Submission of grants National Institutes of Health

Reason
The National Institutes of Health ("NIH") has made a number of changes for grant applications. These include the (mandatory) implementation of a Financial Conflict of Interest Policy ("FCOI"), a "yellow book audit," and new data sharing policies. Based on this, VU has considered whether VU would like to submit future grants as master applications or subawards to NIH.

Conclusion
The VU is going to decide to no longer submit grants to NIH as a lead applicant because we can no longer meet the requirements, which NIH mandates for the lead applicant. Submission of grant application as subaward is still possible, provided the research in question does not involve personal data. A more detailed explanation follows below.

What is NIH and FCOI in brief

- NIH is the main federal agency in the U.S., responsible for the conducting and supporting medical research. NIH subsidizes grants, enters into collaborations and supports collaborations aimed at advancing of fundamental knowledge concerning the "nature and behavior of living systems."
- A key requirement of NIH is that the grant applicant meet the extensive requirements of NIH regarding FCOI and financial audits.
- The rules regarding FCOI are to ensure that NIH funded research is free from bias that could result from a potential conflict of interest.
- Further, the grant recipient must comply with requirements under U.S. federal law.

Current state

- NIH requires VU to implement an FCOI policy to be compliant as a lead applicant with NIH requirements. Also, NIH requests a "yellow book audit" for grants above the $750,000 threshold.
- Currently, VU does not have an FCOI policy nor does it have a policy that could serve as a substitute.
- We have spoken with VUmc, among others, who have (by now) implemented a FCOI policy. The VU may be able to learn from VUmc and adopt best practices.

New data access policy

- NIH has announced new data sharing policies effective January 1, 2024.
- NIH's new policy states that foreign sub-recipients (in some cases the VU) will be required to provide access to copies of all laboratory notebooks, all data and all documentation supporting the study results as described in the progress report, to the primary recipient at a frequency of not less than once per year, in accordance with the timing requirements for submission of the progress report research performance. This access may be entirely electronic.
- Acces to all this data can be problematic in case the data contains (special) personal data. In principle, special personal data, such as healthcare data, may not be processed. This requires a basis in the law. If a basis can be justified, the transfer of (special) personal data to the U.S. can only be achieved with additional safeguards.

- According to the “AVG”, in that case the transfer will require extensive legal agreements will have to be concluded before transfer can take place, if the transfer may be permitted.
- As far as "clinical trials/studies" are concerned, the transfer of these (source) documents will will have to comply with European and national rules on clinical studies. According to these regulations it is prohibited to share these data with third parties.
- Handing over source documents to a regulatory auditor is only allowed if the teaching hospital has given its consent and all patient identification has been removed. The latter is often time-consuming and difficult to feasible.
- The (mandatory) sharing of these data may have IP and confidentiality implications.

Implementing FCOI policies

VU's implementation of FCOI policies broadly entails the following obligations:

- The FCOI policy must be made public (e.g., on the website);
- Those involved must make a declaration (not to have a "significant financial interest");
- Data subjects and the institution must comply with request to provide information (to NIH);
- Institution is responsible for management, maintenance, administration and review of significant financial interest/ declarations;
- Persons involved must attend training on FCOI regulations; the institution is responsible for this;
- Key personnel should be appointed; this means that a committee should be established (to check FCOI statements).

Risks and implications of accepting NIH grants.

A 2019 policy memorandum has already identified risks related to the accepting NIH grants. New are:

- Audits: above the $750K threshold and accepting a grant as a lead applicant, VU must conduct "a yellow book audit” or “single audit." The Finance Department indicates that conducting a "yellow book" audit is practically (almost) is not possible. In addition, such an audit will involve significant cost and workload involved.
- Data access: the main risk is that VU will share special personal) data with NIH without basis. NIH in turn has an obligation to the U.S. federal government to be allowed to access this data. This means that VU does not know what will happen to shared data. Should VU choose to accept NIH grants, a case-by-case assessment will have to be made as to whether special (personal) data will be processed in the research. If not, transfer of the data is in principle possible. If so, according to the AVG, transfer is not possible in some cases.
- Implement FCOI policy: if we accept this grant then we must comply with the requirements for FCOI.
- U.S. legislation: we have to comply with various obligations arising from U.S. regulations. This always involves some risk because it is impossible to be certain that we will be able to meet the obligations.