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**Policy Manual** 

## II-27.1 Principles for Determining the Suitability of Research Done in the University

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(President 7/20/84; amended 11/06; 3/10; 11/16; 7/2/23)

Effective July 1, 2023, this policy has been revised. For the most current version without redlining, return to <u>II-27</u>.

- a. General considerations.
  - (1) "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. As used in this policy, "research" also includes other scholarship in which new knowledge or creative works are generated.
  - (2) "Proprietary" means something exclusively owned by an individual or organization (e.g., patent, trade secret, or copyrighted information) which cannot be used by or shared with other parties without approval by the owner.
- b. All research conducted under the auspices of the University shall be proposed and carried out within a regular department or recognized center, or through the cooperation of several departments, to be led by or under the supervision of a member of the University faculty or professional staff.
- one or more of the objectives of the University: the education of undergraduate, graduate, and postdoctoral students; the advancement of knowledge through research and scholarship; the preservation and dissemination of knowledge; and public service. The mere availability of funds for research is not a sufficient justification for a research project to be conducted in the University.

  The terms of any grant or contract for research shall permit flexible operation under regular University policies

and procedures, provide for reimbursement of the direct as well as facilities and administrative (indirect) costs,

c. Appropriateness of sponsored research. All research conducted in the University is expected to be consistent with

Research Information (II-27.2 below), and, in general, permit the University to exercise administrative control and responsibility for the work.

The Division of Sponsored Programs, a unit within the Office of the Vice President for Research, has the

responsibility to approve all applications, budgets, budget revisions, and final research agreements. This process

applies to all externally funded research, irrespective of funding source.

conform to the provisions of the University's Intellectual Property Policy (V-30) and Principles Governing Access to

- d. Dissemination of research results. To ensure that the University and the investigator are not subject to external control, results of the research must be able to be freely discussed in an appropriate forum (scholarly meeting or journal). However, exceptions may be granted for legitimate scholarly reasons. "Legitimate scholarly reasons" do not include efforts to suppress results simply because they are contrary to the business interests of the sponsor, but may include, for example:
  - (1) To allow the sponsor the opportunity to protect any proprietary interest, the sponsor will be given a reasonable period (normally not to exceed 90 days) to identify existing proprietary information that should be removed or to begin the process of filing patents on new information prior to dissemination of the results of the research.
  - (2) Long-term and collaborative projects in which premature release of preliminary results may be prejudicial to the outcome of the research may justify the delay of publication for a reasonable but not unlimited time. An example is a multi-site study for which a publication committee receives data from participating sites and makes decisions about joint publications. Such delays are not considered excessive if based on appropriate collaboration and consultation with members of the research team from other institutions.
  - (3) Publication review and approval may be performed by a multi-institutional academic research consortium for purposes of assuring proper scientific rigor and professional standards such as statistical analysis of data, inclusion of appropriate coauthors, and protection of individual research subject identifiers.
  - (4) Provisions that will allow the investigator to publish within a reasonably defined period of time.

When justified by legitimate considerations related to the research, the Vice President for Research may approve contractual arrangements or grant awards that could lead to excessive publication delays or other restrictions. The Vice President for Research shall obtain a recommendation from the University Research Council when contract award terms do not allow the publication of nonproprietary information without third-party approval. Requests for the Vice President to approve such contractual arrangements should include:

- (a) the rationale for the request,
- (b) a description of who will have authority over publication decisions and the justification for this authority,
- (c) a statement of the provisions that will allow the investigator to publish within a defined period of time,
- (d) measures to provide timely information to the medical community if suppressed information could affect the health and safety of research subjects or patients, and
- (e) a listing of overlapping research activities (e.g., funded by other grants and/or contracts) that may be impacted by the proposed restrictions and how these restrictions might affect these other projects.
- (5) **Note**: Under no circumstances should a faculty member engage a student in a project governed by an extended publication delay agreement or other contractual arrangement that could present a barrier to the timely submission of the student's thesis or dissertation to the institution or materials therein for publication.
- e. Industry-sponsored grant and contract agreements.
  - (1) The University of Iowa is supportive of conducting industry-sponsored research, provided that such research serves the public interest and is compatible with the goals, objectives, and traditions of the University (see paragraphs a and b above).
  - (2) Research agreements with industry for clinical research involving investigational drugs or medical devices should incorporate administrative provisions (indemnification and subject injury reimbursement) to ensure that there are safeguards to protect the University from medical costs, claims, and suits from the adverse effects of the study. Waiver of indemnification and subject injury reimbursement requires concurrence by the DEO, dean, and Vice President for Research.
- f. Fee-for-service contracts. The University recognizes that faculty and professional staff may, as part of their University employment, engage in activities that draw upon their professional expertise but do not represent research as defined within this policy. This body of work is best described as "fee-for-service" when the product is the provision of professional services without the element(s) of research. These activities may represent a range of services such as providing professional consultation or training services, conducting defined laboratory analyses, or conducting a program evaluation for a client with the end product being a proprietary report.

When faculty and professional staff request that the University enter into fee-for-service contracts for the purpose of providing professional services to an outside sponsor, the contract shall be routed for approval by the department, and college, and a designated institutional official (Office of the Vice President for Research or Business Manager). In reviewing such agreements, a determination will be made as to whether the work contributes to one or more of the University's nonprofit missions. Fee-for-service work may be subject to unrelated business income tax if it does not meet the nonprofit mission of the University.

The statement of work and final product of fee-for-service agreements may contain proprietary restrictions. However, information on the existence and nature of such agreements, including the name of the principal investigator, the project title, the amount and source of funding, and the project time period will be available for reporting purposes through the Division of Sponsored Programs (DSP) database in accordance with II-27.3 below. Also, non-proprietary findings associated with the work performed must be freely communicable consistent with II-27.2 below.

- g. Enforcement of these provisions.
  - (1) Responsibility for ensuring compliance with the foregoing provisions in each specific instance of research must necessarily be shared among principal investigator, departmental executive, collegiate dean, and central administrative officers.
  - (2) If the responsible parties referred to above, or any other member of the University community, should disagree about the appropriateness of a particular research proposal and/or its terms and conditions, they will detail in writing to the Vice President for Research their points of disagreement and explain the basis
  - for their position in reference to the specific clauses of this policy.

    (3) If disagreement about the appropriateness of a research proposal persists, the Vice President for Research will consult with the University Research Council and may also consult with other senior

University administrators as they deem appropriate in reaching a decision.