Amsterdam Public Health

Amsterdam UMC University Medical Centers | VU Vrije Universiteit Amsterdam | University of Amsterdam

Relationship with external funder	Compliance, Training & Supervision - Compliance	
	VERSION	3.0

Aim
Ensuring that researchers are doing their research independently from the financers of the study.

Requirements
- Written contract ensuring the independent position of the researchers (for details, see How To)
- Contract must be checked by an organizational lawyer (for details, see How To)

Documentation
- Copy of the contract
- Copy of all other terms or conditions that apply to the granted study, but are not listed in the contract (standard conditions, site letters and appendices ect). This information should preferably be kept digitally or on paper and not as an URL (since conditions may chance over time).

Responsibilities
Executing researcher: Knowledge of the content of the contract;
Project leaders: Negotiate a contract fulfilling the requirements and check with the head of the department who is responsible for approval (and signing) of the contract (depends on the amount of money that is involved).
Research assistant: N.a.

How To
- Please note: Limit preliminary discussions with prospective funding sources to the scientific aspects of the work. All (industry) collaborations must adhere to our institutional principles. Involve Legal counsel (LRS or IXA) to negotiate terms and conditions with the third party early in the process!

Contract
The full independence of the researchers needs to be explicitly guaranteed in the research contract for all phases of the research process, including defining the research design, data collection, data analyses and publication of the results. How much the independence of the researcher is under pressure depends on the arrangements (effort versus result obligation) in the contract and the type of financer (for-profit organization or non-for-profit organization). To ensure the independent position of the researcher the written contract should contain:

1. That there is no publication veto (freedom to publish results independently). Yet an embargo period of reasonable length (up to a maximum of three months) could be agreed upon.
2. That the trial or study can only be stopped in case of serious unexpected circumstances, e.g. serious adverse events (based on planned interim analysis) or problematic participation rates (as documented upfront). Marketing reasons or unwanted short-term results cannot be a reason to stop the study. A clear description on the policies in case the study is prematurely terminated should be provided (e.g. financial consequences).
3. Agreement about data sharing and data ownership. Ownership of the data preferably lies with the research institute.
4. Financial agreements including details about what is to be reimbursed and when (for staff, laboratory costs, travel costs, etc.).

5. Any other financial agreements apart from the payment of the study, such as performance bonuses for individuals or organizations should be listed. This is needed for transparency in financial conflicts of interests.

Contracts must be checked by an organizational lawyer to be reached at the Technology Transfer Office (TTO), which is part of IXA and Legal Research Support. Always seek legal assistance in an early stage of the contract negotiations. Contract may only be signed by authorized people. Most researchers are not authorized by the hospital or University to sign contracts. Ask the head of your department who is authorized to sign your contract.

Agreements

In addition, the following issues need to be agreed upon and documented:

1. The exact location and method of data collection and analysis, and the person(s) doing this. Most often the researcher is responsible for data collection and analyses, which is guaranteeing independency. In exceptional cases, employees of the funder can also be involved in this process. In that case, special agreements need to be made to warrant independency, transparency and controllability of the process.
2. The exact conditions under which the study can be prematurely halted and at what time points these are determined (e.g. serious adverse events, participation rates).
3. The property rights associated with the research data. These belong, in a strict sense, to the organization employing the researcher, but anonymous data should always be shared with other parties if a reasonable and substantiated request is submitted. The researcher and the organization employing the researcher are responsible for following the (privacy) legislations that are applicable, including the statutory retention period for keeping personal data. In exceptional cases, and only when thoroughly motivated, ownership of the data may be officially transferred to the funder, as long as (privacy) legislations are followed.
4. Publication and presentation strategy. The principle is that the researcher has responsibility for the final manuscript and has the freedom to publish and present the findings at any stage. It is good practice to include in the protocol who is responsible for preparing the manuscript and what the procedure is for reporting to and requesting potential input from the funder. It is common practice for funders to receive drafts of articles, and to be allowed two weeks to respond to the text. Potential modifications can then be included with mutual approval. However, the researcher should always have the final say. Additionally, it also needs to be established in advance whether and under which conditions the funders can be included as potential co-authors, and how the role of funders is to be reported in publications and presentations. However, only if the agreements are in line with requirements for good authorship practice [links naar QH richtlijn] and requirements considering transparency about financers and financial conflicts of interest of the organizations involved and journals. Strategic or patent interests should be respected, but should never be allowed to prevent publication.
5. What to report in scheduled progress reports.

Agreement Type	Agreement Purpose
Affiliation Agreement	Standard contract model for institutional level research collaboration agreements between Amsterdam UMC and other research institutions. Not intended for grant proposals or other project specific research affiliation agreements, corporate affiliate membership and giving programs, or international affiliations.
Confidentiality Agreements	Restrict disclosure & use of proprietary or protected info.

	Enable open discussions while protecting the rights of each partner. Also referred to as non-disclosure agreements (NDA), confidential disclosure agreements (CDA) or Proprietary Information Agreement (PIA)
Consortium Agreements	Set the rules between consortium partners receiving European and Dutch grants.
Consultancy/advisory Agreement	This is a contract under which advisory activities are provided by Amsterdam UMC employees to third parties (e.g. participation in an advisory board).
Clinical trial agreement (CTA)	In accordance with the ICH Good Clinical Practice guideline (ICH-GCP), a CTA specifies arrangements made between the sponsor/sponsors of a clinical trial and the investigators' institution or institutions regarding the allocation of tasks and obligations, and any financial matters. CTAs are important to allocate risks and responsibilities, and to protect academic, legal and intellectual property and integrity. CTAs must be submitted to the MREC for approval on the topics of publication and early termination. Various templates for CTAs, compliant with all laws and regulations and approved by the relevant organizations, are provided by the CCMO.
Data Use / Transfer Agreement (DUA / DTUA)	Transfer of data collected or developed such as raw data, data sets, student info, personal health info, etc. Data Use Agreements or Data Transfer & Use Agreements are used when there is a transfer of data collected or developed such as raw data, data sets, student info, personal health info, etc. A DUA must be in place when: • Data is from human subjects, or • If the data contains personally identifiable information, or • Use of data is restricted or regulated by the data owner. DUA's are not necessary when the data is completely de-identified (stripped of all personally identifiable information) there is no way to re-identify that data.
Informed consent	Is a process for getting permission before conducting a healthcare intervention on a person, or for disclosing personal information.
License Agreements and Joint Ownership Agreement	Cover the rights of third parties or spin-off companies to use certain know-how or intellectual property rights.
Material Transfer Agreement (MTA)	Transfer tangible (e.g. biological) material such as cell lines, antibodies, model systems (plants/animals), databases or other items from or to Amsterdam UMC from or to an outside entity.
Research Collaboration and Contract Research Agreements	E.g., draft agreements on matching funds, intellectual property, and exploitation rights.
Research Grant Agreement	Concerns funding for a specific research project or a certain research area. Research grants typically come from governments or charities, but industry can also provide research grant.

Research Service Agreement (contract research)	This agreement facilitates the performance of specialized services by Amsterdam UMC, using the institution's existing expertise and equipment. No further intellectual research efforts are required for the provision of these services.
Spin-off companies contracts	Contracts related to spin-off companies. From a declaration of intent to shareholders agreements.
Sponsored Research Agreement	The formal documentation between Amsterdam UMC and an external entity that memorializes the exchange transaction for a specific scope of work. Sponsors may provide funding, equipment or other tangible items for organized research, instruction, and other sponsored activity. The award terms must be followed for the life of the project and include project dates, restrictions and reporting. Sponsored Awards can be in the form of a grant, contract, cooperative agreement, or other types of funding mechanism.
Visiting Scientist Agreement	A visiting scientist agreement is intended to safeguard the IP rights and confidentiality with regard to information provided to temporary scientific staff and scientific trainees.

Audit Questions

1. Is the project funding based on contract funding (e.g. charities) or private/commercial (e.g business, private investments)?
2. Has a contract been signed with the funder?
3. Does the funder (or has the funder had) a role in one or more of the points described below?
4. Creating the research protocol
5. Data collection
6. Data analysis
7. Interpretation and reporting of results
8. Have other goods or services been offered by the grant provider? If so, which ones? Please describe what was done with them.

LINKS

	Link
Amsterdam UMC Research code	https://www.amsterdamumc.org/research/integrity.htm
Legal Research Support	https://intranet.amc.nl/web/organisatie/domeinen/research/legal-research-support.htm
IXA	https://www.ixa.nl/
AMR HR	https://intranet.amc.nl/web/amr/afdelingen/hr/contact-met-afdeling-human-resources.htm
AMR Project control	https://intranet.amc.nl/web/amr/afdelingen/projectcontrol/contact-met-afdeling-projectcontrol.htm
AMR Finance and Control	https://intranet.amc.nl/web/amr/afdelingen/finance-control/contact-met-finance-en-control.htm https://intranet.amc.nl/web/organisatie/clusters/afdelingsoverzicht/research-policy/incentive-arrangements/guideline-financial-management-of-research-grants.htm

AUMC - research support	https://www.amsterdamumc.org/research/support/about/ethical-review.htm

DOCUMENT HISTORY

Version	Status	Date	Name
3.0	Revision	04APR2021	APH
2.1	Minor textual amendments	06SEP2018	APH
2.0	Revision format	01JUL2015	EMGO
1.3	Reference to VUmc-AMC research code added	31OCT2013	EMGO
1.2	Translated into English	01JAN2009	EMGO
1.1	Minor textual amendments	29SEP2006	EMGO
1.0	Role of manager and director added. Various minor clarifications	17FEB2004	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	04APR2021