

Grants and Contracts	
No.	_____
Date	_____

University of Colorado Health Sciences Center Principal Investigator's Request for Publication Variance

Background:

From time to time, the University of Colorado is asked to enter into clinical trial agreements that contain concessions regarding publications that limit the ability to publish. Academic freedom is essential to the mission of the University. "Academic freedom is defined as the freedom to inquire, discover, *publish*, and teach truths as the faculty member sees it, subject to no control or authority save the control and authority of the rational methods by which truth is established."¹

According to University policy, when principal investigators are not able to freely publish, they are conducting **Classified Research** defined as "industrially sponsored proprietary research for which the sponsor requires a delay in publication in excess of 6 months."² Excluded under the Classified Research policy are **Routine Testing Services** defined as "...activities requiring University expertise and university health care facilities for technical measurement, analysis, observation, or evaluation in a controlled clinical setting. Testing services such as these that do not lead to publishable information are excluded from the classified research policy."³ (Clinical trial research that does not fall within the exclusion and for which publication issues cannot be negotiated with the Sponsor, require special approval of the President of the University of Colorado.) "University research projects for which the sponsor requires a delay in publication of the results in the open literature in excess of six months from the date of submission of the final project report to the sponsor are considered classified."⁴

Before Grants and Contracts can accept more restrictive publications language (in excess of a 6 month delay), review and input from the Principal Investigator, the Department Chair or Unit Head, and the Dean is required. Please complete the following information and required signatures before submitting to Grants and Contracts.

Request for Variance:

Principal Investigator Name: _____
Sponsor Name: _____
Agreement Title: _____

1. Publication delay requested by Sponsor includes: Initial Review: _____ months Publication/presentation delay: _____ months
2. Does the work being performed on the study fall within the definition of **routine testing services** stated above?
 Yes (If yes, please explain: _____)
 No (If no, variance will not be approved)
3. If clinical trial, what phase is this? Phase I Phase II Phase III Phase IV. Variance requests will only be granted for research when it can be documented that it is routine testing.

Certification:

As Principal Investigator, I understand that the limitations on publication rights specified in the Agreement extend beyond what normally is accepted. I understand that the limitation on publication under routine testing services normally deems the study taxable since this work is as defined a "work for hire". I also acknowledge full responsibility for informing all investigators involved or who become involved with the study that the ability to publish in a timely manner is being waived. I request that the University accept these concessions and I agree to abide by them. I am making this request because I believe that (check all that apply):

- _____ I have no interest in publishing in this area.
- _____ The probability of a publication arising under this Agreement is very low.
- _____ This Agreement constitutes personal consulting.
- _____ Other (please specify): _____

Approval Signatures:

Principal Investigator: _____ Date _____

Department Chair/Unit Head: _____ Date _____

Dean: _____ Date _____

¹ Source: University of Colorado Faculty Handbook, Academic Freedom, pg. V-1.
²⁻⁴ Source: University of Colorado Faculty Handbook, Classified Research, pg. V-6 and V-7.