POLICY GOVERNING RELEASE OF
NEW PLANT VARIETIES and GERMPLASM

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Introduction
Oregon State University (OSU) is Oregon’s land-grant university and has a mission to serve Oregon agriculture. The Oregon Agricultural Experiment Station (AES) receives federal and state funds to conduct research consistent with its mission. The development of new plant materials by AES researchers is clearly consistent with this mission. Development efforts are a partnership between OSU, commodity groups, and others. The large impact of OSU plant materials has been well documented.

Plant breeding programs are funded by diverse sources. Federal and state funds have diminished in recent years. Government funds (federal and state) largely support faculty salaries while dollars to hire research assistants and students, pay user fees, and operate programs come from other sources. Growers in Oregon tax themselves to support research through commodity commissions and the Agricultural Research Foundation. Although most commissions do not pay “indirect costs” (F&A), they pay substantial “user fees” for greenhouse space and plots at research farms. In short, OSU plant breeding programs receive funding from many sources and federal and state guidelines are but one piece of information that must be utilized when considering variety release.

The Bayh–Dole Act or Patent and Trademark Law Amendments Act was enacted by Congress in 1980, dealing with intellectual property arising from federal government-funded research. The Act gave universities intellectual property control of their inventions and other intellectual property that resulted from federal funding. Prior to the Act, inventions funded by a federal grant belonged to the federal government. The Bayh-Dole Act is codified in 35 U.S.C. 200-212, and implemented by 37 C.F.R. 401. The Act allows the university to retain title and interest throughout the world to a federally funded “invention”. In exchange, the university is required to perform the following:

- Report each disclosed invention to the funding agency within 2 months of the disclosure date (when Appendix 1 is signed by the AES Director)
- Elect to retain title in writing within 2 years of disclosure to the university (when Appendix 1 is signed by the AES Director)
- If the university retains title, it must grant the federal government a non-exclusive, non-transferable, irrevocable, paid-up license to practice on its behalf throughout the world
- File for patent or Plant Variety Protection within one year of electing to retain title
- Actively promote and attempt to commercialize the invention
- Share royalties with the inventor
- Use any remaining royalty income after expenses for scientific education and research with preference given to the originating department and breeding program
- Give preference to U.S. industry and small business

There may be instances where legal protection simply does not make sense and other cases where some form of legal protection may be pursued. As such, options for release may include: public release with no restrictions, Plant Variety Protection, plant patent, utility patent, trademark, trade secret and licenses implemented with or without other forms of intellectual property protection.

Oregon’s AES continues to be diligent in its mission and responsibility to the citizens of Oregon in developing, introducing and releasing new varieties of plants to support agricultural development and natural resource management in Oregon. The policy and procedure statements outlined in this document are intended to provide guidelines for the release and protection of new plant varieties and germplasm developed by OSU personnel or

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37 C.F.R. 401
originating through cooperative efforts with other state, federal, or private organizations. This policy does not address the protection of genetically-modified plants, which are handled directly by OCDD at present. This policy is set forward to ensure quality releases by peer review and to provide an orderly variety release process.

I. Legal Protection of New Plant Varieties
Options for legal protection of new varieties include: Plant Variety Protection (PVP) certificate for seed-propagated and tuber-propagated crops, plant patent for other asexually propagated crops, utility patent, trade secret, trademark and international protection under the International Union for the Protection of New Varieties of Plants (UPOV). Plant breeders must be familiar with the options for plant protection and acquire and record the data needed. Generally, Plant Variety Protection or a plant patent will be the preferred forms.

Plant Variety Protection (PVP)
To obtain protection under a PVP certificate, the plant variety must be new, distinct from other varieties of that crop, uniform (sufficient for commercial acceptance), and stable when propagated by seeds or tubers. Consistent phenotypic, morphological and physiological trait differences between varieties provide evidence of distinction. Supplemental molecular comparison and DNA marker data may provide further evidence that the new variety is distinct from other varieties of the crop.

Plant Patent
To obtain protection under a U.S. plant patent, the variety must be new, distinct from other cultivars of that crop, found in a cultivated state, and stable when vegetatively propagated. The plant patent application also includes a "complete botanical description" of the variety.

Utility Patent
For a utility patent, the criteria are: novel, non-obvious, and useful. Novel means new or previously-unknown plants, and may include specific traits, plant parts, and methods of producing or using plant varieties.

Non-obvious means to someone experienced in the field (for example, a new device for manufacturing widgets must be non-obvious to a widget manufacturer). Useful means that the invention must have some commercial use or purpose. For protection under a utility patent, confidentiality is essential.

Licenses
A license granted by OSU gives the licensee a limited right to use a plant variety, including to reproduce, sell, or distribute the variety. Licenses will almost always be used with other forms of plant protection, most commonly PVP or plant patent.

All of the above vehicles are done through OCDD using the process described below.

II. OSU Committees Reviewing Releases of New Plant Varieties
Crop Advisory Committees (CACs)
CACs provide an opportunity for Oregon growers/commissioners to give advisory input into the release process and share technical expertise and market insights. CACs exist for cereals (wheat and barley), hazelnut, and potatoes.

The membership composition and operational guidelines of the Hazelnut Variety Advisory Committee (HVAC) is specified in an MOU. The membership composition and operational guidelines of the Cereal Variety Advisory Committee (CVAC) are specified in its charter. The structure of other CACs - membership composition, and operational guidelines - shall be decided by each CAC but must be consistent with the following guidelines and approved by the AES Director. Typically, a CAC has three OSU faculty members in addition to the plant breeder (e.g., the VRC Chair, another plant breeder, and an extension agent). An OCDD representative, AES Director (or designee), and Department Head are ex-officio members. Consumers and industry stakeholders may also be members. The CAC Chair will provide invitations or announcement of all the CAC meetings to all committee and ex-officio members.
Minutes of each meeting will be prepared by a pre-determined scribe to detail the discussion and decisions of the committee. The minutes will be distributed promptly (typically within two weeks) to all members, ex-officio members, and others who attended the meeting.

**Variety Release Committee (VRC)**
The VRC assures scientific rigor and provides guidance and consistency in release of plant varieties. Members include a minimum of four of OSU's plant breeders, and three other faculty members in related disciplines (Plant Pathology, Seed Certification, or other plant sciences). It is understood that committee members will not have intimate knowledge of each crop and will depend on the CACs for specific recommendations. Given its broader-scale view, the VRC will provide guidance to CACs on changes that are occurring at institutional, national and international levels.

Administrators who have a role in development and release of new plant varieties are ex-officio members. The administrators with such a role are: 1) Heads of departments with faculty submitting plant varieties for release; 2) the AES Director or designee, and 3) an OCCD representative.

The seven VRC members will be appointed by the AES Director for three-year terms. They may be reappointed if such is deemed beneficial to committee function. From among the VRC members, the AES Director will appoint the Chairperson. The term of a Chairperson is three years. Meeting organization support for the VRC shall be provided by the AES Director.

Minutes of each meeting will be prepared by a pre-determined scribe to detail the discussion and decisions of the committee. The minutes will be distributed promptly (within two weeks) to all members, ex-officio members, and others who attended the meeting.

**III. Process for release of a plant variety**

![Diagram](image)

**Figure 1.** Process for release of new plant varieties by the Oregon Agricultural Experiment Station. The potato breeder proposes a new variety first to the Tri-State Potato Advisory Committee (1) and then to the OSU Potato Advisory Committee (2).
Plant breeding programs in the Oregon AES are in the Department of Horticulture (vegetables, hazelnut, mint and ornamentals) and the Department of Crop and Soil Science (wheat, barley, potato, and aroma hops). Other OSU research programs also include plant breeding as a component and leaders of these programs are referred to as breeders in this document. One of the plant breeders initiates the release process as follows.

The breeder prepares the variety release proposal. The release proposal includes a description of the breeding history, comparative trait description, and an assessment of the commercial potential of the proposed release. If seed of the variety will be increased by a certification agency, this should be indicated in the release proposal. The proposals also include supporting technical data to substantiate the release.

The breeder prepares a Variety Release Form (Appendix I). The release form includes a proposed cultivar name or trade name. Names are used not only to identify the variety, but also to help market the variety. The name should be fairly easy to spell and pronounce, without ties to an external enterprise, inferring any negative issues, or invoking detrimental thoughts. The name should be vetted with the naming agency appropriate for the specific crop. For seed propagated and tuber-bearing crops, the name will be cleared using a letter from the USDA Agricultural Marketing Service and the original must be provided with the PVP application. Final approval for use of a name shall not be sought until after VRC review and concurrence. Prior to actual release, the breeder, CACs and VRC must only use the experimental number when referring to the proposed release so that the proposed name remains available for later protection by trademark registration.

The breeder prepares a Distribution of Royalty Sharing Agreement form (Appendix II) and obtains signatures of all inventors.

The completed documents (i.e., variety release proposal, variety release form, and distribution of royalty sharing agreement) are forwarded to the Department Head for signature. The breeder then arranges for a meeting of the CAC, which reviews all documents. For most crops, the breeder submits the documents to the VRC with a recommendation from the CAC. For hazelnut, the HVAC Chair forwards the proposal to the VRC. For crops with no CAC, the breeder submits the proposal directly to the VRC.

Following a recommendation for release by the VRC, the breeder forwards the completed document package to the AES Director. Once signed by the AES Director, the complete original document package will be forwarded to the OCCD representative.

OCCD will review the AES release document package and work with the AES Director and breeder to file applications to secure legal protection of the plant variety.

**Time to file for protection**

The form of legal protection for new varieties typically will be a PVP or plant patent, but other forms (e.g., utility patent, license, International Plant Breeder Rights (UPOV), or trademark) may be considered. The date of the AES Director's signature on Appendix I is the cultivar's release date and starts the clock on the application for protection. If the date of first sale occurs before Appendix I is signed, then the first date of sale starts the clock. The breeder is to complete all necessary application documentation and submit it to the OCCD within nine months of this date, unless a later deadline is agreed to by OCCD, so that the one-year deadline for PVP and plant patent applications can be met. After Appendix I is signed by the AES Director and an application for legal protection has been filed through OCCD, the breeder may publish the variety description in an OSU release document or a journal. Breeders contemplating release of advanced selections may describe them publically as long as it is only in general terms meeting the requirements of the type of protection being sought. Information on these requirements will be provided by OCCD upon request. OCCD will assist breeders in the protection and commercialization of the new variety.

**IV. CAC Handling of Release Proposals**

Upon request from a plant breeder, the CAC will meet, make a determination regarding release, and write a report on their deliberations and recommendations. Minority opinions or concerns shall be included in reports. CAC members recognize that they make a recommendation, and the AES Director and OCCD make the final decision on release.
CACs should provide guidance on the general suitability of a variety for release, any potential risks involved with a release, and the best choice of intellectual property protection (if any) based on the CAC’s and OCCD’s knowledge of market opportunities and commercial potential. Specific questions to be addressed include the following: Should the new cultivar be legally protected? Should the release be exclusive or non-exclusive? What licensing fee is recommended? What royalty is suggested? Should the license be for a specified territory or specific use? Trade secrets, trademarks and special terms can be considered. When legal protection is to be sought, the CAC should consult with the OCCD representative to assure that the criteria can be met.

The breeder will provide additional information to the CAC, upon request.

The facilitator (CVAC, for cereals) or CAC Chair signs the release proposal. The Chair of the CAC (HVAC, for hazelnuts) or the breeder (all other crops) forwards the signed proposal and the CAC report to the VRC Chair. The CAC report will accompany the release proposal as it moves forward and receives signatures from the CAC Chair, VRC Chair, and AES Director.

The CAC will respond to any questions and comments from the VRC. This communication can often be done by e-mail but the CAC Chair or breeder can request a face-to-face meeting with the VRC to resolve issues.

Other CAC functions
CACs will establish a set of guidelines specific to their crop. Guidelines should make sense for that commodity and be described in release proposals. Breeders will be expected to follow these guidelines. As a general rule, the expectations for release data include results from trials conducted in a statistically-sound fashion over multiple years. If a crop is grown across several geographic areas, performance data are expected across locations. The material should be evaluated for key identifiable trait characteristics (i.e., physiologic and morphologic traits; quality parameters; disease resistance; if a seed crop, seed quality; if a nursery crop, ability to be successfully grown under accepted production practices; etc.). Possible plant invasiveness should be addressed if this is an issue.

V. VRC Handling of Release Proposals
The Chair of the VRC will be notified by the originating breeder when the CAC recommends that a material should be considered for release.

The VRC Chair will make available to members of the VRC the release proposal documents and the CAC report.

VRC members will evaluate the proposal in a timely manner (maximum three weeks). Most decisions do not require a formal meeting, but rather can be conducted via e-mail to provide timely review of the proposal by the committee.

The VRC Chair will call a formal VRC meeting to evaluate the proposal if two or more committee members request such a meeting. The breeder of the material to be considered for release must attend the formal VRC meeting and speak to the proposed release. The Chair of the CAC that has recommended release may also be asked to attend the formal VRC meeting.

The VRC shall review all evidence and make a recommendation on release. These items may be considered in making a release decision:

- Merits of the variety compared to existing varieties
- The release document contains adequate depth and clarity such that any protection filing dates triggered by release can be met
- Acceptability of a variety name or a trademark
- Protection preferences
- Ownership/inventorship and joint releases of the variety or materials, to be determined in consultation with OCCD
- Foreseen Conflicts / Issues
After review, the VRC will take one of three actions: 1) recommend approval of the proposed release as submitted, 2) reject the proposed release, or 3) return the proposal to the plant breeder and/or CAC for additional data or clarification.

Decisions are made by majority vote of the VRC members. The VRC Chair will summarize the comments of VRC members, pro and con, and forward the recommendation (with vote tally) to the AES Director.

If the VRC disagrees with a CAC recommendation, the Chair of the CAC and breeder will either be invited to meet with the VRC to discuss concerns or asked to provide a written response to questions from the VRC. The CAC Chair and breeder may consult with their CAC in developing any response. The VRC will develop a final recommendation using original and new information and prepare a summary report to the AES Director that includes all points of view, pro and con, regarding their recommendation.

After a recommendation for release by the VRC, the plant breeder will update the release proposal, making corrections and adding clarifications and supporting data where requested. The revised proposal, with the accompanying forms signed by the inventors, Department Head, CAC Chair (if applicable), and VRC Chair will be forwarded to the AES Director. The AES Director will keep a copy of the signed release proposal, and provide the original to the OCCD License Manager for the university record. OCCD handles implementation of the release, protection, and commercial licensing of the new variety going forward.

**Annual meetings**

The VRC will schedule face-to-face meetings at least once a year for the purpose of information exchange. The VRC Chair, after consultation with others, will schedule the meeting. In addition to VRC members and ex-officio members, all of OSU’s plant breeders will be invited and expected to provide a brief update on upcoming (next one to two years) releases. Agenda items should include approval of minutes from the previous meeting and a summary of activities (the status of variety release proposals submitted) since the last meeting. Included in the agenda items will be an update by OCCD on their activities associated with cultivar releases. As stated above for all VRC meetings, minutes of the meeting will be recorded by a predetermined scribe and distributed within two weeks of the meeting to VRC voting members, ex-officio VRC members, and others who attended the meeting. These individuals will have two weeks to review the minutes and provide corrections to the scribe.

**VI. Collaborative Releases**

Public institutions may be offered the option to join in on publicizing the release of OSU developed varieties with the intent to acknowledge collaborative research contributions and assure that growers in target production areas have access to Foundation Seed. The OSU AES may join collaborative release of varieties developed by other public institutions when justified by performance in Oregon research trials. Invitations for publicizing release of new varieties are expected to be offered on a reciprocal basis to assure continued cooperation and collaborations among institutions. Care will be taken to identify legal inventors, cooperators, and OSU’s involvement in the development of the variety. Breeders, as a condition of their employment, will provide an assignment of all variety rights to their respective institutions and their percentage of contribution using the attached Appendix II.

The breeder will submit proposals for collaborative releases of cereal varieties to the CVAC and those for collaborative releases of potato varieties to the tristate potato advisory committee followed by the OSU potato advisory committee. Following review by those committees, proposals will be submitted by the breeder to the VRC. The VRC will review collaborative release proposals and make a recommendation to the AES Director.

In the case of a USDA-ARS joint release, the USDA-ARS plant breeder must file an in invention report (Inventions- Plant Material Dockets) for review with the USDA-ARS Office of National Programs and the Plant Protection Committee. The draft formal release notice for a cultivar is part of the invention report and, upon approval, the final release notice will be submitted to the Director of the Oregon AES, or his/her designee, for approval as a joint release. Once approved by the USDA-ARS, the draft release notice should be shared with the VRC as notification that a release is in process and to give the VRC the opportunity to review.
The OCCD has often been designated by the USDA-ARS as the licensor managing USDA-ARS cultivar licenses that go through OSU. All USDA-ARS selections that may be released will be controlled under material transfer agreements (MTAs) managed by the USDA-ARS Office of Technology Transfer during any testing. Once released, if OSU receives the license to manage the USDA-ARS cultivar, all MTAs will be handled by OCCD.

VII. Material Transfer Agreement Policy
The material transfer agreement (MTA) is a binding contract that governs the transfer of tangible research materials and protects the rights of the entities transferring the material. The MTA is designed to prevent misunderstandings between the parties and liabilities resulting from the misuse of university material being transferred. The MTA allows for continued research of the variety and prohibits commercial sales in order to preserve all intellectual property rights for OSU. The university employee or principal investigator is usually requested to sign acknowledgement of the content of the document and materials being transferred. Only authorized officers of the company and of the university (OCCD) may sign an MTA, thereby, legally binding the parties to an agreement. It is incumbent on breeders to understand legal requirements that have been imposed on them when sharing germplasm with others and to abide by these requirements to avoid liability for themselves or OSU.

Experimental use agreements (i.e., MTA or other agreement) must be in place ahead of any commercial activity to ensure OSU’s ability to protect the experimental selections and germplasm. MTAs allow OSU selections to be used for evaluation by growers and other people, for research purposes, as parents in other breeding programs, and increase prior to release of the new variety. In situations where there is an on-going working relationship between two parties, a simple MTA that describes the understanding between the two parties can be an adequate vehicle for exchange of materials. Having such MTAs in place is essential to protect the breeder and OSU’s interest.

MTAs define the ownership rights of the provider and identify the allowable uses of material transferred between the parties. It will spell out whether and under what circumstances the material may be used and modified. The MTA may limit the rights of the recipient to forward the material to a third party, and outlines publishing rights and patents resulting from use of the material. No warranties as to the performance of the materials are provided to the recipient.

If an MTA is needed, contact OCCD. The following information is to be provided to OCCD:

- Material identification list (i.e., label ID’s, genus and species, selection numbers, specific traits, etc.)
- Providers name and title and contact information (i.e., address, E-mail, phone)
- Recipient’s address (company name, division, physical location address, website); name of the recipient’s principal investigator, title and contact information (i.e., address, E-mail, phone); recipient’s name of the signing officer and title of who is authorized to give binding approval to the MTA.

VIII. Plant Breeder Roles and Responsibilities
1. The breeder has the primary responsibility to develop cultivars and to manage the breeding program. This includes choice of genetic materials for crossing, determination of appropriate breeding methods and strategies, number of generations of advancement, and type of cultivar (pure line, open pollinated, F1 hybrid, clone) used for release. The plant breeder consults with industry groups and other stakeholders to determine the goals and objectives of the breeding program.
2. The breeder has primary responsibility to ensure that variety trials are conducted. These trials may be performed directly by the breeder, extension personnel, farmer or industry cooperators, or by submission to regional testing nurseries, as determined appropriate by the breeder.
3. When sending out genetic materials for evaluation and testing, the breeder must have an MTA in place, ensuring OSU retains ownership of the materials and these rights are not waived with the distribution of the materials. The breeder may also exchange genetic materials with other breeding programs under MTA for further breeding and selection. In those situations (i.e., network trialing, multi-investigator, and farmer-
participatory projects in which seed is distributed for testing in many field sites) where it is not feasible to have MTAs in place, the breeder must contact the AES Director to discuss the issue.

4. The breeder has primary responsibility to compile data and to develop a release proposal package to submit to the appropriate CAC (if the program has one), and/or directly to the VRC (if no CAC exists for that crop).

5. The breeder makes recommendations to the VRC as to terms of release. This may include information on any cooperative arrangements utilized in the development of a cultivar (such as tri-state releases), the type of release proposed, and whether legal protection should be sought, and in what form. The breeder may also recommend which entities in industry might have an interest in commercializing the released materials. The breeder has input on the amount of royalties assessed or other assessments on the released materials.

6. The breeder will work with OCCD to implement commercialization of the cultivar. The cultivars and selections developed by the plant breeder are owned by OSU, and any decisions regarding the disposition of those cultivars and selections must be approved by the AES Director and OCCD in consultation with the plant breeder.

7. Breeders will arrange increase of the new cultivar.

8. Plant breeders will inform AES and OCCD of upcoming field days and meetings where potential releases may be viewed and discussed.

9. Plant breeders will provide a brief written description of their breeding program and short and long-term goals to all members of the VRC and CAC (if one exists for his/her crop).

IX. AES Director Roles and Responsibilities

1. The AES Director has authority and responsibility for all research programs in AES and the information and materials generated by those programs, including plant varieties.

2. Roles and responsibilities of the AES Director are typically delegated to an Associate Director of the Oregon AES, who assumes the full authority of the AES Director in carrying out these functions.

3. The AES Director reviews all release proposals in a timely fashion (three weeks), communicates with the plant breeders to resolve questions or obtain additional information, and forwards proposals to OCCD.

4. The AES Director will distribute pertinent information from OCCD reports of prior fiscal year end revenue summary statements to plant breeders within one month of receipt from OCCD, in a manner consistent with confidentiality restrictions.

X. OCCD Roles and Responsibilities

1. OCCD manages the protection, licensing and agreements concerning plant varieties in accordance with laws, policies and guidelines of OSU, the state of Oregon and USA. OCCD is required by OSU IP Policy to review and determine the best protection and licensing path forward, if any, on behalf of the university. OCCD will consult with the breeder and the CAC when determining the best protection and licensing path on a crop by crop basis.

2. OCCD works with the plant breeders to develop binding legal documents for the external distribution of OSU plant materials.

3. OCCD issues MTAs in a timely manner when the plant breeder provides the information detailed above (section VII).

4. OCCD maintains records of MTAs and provides to the plant breeder a list of MTAs when a selection is proposed for release.

5. OCCD reviews release proposals and alerts the breeder and the VRC of possible legal protection issues resulting from the included data and descriptions (see examples in Appendix I).

6. OCCD provides financial statements for each of OSU’s plant breeding programs annually. The financial statement should show income by cultivar and licensee, and expenses. The financial statement should be sent to the AES Director or his/her designee.

7. OCCD advises the breeders and others involved in variety release to assure that publication of information about potential releases does not jeopardize possibilities for protection while at the same time recognizing the
need for authors to publish in a timely fashion to meet OSU promotion and tenure and annual performance guidelines.

XI. Final Decisions on Legal Protection of OSU Plant Varieties
In those cases in which the AES Director’s designee, VRC, OCCD, and plant breeder disagree on legal protection and/or licensing terms of a plant variety, the issue and determination of the final outcome will be escalated to the AES Director and the VP for Research. For example:

If OCCD decides not to pursue legal protection because a plant variety is not predicted to have the commercial potential needed to justify the costs incurred, AES can either pay the costs or approve public release of the material.

If there is a recommendation by the VRC or plant breeder to release a plant variety at terms less than market value, the AES Director and the VP for Research will determine the holistic value proposition to OSU and make a determination.

XII. Royalty Income
Transparency in the handling of royalty income is essential to maintain confidence in the process both inside and outside the university. OCCD will distribute revenues to the inventor and the department account indexes. Prior fiscal year end revenue summary statements will be sent to the AES Director for review and further distribution internally and externally on a need to know basis. Royalty income will be distributed as described in any active Memorandum of Understanding (MOU) related to a specific commodity (such as hazelnuts, potatoes or wheat). In the absence of an MOU, fiscal year end royalty income will be distributed according to OSU policy (see table below). OSU Inventors and collaborating inventors may waive their rights to royalties and channel these back to the breeding program by assigning their share to the department. A separate memorandum of understanding between the breeding program and the Department Head should be established to indicate into which index these funds are to be distributed.

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