

## Conflict of Interest

*This Appendix is also available in Dutch and can be requested by sending an email to [tki@health-holland.com](mailto:tki@health-holland.com)*

According to Articles 28.d and 29.c of the Framework, applicable to the PPP Subsidy regulation, research organisations are to receive a remuneration equivalent to the market price for the intellectual property rights arising from their activities during the course of a project. The absence or inadequacy of agreements pertaining to a remuneration based on the market price, leads to the indirect granting of state aid to the participating private parties.

'A remuneration equivalent to the market price' creates a best-effort obligation between the parties involved. It means that the research organization and the participating private parties must make an effort to negotiate this remuneration on so-called 'arm's length' terms. Arm's length conditions mean that the terms of the remuneration do not deviate from those which would be agreed upon in a private setting, between independent parties. Any transaction resulting from an open, transparent and non-discriminatory procedure will be deemed to comply with the arm's length procedure.

Every project has the potential for a conflict of interest between the research organization and one or more private companies. A conflict of interest can exist on a personal level or on an organizational level. The presence of a conflict of interest means that the arm's length conditions are potentially not met. Promptly upon identification of an objective conflict of interest, the consortium and Health~Holland should be notified. A pertinent example is when the director of a participating company, also has an employment relationship with the participating research organization.

Potential COI can arise in multiple ways, including but not limited to:

### *Individual potential COI*

- Does the Principal Investigator in the Project have any financial interest in (one of) the industrial participant(s)? If so, how many shares, options and/or other financial benefits do you (or your relatives) have rights to?
- Does any other Institutional investigator involved in the Project have any financial interest in the industrial participant(s)? If so, how many shares, options and/or benefits do you (or your relatives) have rights to?

Examples of financial interest may be: the PI or its direct family member have shares, options and/or other participation in any of the Industrial participant(s); the PI receive benefits from patent applications licensed to the Industrial participant(s) or is an inventor listed in any patent application licensed or filed by the industrial participant(s) directly or indirectly related to the subject matter of the Project application.

- In the last 12 months, did any commercial entity or any of the entities that are participating in the Project paid for or reimbursed you (or your employer) for consulting services, salaries or otherwise? If, so does such payments exceed €10.000 per year? If so, will the company benefit from the outcome of the Project?

### *Institutional potential COI*

To the best of your or your Consortium Partners' knowledge

- Are any of the Consortium Partners in the Project affiliated or associated with another Consortium Partner in the Project? If so, how?
- Does any Consortium Partner have directly or indirectly any shares, options and/or any other participation in another Consortium Partners despite of not being an affiliated entity? If so, how many shares, options and/or participations?
- Or, if the financial interest as stated in the two points above does not apply, would a Consortium Partner exercise any control on any of the other Consortium Partners' decision making? If so, how?
- In the last 12 months, did any commercial entity or any of the entities that would be a Private partner in the Project paid for or reimbursed any sponsored research or services to the Research Organization(s) to the same research group(s) involved in the Project? If, so does such payments exceed €10.000 per year? If so, will the company benefit from outcome of the Project?

Health~Holland will not subjectively assess the conflict of interest. Health~Holland will assess whether the performance of the consortium will be hindered or compromised by the existence of such potential conflict of interest. Health~Holland will therefore require full transparency if and when an objective conflict of interest arises or is likely to arise. 'Objective' means that potentially, a conflict of interest can occur, regardless of whether a party or person can derive any benefit or disadvantage from it.

It is up to the parties concerned – and in particular the directors of the participating companies – to recognize, interpret and report such an objective conflict of interest. This obligation to report may already exist at the time of the Match Call application being made. And thus, a notification should be made upon submission of the Match Call application.

Such a notification must be accompanied by the response to the following questions:

- What are the motivations to indicate the presence of a conflict of interest?
- Has the director concerned weighed up the interests?
- Has the potential conflict of interest been adequately addressed?
- Is there a transparent procedure in place to ensure that the director can abstain from involvement in certain decisions (which may involve a conflict of interest)?
- How are the arm's length conditions adequately met?
- Has the director provided for the involvement of other researchers who can make these decisions without bias?
- Can the director involve his or her fellow director(s) in the decision-making process and is it possible in the management relationship for the director concerned to abstain from taking management decisions (four eyes principle)?

The duty to provide adequate answers to the above questions rests exclusively with the consortium parties involved. This means that the consortium parties involved have the duty to assess whether and to what extent the potential conflicting of interest has been adequately addressed and whether they are satisfied with the precautionary measures that the director(s) concerned have taken.

If, as a result of a conflict of interest, situations occur that violate the arm's length conditions, the (consortium) parties involved are liable for the resulting damage. Such damage may include the consequences of establishing that indirect state aid has been granted to one or more participating undertakings.

For the sake of completeness, Health~Holland recommends involving legal support from the consortium partners, preferably from the research organization, in order to adequately address a potential conflict of interest.