University Procedures for Compliance with Bayh-Dole Act and Reporting Obligations for Inventions Developed with Federal Funds

1. **Reason for Procedure**

The University is committed to maintaining its standing and status as recipient of federal research funds and respected partner of federal research agencies. The University is equally committed to complying with statutes, regulations, and contract terms that, as a condition of federal research grants, require reporting and stewardship of inventions created with use of federal funds. This procedure describes the standards that the University will follow in assuring awareness of, and compliance with, intellectual property policies and invention reporting obligations, in particular all applicable federal funding requirements of the Bayh-Dole Act, all applicable funding agency policies, procedures and regulations, and relevant funding conditions. Additional information concerning the University’s Bayh-Dole Compliance process can be found here.

2. **Definition of Terms [In accordance with 37 CFR 401].**

**Federal Funding Agency.** A United States government agency that has entered a Funding Agreement with the University.

**Funding Agreement.** Any contract, grant, or cooperative agreement entered into between the University and any agency of the United States government for the performance of experimental, developmental, or research work funded in whole or in part by the United States government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

**Invention.** Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. §2321 et seq.).

**Subject Invention.** Any invention conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

**Invention Compliance Responsibilities.** The Bayh-Dole Act, 35 U.S.C. §200, its implementing regulations, 37 C.F.R. 401, the National Institutes of Health (NIH) Grants Policy Statement (Section 8.2.4), and funding award terms and conditions

**Inventor.** The person or persons who conceived an Invention.

**Patent Application.** A provisional or nonprovisional U.S. national application for patent, as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

**Initial Patent Application.** A nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).
**Practical Application.** Manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

3. **Procedure Statement**

**A. Ownership of Subject Inventions**

(i) Ordinarily, the University will retain the entire right, title, and interest throughout the world to each Subject Invention subject to the provisions of the Bayh-Dole Act. With respect to any Subject Invention in which the University retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the Subject Invention throughout the world. In limited circumstances and in accordance with the University Patent Policy, the University will consider transferring ownership of a Subject Invention to the Inventor(s), but any such transfer would require consent of the applicable Federal Funding Agency (which may or may not be granted). In the event of a conflict between the University Patent Policy and the Invention Compliance Responsibilities, the latter shall govern University administration of Subject Inventions.

**B. Invention Disclosure**

(i) As set forth in the University’s Patent Policy, any person involved in University research must disclose any Subject Invention within thirty (30) days of conception in the form of the approved University Disclosure Form to a person or entity designated by the University to handle University patent matters (“Designee”). The present Designee is University of Virginia Licensing and Ventures Group (“UVA LVG”). The University Disclosure Form, which includes the information required for the Invention Compliance Responsibilities, is available [here](#). Once an invention has been disclosed, the University confirms that the disclosed invention is subject to the University Patent Policy and decides whether the invention should be assigned to UVA LVG for intellectual property management and commercialization. After such disclosure, the Inventor(s) have a continuing obligation to cooperate with the University and UVA LVG to amend or supplement the disclosures, as deemed necessary by the University or UVA LVG, and to notify the University (or its Designee) of the acceptance of any manuscript describing the Subject Invention for publication.

(ii) Within sixty (60) days thereafter, University (or its Designee) shall disclose the Subject Invention to the applicable Federal funding agency in the form of a written report, which identifies the grant and/or contract under which the invention was made and the Inventor(s). The disclosure to the Federal Funding Agency shall also provide sufficiently complete technical detail to convey a clear understanding (to the extent known at the time of the disclosure) of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the Subject Invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so,
whether it has been accepted for publication at the time of disclosure. In extreme cases of imminent publication, the disclosure and compliance process may be accelerated.

(iii) In addition, after disclosure to the Federal Funding Agency, the University (or its Designee) will promptly notify the Federal Funding Agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned for the Subject Invention.

(iv) University researchers are required to disclose promptly in writing to the University of Virginia Licensing & Ventures Group (UVA LVG) or such other personnel identified as responsible for the administration of patent each Subject Invention made to enable the University to comply with the disclosure provisions set forth above and to execute all papers necessary to file Patent Applications on Subject Inventions and to establish the government’s rights in the Subject Inventions. Such agreements are typically prepared by and returned to UVA LVG.

(v) Through written agreements, orientation and periodic education programs, the University instructs faculty and other employees on the importance of timely reporting inventions in compliance with the Bayh-Dole Act, particular the need to report in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

C. Election of Title and Patent Prosecution

(i) Within two (2) years of disclosure to the Federal Funding Agency of a Subject Invention, the University (or its Designee) will elect in writing whether or not to retain title to such Invention. The University understands, however, that where publication, offer for sale, sale or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period. However, that where publication, offer for sale, sale or public use is imminent, the period for election of title may be shortened by either the University or the Federal Funding Agency to a date that is no more than 60 days prior to the end of the statutory period, wherever possible. In extreme cases of imminent publication where the 60 day rule cannot be followed, the University and UVA LVG will be expeditious about assessing commercialization and electing to retain title to the subject invention so as to avoid losing patent rights.

(ii) The University (or its Designee) will file its initial Patent Application on a Subject Invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, offer for sale, sale or public use. The University (or its Designee) will thereafter file Patent Applications in additional countries or international patent offices within either ten months of the corresponding initial Patent Application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign Patent Applications where such filing has been prohibited by a Secrecy.

(iii) Where appropriate, the University (or its Designee) may seek extension of the time for disclosure, election, and filing of patents in accordance with Invention Compliance Responsibilities, which may or may not be granted at the discretion of the Federal Funding Agency.
D. Licensing and Royalties; Restriction on Assignment; Protection of Government Rights

(i) The University (or its Designee) will diligently seek to achieve expeditious Practical Application of Subject Inventions through exclusive (or non-exclusive) license agreements in accordance with the Invention Compliance Responsibilities and its mission.

(ii) The University (or its Designee) will make efforts that are reasonable under the circumstances (a) to attract licensees of Subject Invention that are small business firms and (b) to prefer licensing a Subject Invention to a small business firm when licensing a Subject Invention if it determines that the small business firm has a plan or proposal for marketing the Invention which, if executed, is equally as likely to bring the Invention to Practical Application as any plans or proposals from applicants that are not small business firms; provided, that the University is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal.

(iii) In the event the University realizes royalties on a Subject Invention:
   a. Such royalties will be shared with the Inventor in accordance with the University Innovation Revenue Distribution Formula, including Federal employee co-inventors (when the Federal Funding Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10; and
   b. The balance of any royalties or income earned by the contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions, will be utilized for the support of scientific research or education.

(iv) The University (or its Designee) shall not assign rights to a Subject Invention without the prior approval of the Federal Funding Agency, except where such assignment is made to UVA LVG or other organization that has as one of its primary functions the management of inventions, provided that UVA LVG or such Designee will be subject to the Invention Compliance Responsibilities to the same extent as the University. When making an assignment to a Subject Invention with the prior approval of the Federal Funding Agency, the University will notify the assignee of its obligations regarding the University’s Invention Compliance Responsibilities and, post-assignment, will attempt to confirm with the Federal Funding Agency that the University’s Invention Compliance Responsibilities have ceased.

(v) The University (or its Designee) will include, within the specification of any United States Patent Applications and any patent issuing thereon covering a subject invention, the following statement, “This invention was made with government support under (identify the contract) awarded by (identify the Federal Funding Agency). The government has certain rights in the invention.”

(vi) In keeping with the Invention Compliance Responsibilities, the University (or its Designee) shall convey title to a Subject Invention to the applicable Federal Funding Agency:
   a. If the University (or its Designee) fails to disclose or elect title to the Subject invention within the times specified in (ii), above, or elects not to retain title; provided that the Federal
Funding Agency requests title within 60 days after learning of such failure to disclose or elect within the specified times.

b. In those countries in which University (or its Designee) fails to file Patent Applications within the times specified in (ii) above; provided, however, that if the University has filed a patent application in a country after such time, but prior to its receipt of the written request of the Federal agency, the University (or its Designee) shall continue to retain title in that country.

c. In any country in which the University decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a Subject Invention.

(vii) The University shall otherwise comply with the Invention Compliance Responsibilities including as amended or modified by the United States Government or authorized Federal Funding Agency.

E. Preservation and Protection of License and Patent Rights

(i) The University shall execute or have executed and promptly deliver to the Federal Funding Agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the University elects to retain title, and (ii) convey title to the Federal Funding Agency when requested under (i) above and to enable the government to obtain patent protection throughout the world in that Subject Invention.

(ii) The University or its Designee will notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty (30) days before the expiration of the response period required by the relevant patent office.

(iii) The University shall include, within the specification of any United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, “This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.”

(iv) The University will retain a nonexclusive royalty-free license throughout the world in each Subject Invention in the event the Government obtains title, except if the University (or is Designee) has failed to disclose the invention within the times specified in above. The University’s license would extend to its domestic subsidiary and affiliates, if any, within the corporate structure of which the University is a party and include the right to grant sublicenses of the same scope to the extent the University was legally obligated to do so at the time the contract was awarded. The license would be transferable only with the approval of the Federal agency except when transferred to the successor of that part of the University’s business or operations to which the invention pertains.

a. The University’s domestic license under (i) above could be revoked or modified by the Federal Funding Agency to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and licensing regulations of the Federal Funding Agency (if any). This license would not be revoked in that field of use or the geographical areas in which the University has
achieved Practical Application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the University, its licensees, or the domestic subsidiaries or affiliates have failed to achieve Practical Application in that foreign country.

b. Before revocation or modification of the license, the Federal Funding Agency is obligated to furnish the University a written notice of its intention to revoke or modify the license, and the University will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the University) after the notice to show cause why the license should not be revoked or modified. The University would have the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and regulations of the Federal Funding Agency (if any).

F. Subcontracts and Flow-through Requirements

(i) In any subcontract (regardless of tier) for the performance of experimental, developmental or research work by a small business firm or domestic nonprofit organization under a Federal Funding Agreement, the University shall include contract terms required to implement the Invention Compliance Responsibilities suitably modified to identify the parties and pursuant to which the subcontractor will retain all rights provided for the contractor in the standing patent rights clause set forth in 37 CFR 401.14 and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor’s Subject Inventions.

(ii) The University will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by regulations of the Federal Funding Agency.

(iii) In the event the University enters into a subcontract, at any tier, pursuant to a prime award with a Federal Funding Agency that is a contract (but not a grant or cooperative agreement), the University will agree (with the agency and subcontractor) that the mutual obligations of the parties created by the standard patent rights clause set forth in 37 CFR 401.14 constitutes a contract between the subcontractor and the Federal Funding Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act, 47 U.S.C. § 7101 et seq., in connection with proceedings under the “March-in Rights” provisions thereof.

G. Utilization Reports

(i) The University (or its Designee) shall submit annual reports to the Federal Funding Agency (unless requested more frequently) on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the University or its licensees or Designees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the Federal Funding Agency may reasonably specify.

(ii) The University shall also provide additional reports as may be reasonably requested by the Federal Funding Agency in connection with grant-reporting and any march-in proceeding undertaken thereby in accordance with 37 CFR 401.14(j). Such information is expected to be
maintained in confidence by the Federal Funding Agency as required by 35 U.S.C. 202(c)(5). Grant reporting includes the following:

a. In accordance with the NIH Grants Policy Statement (Section 8.2.4), the University (or its Designee) shall provide to the NIH an Annual Invention Statement indicating any Inventions made during the previous budget period on all grants award by the NIH.

b. In accordance with the NIH Grants Policy Statement (Section 8.2.4), the University (or its Designee) shall provide to the NIH awarding institute or center Grants Management Officer a summary of all Subject Inventions made during the entire term of each NIH grant award.

H. Preference for U.S. Industry

(i) Notwithstanding any other provision of Invention Compliance Responsibilities, neither the University nor any Designee will grant to any person the exclusive right to use or sell any Subject Inventions in the United States unless such person agrees that any products embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in appropriate individual cases, the University may request the Federal Funding Agency to waive this requirement upon a showing that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

I. Federal March-in Rights

(i) The University acknowledges that, with respect to any Subject Invention in which it has acquired title, the Federal Funding Agency has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations to require the University, an Designee or exclusive licensee of a Subject Invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the University, Designee, or exclusive licensee refuses such a request that the Federal Funding Agency has the right to grant such a license itself if it determines that:

a. The University has not taken and is not expected to take within a reasonable time, effective steps to achieve Practical Application of the Subject Invention in such field of use.

b. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the University, Designee or their licensees;

c. Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the University, Designee or licensees; or

d. Such action is necessary because the agreement specifying a preference for United States industry has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such agreement.

4. Responsibilities

A. The Office of Vice President of Research (OVPR) is responsible for:
(i) Appointment of UVA Bayh-Dole Compliance Officer responsible for implementation of compliance controls;

(ii) Entering agreements with faculty and research staff that implement the Invention Compliance Responsibilities;

(iii) Administering disclosures of inventions by faculty to UVA LVG, including confirming that inventions are subject to the University’s Patent Policy and should be assigned to UVA LVG for patenting and commercialization

(iv) Close-out of awards including (with Office of Sponsored Programs and UVA LVG assistance) final utilization reports;

(v) Facilitation of training on Invention disclosure and Invention Compliance Responsibilities; and

(vi) Orientation and periodic training of University personnel with respect to Invention Disclosure and Invention Compliance Responsibilities agreements.

B. The Office of the University Counsel is responsible for:

(i) Communications that relate or refer to Federal March-in Rights or reversion of patent rights to Federal Funding Agency; and

(ii) Review and approval of compliance documents.

C. UVA LVG is responsible, subject to its agreement(s) with the University and in its capacity as the University’s Designee, for:

(i) Receiving Initial invention disclosures and forwarding to the University, and subsequent reporting to Federal Funding Agency;

(ii) Orientation and periodic training of UVA LVG staff and licensing managers with respect to Invention Disclosure and Invention Compliance Responsibilities agreements.

(iii) Patent Prosecution of Subject Inventions;

(iv) Licensing and administration of Patents that arise from Subject Inventions; and

(iv) Royalty administration (in collaboration with the OVPR).

D. Faculty members and staff are responsible for:

(i) Disclosures of subject inventions and related manuscripts or publications with sufficient information for the University to discharge federal reporting requirements and other Invention Compliance Responsibilities;

(ii) Cooperation with OVPR and UVA LVG in the management of Subject Inventions; and

(iii) Taking steps to complete Inventor certification (registration) in the event the University has waived or non-elected title to a Subject Invention and requested Federal Funding Agency approval to assign rights in the Subject Invention to the Inventor(s). This includes registration with Interagency Edison (iEdison), a unified federal reporting database designed to aid Bayh-Dole compliance.

E. Other Responsibilities as designated to Responsible Parties in the established controls document for this Procedure.
5. Processes

Invention disclosure processes, forms and templates are posted here.