

German Uranium Miners Cohort Study Information on Declaration of Conflict of Interest for Proposal Submitters

Public and occupational health considerations have a primary importance in analysing the data of the German Uranium Miners Cohort Study. To achieve this goal, the German Federal Office for Radiation Protection (Bundesamt fuer Strahlenschutz, BfS) makes the data set of this study (the Data Set) available to interested and competent researchers for further evaluation. Measures need to be taken to ensure that the best possible assessment of scientific evidence gathered from the Data Set is achieved. Thus, to assure the technical integrity and impartiality of BfS' work, it is necessary to avoid situations in which financial or other interests might affect the outcome of that work. In making the Data Set available to others, BfS is advised by an International Advisory Board. Its composition is made public on the BfS homepage (<http://www.bfs.de/en/www/bfs/forschung/Wismut>) or can be asked for directly at BfS (e-mail: wismutstudies@bfs.de)

Each individual or group who submits a proposal for analysing the Data Set is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in commercial entities. "Commercial entity" refers to any company, association (e.g., trade association), organisation or any other entity of any nature whatsoever, with commercial interests.

In addition, based on the fact that both underground occupational exposures and tobacco consumption are risk factors for lung cancer, it is considered relevant for BfS to know whether experts working with the Data Set have, or have had, any relationship with any part of what may be called "the mining industry" on the one hand or "the tobacco industry" on the other. Nevertheless, declaration of such an interest would not necessarily be considered a reason to disqualify an expert.

What is a conflict of interest?

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. Furthermore, any interest that may raise the *perception* of conflict of interest or bias should also be considered to represent a potential conflict of interest and be reported.

Different types of financial or other interests, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged. The following list, which is not exhaustive, is provided for your guidance. For example, the following types of situations should be declared:

1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in—or otherwise related to the subject-matter of—the work;
2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);
3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject-matter

of the work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;

4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject-matter of the work;
5. payment or other support covering a period within the past 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this Declaration: Please complete this Declaration and submit it together with the proposal. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest are required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome: The information submitted by you will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in (i) you being asked not to conduct the proposed analysis, or (ii) if deemed by BfS and the International Advisory Board to be appropriate to the particular circumstances, and with your agreement, your interest being publicly disclosed.

Information disclosed on this Form may be made available to persons outside of BfS and the International Advisory Board only when the objectivity of the work has been questioned by BfS or any member of the International Advisory Board, and then only after consultation with you.

