

Appendix G: Conflict of Interest

This Appendix is also available in Dutch and can be requested by sending an email to tki@health-holland.com

1. Introduction and Legal Framework

According to Articles 29.d and 30.c of the Framework, applicable to the PPP Subsidy regulation, research organisations must receive remuneration equivalent to the market price for the intellectual property rights generated during the 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 industrial parties.

'Remuneration equivalent to the market price' entails a best-effort obligation for the parties involved. It means that the research organisation and the participating industrial parties are expected to actively negotiate this remuneration on so-called 'arm's length' terms – conditions that reflect what would reasonably be agreed upon between unrelated parties in a competitive, commercial setting. Any transaction resulting from an open, transparent and non-discriminatory procedure will be deemed to comply with the arm's length procedure.

2. Definition of Conflict of Interest (COI)

Every project has the potential for a conflict of interest between the research organisation and one or more industrial partners. A conflict of interest can exist on a personal (individual) level or on an organisational (institutional) level. An objective conflict of interest exists when a situation has the potential to create undue advantage or disadvantage – regardless of whether harm or benefit actually occurs. The presence of a conflict of interest means that the arm's length conditions are potentially not met.

Conflict of Interest often arises when financial interests are present that may influence the objectivity of decision-making or project execution. 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); a participating company is a recent spin-off from the research organisation with, for example, overlapping personnel, shared IP rights, or ongoing financial interests

Individual Conflict of Interest: *An individual conflict of interest arises when a person's personal interests — such as financial gain, intellectual property rights, or family ties — have the potential to influence their professional responsibilities and objectivity within the project.*

Examples, but not limited to:

- A researcher, for example, the Principal Investigator (PI), working on the project holds shares in or has a formal role (founder, advisor, or board member) within a (spin-off) company participating in the consortium.
- A researcher receives royalty payments from a patent licensed to an industrial partner within the consortium.
- A project member has been paid over €10,000 in consulting fees by a partner company in the last year.
- A researcher is employed by both the research institution and a company in the consortium.
- A close relative of a researcher is a shareholder or executive at one of the participating industrial partners.

Institutional Conflict of Interest: An institutional conflict of interest occurs when an organisation involved in the project has financial, structural, or governance-related ties to another participating organisation, which could affect objective project decisions or create preferential outcomes.

Examples, but not limited to:

- A participating company is a recent spin-off from the research organisation, with, for example, overlapping personnel, shared IP rights, or ongoing financial interests.
- A research organization and a participating industrial partner share employees, board members or management.
- One consortium partner holds equity in another partner without being a formal affiliate.
- An industrial partner funds sponsored research in the same department that is executing the PPP project.
- Decision-making authority within the consortium is disproportionately influenced by a single institution.

It is up to the parties concerned – and in particular the directors of the participants – to recognize, interpret and report such an objective conflict of interest. This obligation to report may already exist at the time of the application being made.

3. Identifying Conflicts of Interest

To help identify potential conflicts of interest, the following questions can be used as a reference.

These are not exhaustive but aim to prompt transparent disclosure.

3.1 Individual potential COI

- Is any individual involved employed by both (one of) the research organization(s) and (one of) the industrial partner(s)?
- Does the Principal Investigator (PI) 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 the PI (or the relatives) have rights to?
- Does any other investigator(s)/employee(s) of the research organisation have any financial interest in the industrial participant(s)? If so, how many shares, options and/or benefits do the investigator (or the relatives) have rights to?
- Have the PI or their immediate relatives received financial benefits (e.g. shares, patent rights, consultancy fees) from any industrial participant(s) involved in the project?
- Does the Principal Investigator (PI) have an inventorship role in a patent that has been licensed to, or is being developed by, a participant in the project?
- In the last 12 months, did any commercial entity or any of the entities that are participating in the project pay for or reimburse you (your employer, or your relatives) for consulting services, salaries or otherwise? If, so does such payments exceed €10.000 per year? If so, will the company in question benefit from the outcome of the Project?

3.2 Institutional potential COI

- 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 partner despite not being an affiliated entity? If so, how many shares, options and/or participations?
- If the financial interest as stated in the two points above does not apply, would a consortium partner exercise any control over any of the other consortium partners' decision-making? If so, how?
- In the last 12 months, did any Industrial partner in the Project pay for or reimburse any sponsored research or services to the Research Organisation(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 in question benefit from the outcome of the Project?

4. Reporting Obligations

Upon identification of a (potential) conflict of interest, Health~Holland must be notified immediately. This included situations already present at the time of application.

The following questions must be answered **in a separate document**:

- What is the nature of the potential conflict of interest? Please use the questions in 3.1 and/or 3.2 to describe the nature of the potential COI.
- Have the involved participants, including relevant directors, adequately weighed the interests?
- Has the potential conflict of interest been adequately addressed?
- Is there a transparent procedure in place to ensure that the participants, PI's, researchers or directors 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 participant/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 making management decisions (four eyes principle)?

The responsibility for answering these questions rests exclusively with the consortium partners. This means that the consortium parties involved have to assess whether and to what extent the potential conflict of interest has been adequately addressed and whether they are satisfied with the precautionary measures that the director(s) concerned have taken.

5. Role of Health~Holland

Health~Holland will not subjectively evaluate the conflict of interest. Health~Holland will assess whether the performance of the consortium will be hindered or compromised by the existence of such a 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.

If, as a result of a conflict of interest, situations occur that violate the arm's length conditions, the consortium parties are liable for any resulting damage, including implications of indirect state aid.

6. Legal Support

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