Publication Concerns & Pitfalls

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 give Sponsor the right to approve our publication	Replace 'approve' with 'review and comment'
Clause gives Sponsor unlimited or unreasonably	Add time limits to the clause ~ 30-60 days is okay
long time to review publication	(if Sponsor insists on a longer review period, discuss this with your PI)
Clause give Sponsor the right to delay publication	Specify length of delay ~ 30-90 days is okay – agree
to protect IP rights BUT does not specific length of delay	to longer times for delay only under special circumstances
Clause gives Sponsor the right to publish a joint	Add time limit that Sponsor can delay our right to
publication before Institution can publish	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, give Sponsor	Insert a cross-reference to UT's right to publish the
ownership of the Study results	results at the place in the agreement ~ "Subject to
	Institution's right to publish"
Clause in Confidentiality Section makes study	First Choice – delete the sentence that makes the
results confidential	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, anywhere 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, anything 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 generally acceptable, anything beyond that you should check with PI).
 - 4. Add time limit to Sponsor's right to delay UT's publication until joint publication is published (18 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 cannot 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 multi0site, 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 fo 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

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iuc	intiality of Ownership Frovisions
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 the property of the Sponsor.
5.	Data which is generate3d as a result of this Study shall be considered confidential. The preceding obligation shall not apply to data or information (i) which is published in accordance with

Paragraph ___ (Publication) of this Article ____.

- 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 authorize other parties to reference the Research Data.
- 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)

- (provided that the results of the Study shall not be deemed to constitute Confidential Information for the 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 to 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 <u>publication 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 to review and comment on <u>such publication</u>. Sponsor may request University to delay publishing such proposed publication for a maximum of an additional <u>180_60</u> 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.</u>

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 180 60 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.