

UIHC COI Consulting Agreement Issues

Individual Capacity:

The agreement should be clear that the consultant is entering into the agreement in his/her individual capacity and not as an employee or agent of, or in any way acting on behalf of, the UI. Usually in the introductory paragraph of the contract it will state something to the effect of “This agreement is made by and between [Company] and [Consultant].” Add the following language after the consultant’s name:

...and [Consultant], in his/her individual capacity and not as an employee or agent of the University of Iowa.

No University Signatory or Acknowledgement:

Again, since this is a personal consulting agreement, the University is not and should not be a party to the contract. If the contract contains a signature block for a University official, remove it. Also, some companies’ contracts ask for an acknowledgement signature from a University official (“Acknowledged by”); this should be removed as well.

Term:

Agreement must be time-limited (e.g. one day, one month, one year, three years, etc.). No Evergreen contracts that automatically renew.

Compensation:

Must state all forms of compensation being paid to consultant including, but not limited to, fees/payments, expenses that are paid or reimbursed (e.g. hotel, air/ground transportation, meals, materials, etc.), shares/ownership interests in the company, etc.

Services:

The services being provided by the consultant must be specifically described in detail in the contract. What is the product, what is the topic of the educational presentation, what is the focus of the advisory board, etc.

Note: An agreement to participate in/conduct a study does not belong in a personal consulting contract.

Amendments/Modifications:

Usually the contract will state that it can only be modified or amended by a written amendment signed by both parties. Since COI policy requires DEO/COI Office approval of all consulting contracts, any amendment/modification to an existing contract also must be approved to ensure that the addition/deletion/revision of the terms are still in compliance with COI policy. Add the following language (or language similar in nature):

...subject to Consultant obtaining prior approval of any such modification or amendment from the University as his/her employer during the term of his employment with the University.

Additional Services:

Some contracts state that the consultant will provide a specific service, but also that the consultant may provide additional services in the future as requested by the company and as agreed upon by the parties. Again, since DEOs have to approve the services being provided and COI policy requires the services to be described in the contract, this must be revised to include the following language (or language substantially similar):

Any additional services are to be determined by mutual agreement between Consultant and the Company and must be set forth in writing in an Addendum to this Agreement signed by the parties. Consultant must obtain prior approval of the Addendum from the University of Iowa as his/her employer during the term of his/her employment at the University prior to execution by the parties.

Publicity/Disclosure:

Some contracts prohibit consultant from disclosing information regarding the nature of the contract and services. If applicable, add the following language:

Company acknowledges that Consultant is required to disclose to the University of Iowa (“University”), pursuant to University policy, the terms and conditions of this Agreement and that upon doing so, the University will make publicly available (including, but not limited to, on the UI Health Care public website) the fact that this consulting relationship exists by referencing the [insert company name] company name, the general type of consulting services provided by Consultant, and the amount of compensation paid to Consultant pursuant to this Agreement. [Optional-include if contract addresses marketing/promotion: Company agrees that such public disclosure is not considered to be marketing or promotional in nature or effect].

Company Use of Consultant’s/Consultant’s Employer’s Name:

Company may use Consultant’s name, and in doing so may cite the consultant’s relationship with his/her employer, so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of Company or of any Company program, product, or service.

Content/Control of Publications/Presentations/Literature:

If the services provided involve presentations, preparation of written materials, etc., include the following language:

With regard to all Services provided by Consultant, Consultant shall have control over the content of his contribution to any written materials to be used in any publications, abstracts, manuscripts, reports, presentations, training materials, meetings, symposia, seminars, conferences, or similar form or forum. Consultant shall ensure the content is accurate, fairly balanced and not misleading. Any written materials prepared by and/or attributed to Consultant must be his/her original work. Company shall not revise the content of Consultant’s written materials without obtaining prior approval from Consultant. Consultant shall not promote Company products at any time. Consultant shall disclose to all attendees of any presentation that is given by Consultant pursuant to this Agreement that Consultant is being compensated by Company for the presentation and his/her expertise.

Some contracts involve presentations and/or preparation of written materials regarding the company's product(s). If so, the contract might contain the following language, which is okay as long as the UIHC language directly above is also included.

All presentations regarding the Products must be consistent with the Products' FDA approved indications, including, without limitation, representations regarding their use, safety and effectiveness and/or actual or potential clinical outcomes. All presentations must be accurate, fairly balanced and not misleading. Company reserves the right to review and/or request revisions of all materials, handouts and/or visual aids, with regard to the above, prior to their distribution or use at a Company meeting or presentation.

OR

Consultant will prepare written surgical techniques, articles, abstracts, poster exhibits, written review of relevant articles from the general scientific literature and other such information ("Literature") regarding FDA approved uses of the Products. All Literature must be submitted to the Company for Company's prior written approval, to ensure Literature is consistent with the Products' FDA approved indications, including, without limitation, representations regarding their use, safety and effectiveness and/or actual or potential clinical outcomes. Company, at its option, may submit such information for publication in the general scientific literature or use at professional association meetings.

Ownership/Assignment of Intellectual Property (IP):

If the contract addresses ownership and/or assignment of intellectual property, which includes, but is not limited to, information, data, developments, inventions, ideas, discoveries, innovations, patents, work product, etc., then the following paragraph MUST be included (this paragraph can be found on p.4 under the "What can I do?" section of the memo regarding "Information for University of Iowa Faculty on Outside Consulting Activities"):

Start using as of 2/11/2011 (per Grainne Martin and Jordan Cohen, , the UI has developed the language that needs to be in any consulting contract that assigns IP and we won't negotiate any changes to that language.)

Consultant may enter into this Agreement with Company and consult with Company as contemplated herein, so long as such activity is not inconsistent in any way with any applicable University policy. Specifically, Consultant agrees that in performing this Agreement, s/he will not use any University resources, including, but not limited to, University time, funding, equipment, resources, personnel, information, or materials in any manner inconsistent with applicable University policies. In addition, Consultant confirms that the work to be performed under this Agreement is not within the scope of his/her employment with the University. Company acknowledges that any such use of University resources by Consultant and/or any intellectual property rights or obligations that arise from Consultant's scope of University employment will render ineffective any assignment of intellectual property rights (and licenses/licensing) provided for by this Agreement. Company further acknowledges that nothing in its Agreement with Consultant will supersede any obligations Consultant has to the University as his/her employer.

Here is some wording that may clarify the IP para, and may be added:

By entering into this Agreement with Consultant, Company does not, in any way, grant Consultant or University any rights in Company's intellectual property or other proprietary rights or information. Neither Consultant nor Company anticipates that any intellectual property will arise out of the performance of the Services by Consultant. Consultant agrees to execute all necessary documents or take such other actions as the Company may reasonably request in order to perfect any and all such rights.

Consultant represents and warrants to Company that (i) the Services to be performed under this Agreement are not inconsistent in any way with any applicable University policy; (ii) will not involve the use of or reference to any University time, funding, equipment, resources, personnel, information or materials; (iii) are not within the scope of Consultant's employment with the University; and (iv) that none of the obligations of Consultant under this Agreement conflict with the obligations of Consultant to the University.