Institution cannot give away licenses to or other rights in the PI's publication.
- Use the Problem-Solver Checklist

II. Cross-Reference Examples

A. In Confidentiality or Ownership Provisions

1. Investigator shall have the right to obtain and use the data and results in order to publish the Study results as set forth in Publication Section __, above.
2. , or as permitted by Article __ (Publication) of this Agreement.
3. ,subject to the publication rights set out in Section __ below.
4. copyrightable work created in connection with the performance of the Study (*except any publication by the Principal Investigator as provided for hereafter*) shall be considered a work made for hire, whether published or not, shall be property of the Sponsor.
5. data which is generated as a result of this Study shall be considered confidential. The preceding obligation shall not apply to data or information (1) *which is published in accordance with paragraph C (Publication) of this Article* (2)

...

6. Institution and Investigator shall have a non-exclusive, non-transferable, non-assignable permanent license to use such Research Data for the sole purpose of preparing a scientific or academic publication or presentation of the Research in accordance with this Agreement. Institution and Investigator may not otherwise disseminate, license, or use or authorized other parties to reference the Research Data.
7. Institution shall have the right to obtain and use the data and results in order to publish the Study results as provided in Article _ below, for continuing academic research purposes and for the treatment and medical care of any Study subject.

B. In Publication Provision

Sponsor shall identify any Confidential Information to be removed from such publication, (1 or 2 below)

1. *(provided that the results of the Study shall not be deemed to constitute Confidential Information for purposes of publication hereunder).*
2. *(other than Study results)*

PUBLICATION

University shall have the right at Sponsor's discretion to release information or to publish any material resulting from the Research. University will furnish Sponsor with a draft copy of any proposed publication thirty (30) days in advance of proposed publication date. Sponsor agrees to limit circulation and use of such material to internal distribution within Sponsor and agrees that such distribution will be solely for the purposes of approval unless otherwise agreed in writing by University. Sponsor may request University of delay publishing such proposed publication for a maximum of an additional 180 days in order to protect the potential patentability of any Inventions described therein. Such delay shall not, however, be imposed on the filing or publication of any student thesis or dissertation.

REVISED PUBLICATION

(2 different examples of revised language)

1. *(to correct problems and to simplify language)*

University shall have the right at Sponsor's discretion to release information or to publish the results of any material resulting from the Research. University will furnish Sponsor with a draft copy of any proposed publication thirty (30) days in advance of proposed publication date. Sponsor agrees to limit circulation and use of such publication material to internal distribution within Sponsor and agrees that such distribution will be solely for the purpose s of approval unless otherwise agreed in writing by University to review and comment on such publication. Sponsor may request University to delay publishing such proposed publication for a maximum of an additional 60 ~~180~~ days in order to protect the potential patentability of any Inventions described therein. Such delay shall not, however, be imposed on the filing or publication of any student thesis or dissertation.

2. *(to correct problems, only)*

University shall have the right at Sponsor's discretion to release information or to publish the results of any material resulting from the Research. University will furnish Sponsor with a draft copy of any proposed publication thirty (30) days in advance of proposed publication date. Sponsor agrees to limit circulation and use of such material to internal distribution within Sponsor and agrees that such distribution will be solely for the review and comment of such publication ~~purposes of approval~~ unless otherwise agreed in writing by University. Sponsor may request University to delay publishing such proposed publication for a maximum of an additional 60 ~~180~~ days in order to protect the potential patentability of any Inventions described therein. Such delay shall not, however, be imposed on the filing or publication of any student thesis or dissertation.