Introduction
The Kansas Agricultural Experiment Station (KAES) improves plant genetic resources through plant breeding and genetic enhancement programs. These activities primarily involve the crop species of wheat, soybean, sorghum, and canola but also include other crops, grasses, and plants with horticultural uses.

This document describes procedures for release of plant genetic resources and exchange of unreleased plant materials among plant breeders. The decision to release plant genetic materials is based on the following basic principles:

All releases must
1. clearly exhibit a substantial improvement over existing plant materials, even if only by a single characteristic such as resistance to a plant disease,
2. have demonstrated potential value in commercial agriculture or horticulture,
3. be distinguishable from existing plant materials to allow for the appropriate protection as intellectual property.

Exchange of plant genetic materials refers to the interchange of early generation plant materials (i.e., not suitable or ready for release) between plant breeders as part of the support KAES provides for genetic improvement of plant species of interest both nationally and internationally.

Plant genetic materials considered for release include varieties, parent lines, germplasm, clones, populations, inbreds, and hybrids. Development of such materials is the result of the work of plant breeders, geneticists, plant pathologists, entomologists, weed scientists, or others, individually or as teams.

This document represents a significant revision over previous versions in that all plant genetic materials are considered under a uniform set of procedures.

The decision to release plant genetic materials is made similarly for all plant species. However, actions taken after that decision will vary considerably by species and because of intellectual property issues. The policies and procedures outlined in this document provide uniformity in making decisions regarding release and exchange and guidance on the options available after such a decision.

Key terms
KAES – Kansas Agricultural Experiment Station
K-State – Kansas State University
KSURF – Kansas State University Research Foundation
KWA – Kansas Wheat Alliance
MTA – Material Transfer Agreement
NVRB – National Variety Review Board
PGMRC – Plant Genetic Materials Release Committee
PVP – Plant Variety Protection
PVPA – Plant Variety Protection Act

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Intellectual Property Protection

Intellectual property protection provides a number of avenues to protect plant genetic resources from unauthorized use, distribution, or sale; ensures that appropriate credit is given for scholarship of development of novel plant genetic resources at Kansas State University (K-State); and represents an opportunity for revenue generation for K-State as well as the breeders/inventors. Appropriate protection could include utility patents, plant patents, licensing, the plant variety protection (PVP) process, material transfer agreements (MTA), or a combination of these. Intellectual property issues most often involve protecting plant genetic resources developed by KAES scientists but could also include proprietary traits or other genetic resources owned by outside parties that have been or could be incorporated into releases from KAES.

The KAES Director may assign intellectual property rights for some plant genetic resources to the Kansas State University Research Foundation (KSURF), in which case KSURF is responsible for coordinating all necessary administrative issues including collection and distribution of income generated from the intellectual property. Contractual issues for all other plant genetic materials not assigned to KSURF are handled by the Office of the Vice President for Research at K-State.

Plant Variety Protection Act (PVPA)

The PVPA traditionally has been used to provide intellectual property protection for the release of varieties from KAES. This act provides protection for cultivars that are sexually reproduced through seed or propagated by tubers. Title 5 of the PVPA requires that seed from a protected variety be sold as certified seed if sold by variety name. A PVP certificate for a variety prevents unauthorized sale, delivery, consignment, exchange, delivery, conditioning, propagation for sale, or solicitation for sale. Two important exclusions from these infringements are the provision for a farmer to retain seed for their own use and the free exchange of the variety for research purposes. Generally, the PVP process provides nearly all of the requirements for a National Variety Review Board (NVRB) of the Association of Official Seed Certifying Agencies, which makes the official decision on whether the variety is eligible to be sold as certified seed.

Patents

Utility patents can be used to protect varieties as well as traits in any plant genetic materials. The process for obtaining a patent is generally much longer than that for a PVP certificate. Varieties with a utility patent can be sold as certified seed provided the requirements of the appropriate NVRB are met. Patents generally are used to create protection for proprietary traits rather than protect varieties without any unique traits. In some ways, patents afford a greater degree of control because there are no infringement exclusions for farmer seed retention or free exchange for research purposes. However, the PVP process provides greater protection for the overall seed production process by making seed processors and merchants liable for the unauthorized handling or sale of protected varieties.

The plant patent process is used commonly in the horticultural industry and provides intellectual property protection for asexually propagated cultivated plants, excluding tuber-propagated plants covered under the PVPA (e.g., potatoes) but including some grasses (e.g., zoysia). Plant patents offer slightly less protection than the PVP or utility patent options. Rights for sale, use, and asexual reproduction of the plant and its asexually reproduced progeny are retained by the plant patent owner.

Licenses

Licenses can be used in lieu of or in addition to PVP status or patents. Licenses provide specific terms under which two parties agree on the use, distribution, and sale of plant genetic materials. Under some circumstances, a license may provide sufficient protection or may be the only option to provide authorized use of the materials in question. Similarly, once a utility or plant patent is granted, licenses must be used to provide authorized use unless the plant genetic materials are used only by the owner of the patent.

Intellectual Property Issues

Intellectual property issues have become increasingly important. For example, development of proprietary traits in some crops has dramatically changed the way plant genetic materials are released and exchanged. Creation of the Kansas Wheat Alliance (KWA) also has contributed to this trend.
If entities outside K-State own proprietary traits or have other rights to plant genetic materials and KAES scientists wish to incorporate these traits or materials into their breeding programs for eventual release, appropriate measures must be taken to address the intellectual property requirements of the outside entity. The responsibility for meeting those requirements lies with the Office of the Vice President for Research, KSURF, or both.

Intellectual property protection also defines any revenue streams that might develop as a result of the release or exchange of plant genetic materials. When intellectual property rights have been assigned to KSURF, it will administer the rights and collect any royalties or license fees. Distribution of the revenues occurs according to K-State intellectual property policies. Research, seed stock, and other fees may be charged for use of plant genetic materials for which intellectual property rights have not been assigned to KSURF. The Office of the Vice President for Research administers these agreements, and the fees are returned directly to the department or unit.

For released plant genetic materials, formal application for intellectual property protection is not to take place until the KAES Director grants final approval of the release. It is incumbent on the breeder/inventor to ensure that intellectual property rights are not jeopardized by premature disclosure, sale, or other activities.

See additional information in the Kansas State University Research Foundation section on p. 7.

Increase and Release Procedures

**Plant Genetic Materials Release Committee (PGMRC)**

The overall goal of the PGMRC is to ensure that plant genetic materials released from K-State represent adequate advancement over materials that are already generally available. As such, PGMRC approval is one of many steps that helps ensure scientific integrity of the research and other processes involved in enhancement of plant genetic resources. An increase is considered under the same criteria as a release. Actions of the PGMRC are advisory to the KAES Director, who must approve all recommendations on policies, procedures, increases, and releases before they become final.

**Membership and Meetings**

The KAES Director appoints PGMRC members to 3-year terms. The committee membership is:

1. KAES Associate Director (chairperson)
2. Head of the K-State Department of Agronomy (vice chairperson)
3 & 4. Two plant breeders (not eligible to vote on materials developed in their programs)
5. Extension agronomist
6. Plant pathologist
7. Executive director of the Kansas Crop Improvement Association
8. Manager of the KAES Foundation Seed Program
9. Milling and baking representative from the K-State Department of Grain Science and Industry
10. Representative from the Kansas Wheat Commission
11. Representative from the Kansas Soybean Commission
12. Representative from the Kansas Sorghum Commission
13. Head of the K-State Department of Horticulture, Forestry, and Recreation Resources

The KAES Director, at the request of the chairperson, may appoint additional persons as needed to provide special expertise not available from the existing members. In particular, composition of the PGMRC for release of horticultural materials may be substantially different, with committee positions 3 to 5 and 9 to 12 being filled by persons with more appropriate expertise. Because the release of horticultural materials is expected to be relatively infrequent, an ad hoc committee will be formed as needed for each release. In such cases, committee positions 1, 2, 6 to 8, and 13 always should be retained.

The PGMRC will meet annually in late July or early August to accommodate releases from the wheat and canola breeding programs and again
in early winter to accommodate releases from the soybean and sorghum breeding programs. However, the committee can consider any plant genetic material at either meeting if requested. Meetings may be canceled or handled electronically as appropriate. The chairperson may call special meetings if necessary.

The vice chairperson is responsible for making arrangements for the meetings. The location should be as convenient as possible for the committee membership and could be held in conjunction with another event in which several committee members would normally participate.

**Responsibilities of the PGMRC**

1. Maintain confidentiality of all information associated with committee business.
2. Review and recommend to the KAES Director for approval the official release of new varieties, hybrids, parent lines, inbreds, clones, and germplasm developed by KAES — this includes all crop species, grasses, and plants with horticultural uses.
3. Review and recommend to the KAES Director for approval the name or designation of released varieties, parent lines, hybrids, inbreds, clones, populations, and germplasm developed by KAES.
4. Advise the KAES Director on policy related to release procedures.
5. Advise the KAES Director on appropriateness of exclusive or restricted releases.
6. Advise the KAES Director on the appropriate protection mechanism(s) for intellectual property protection of released plant genetic materials.
7. Review and recommend to the KAES Director the use of resources required to increase seed or plant material supply for plant genetic materials that appear promising for future release. For wheat, this involves the Foundation Seed Program. For other plant species, this may involve the Foundation Seed Program, contract growers, or KAES scientists.

**Permission to increase does not imply consent to release.**

8. Review and recommend to the KAES Director plans for publication of any proposed releases in refereed journals.
9. Formally submit a cover letter, set of minutes, and all release proposals to the KAES Director within 2 weeks of the conclusion of each committee meeting.

**Responsibilities of Breeders/Inventors**

1. Make proposals to the PGMRC for increasing and releasing new varieties, hybrids, inbreds, parent lines, clones, populations, and germplasm as described below. Proposals should be submitted electronically to the vice chairperson of the committee. Whenever possible, proposals should be submitted in response to a request for proposals from the PGMRC chairperson or vice chairperson. Proposals can be considered at any time but require a minimum of approximately 1 month for consideration by the PGMRC. Proposal preparation guidelines are given below.

2. Take appropriate steps to secure and protect an official name or designation for any releases, once approved.

3. Take necessary steps to provide adequate protection of intellectual property. This could include filing utility patent and PVP applications as necessary and working with KSURF or the Vice President for Research on license agreements or MTA.

*See additional information in the Exchange of Plant Genetic Materials section on p. 7.*

4. Prevent distribution of seed or plant parts before the official release or increase date.

**Preparation and Presentation of Increase and Release Proposals**

1. Proposals should be submitted well in advance of scheduled PGMRC meetings to allow sufficient time for distribution to and consideration by committee members.
2. Proposals should include the following:
   a. Whether the proposal is for an increase or release
   b. Clear articulation of the attributes of the plant genetic material that make it suitable for increase or release according to the guiding principles outlined in the introduction (i.e., substantial improvement over existing materials, demonstrated potential value, and distinguishable from existing material)
   c. Existing and proposed intellectual property protection mechanisms
   d. Proposed name or designation and a description of planned efforts to secure and protect said name or designation
   e. Complete list of collaborating scientists and their relative contributions
   f. For joint increases or releases, a complete description of the relative contributions of each entity and how intellectual property issues will be handled between the various parties
   g. Plans for publication of a release in a refereed journal
   h. Proposed release date
   i. For increases, plans for increasing supply of seed or plant parts and proposed timeline for presentation of release proposal
   j. For releases, an indication of the type of release requested (see descriptions below) with justification
      For exclusive or restricted releases, any existing agreements must be disclosed.
   k. Draft notice of release that can be modified, if necessary, after committee deliberations and signed by the KAES Director if the release is approved

3. Breeders/inventors are encouraged to make a presentation of their proposal directly to the PGMRC and may be specifically requested to do so.

4. Breeders/inventors may appeal directly to the KAES director in the event the PGMRC recommends against increase or release.

Type of Releases
Following release, it is assumed that a sufficient supply of seed or plant parts will be available for distribution. The supplier will vary depending on the plant species. The type of release section of the proposal describes potential recipients. In addition, intellectual property issues and licenses may dictate the identities of both the supplier and the recipient. Such arrangements may not be known at the time the PGMRC considers the release. Information that is known or the intent of the type of release should be disclosed in the release proposal.

Nonexclusive releases are available to any party provided they agree with any intellectual property or license restrictions.

Exclusive releases are available only to a single or select number of parties, who also must agree to any intellectual property or licensing restrictions. Such arrangements may be necessary because of existing intellectual property restrictions. The most relevant example is the existence of the KWA. In this circumstance, all new wheat varieties are assigned to KSURF, which provides the first negotiation opportunity to KWA. The KWA then markets the varieties and collects royalties that are returned to K-State. A portion of these royalties is used to support wheat breeding and related research efforts. Exclusive releases also may be used to ensure the availability of an improved variety that otherwise would not be effectively increased or marketed because of competition or other market factors.

Restricted releases have additional requirements that may limit the use of the plant genetic material. One example is specialty grains for a niche market that requires identity protection throughout the production, storage, and processing chain. Restricted releases may be nonexclusive or exclusive.
Post-Release Actions

KAES Director

The KAES Director should send a copy of the signed notice of release to the breeder/inventor and, if appropriate, to KSURF along with any special instructions regarding the type of release or intellectual property issues. Formal transfer of intellectual property to KSURF may be required at this time.

Breeder/Inventor

The breeder/inventor should obtain a copy of the signed notice of release from the KAES Director for their files. Complete and timely follow-through on all intellectual property issues is required. This may involve preparing a PVP application, licenses, patent applications, or a proposal for a NVRB; preparing and shipping any samples to repositories; and providing assistance with the preparation of any licenses or other required information. The breeder/inventor is expected to participate in the necessary steps to advertise the release to all potentially interested parties and to ensure adequate availability of seed or plant parts.

The breeder/inventor is strongly encouraged to publish the release in an appropriate refereed journal (e.g., Journal of Plant Registrations). A PVP certificate may substitute for a journal article, although publication is still encouraged. A journal publication provides appropriate credit for scholarship of the new product and recognition of the investment associated with development of the release. Note that intellectual property issues do not preclude publication in a refereed journal. For example, once a utility patent application is filed, publication can proceed without problems related to premature disclosure. Some licenses may require prior approval before submitting a journal manuscript for publication.

Foundation Seed Program

The Foundation Seed Program maintains genetic purity and seed availability for various crop varieties; some are KAES releases, and some are handled under the certified seed guidelines. As defined in the Federal Seed Act regulations, the foundation class of certified seed is the progeny of breeder or foundation seed produced under control of the originator or sponsoring plant breeding institution, or person, or designee thereof. As applied to certified seed, foundation seed is a class of certified seed produced under procedures established by the certifying agency for the purpose of maintaining genetic purity and identity.

For improved crop varieties developed by KAES, the PGMRC has administrative responsibility for variety release and associated seed activity. The PGMRC’s decisions regarding seed distribution of varieties will be implemented by the manager of the Foundation Seed Program in consultation with the head of the Department of Agronomy, the executive director of the Kansas Crop Improvement Association, and a representative of any licensees, if appropriate. Decisions should be made in a manner deemed to be of the greatest benefit to Kansas agriculture, including maintaining genetic purity and multiplication of the variety for certified seed sales. Considerations include uniform distribution over the area of adaptation of the variety, available seed supply in relation to the number of seed requests, and history of seed production by growers. For purposes of seed allocation, seed growers are placed in one of four categories. Conditional foundation seed orders are considered in sequence starting with Category I and progressing, as long as seed remains, toward Category IV. Conditional orders are adjusted so that all growers within a category receive seed after orders in the preceding category are filled, but some complete categories may not receive seed. Grower categories are as follows:

- Category I: growers who have produced certified seed of the crop being released in each of the previous 3 years
- Category II: growers who have produced certified seed of the crop being released in 2 of the previous 3 years
- Category III: growers who have produced certified seed of any crop in 1 of the previous 3 years
- Category IV: growers who do not meet the requirements of Categories I, II, or III

If circumstances deemed to be beyond the control of a grower result in classification in a category lower than history of certified seed production would indicate, the manager of the Foundation...
Seed Program may consider such circumstances and classify the grower on the basis of the total certification record. Growers who believe they have been treated unfairly by the seed allocation system may appeal to the KAES Director.

Foundation seed prices are determined by the manager of the Foundation Seed Program in consultation with the head of the Department of Agronomy and the executive director of the Kansas Crop Improvement Association. Prices reflect the costs of converting a grain crop to a foundation seed crop, and such prices are set above registered and certified seed prices. Foundation seed production costs include, but are not limited to, refining and maintaining varietal purity, quality control, land use, seed inventory control, cleaning, warehousing, production, and distribution.

**Exchange of Plant Genetic Materials**

Exchange of unreleased plant genetic materials between K-State plant breeders and others must either use an MTA or be subject to the Wheat Workers Code of Ethics or its equivalent, both of which clearly articulate limitations on use, commercialization, and disposition of the materials when work is complete. Such transactions do not need to be approved by the PGMRC but are subject to the appropriate approval processes as directed by the Office of the Vice President for Research or KSURF. At the end of each fiscal year, breeders/inventors must submit a list of such exchanges for the previous fiscal year to the KAES Associate Director. By June 30, 2010, a standard MTA statement will be developed and will need to be included with all exchanges of plant genetic material. This blanket document will not require signatures because receipt and use of the plant genetic material will imply consent with the MTA.

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**Kansas State University Research Foundation:**

**Intellectual Property Issues Related to Genetic Material**

For detailed information about intellectual property issues, visit [www.k-state.edu/tech.transfer/](http://www.k-state.edu/tech.transfer/)

**What is KSURF’s function?**

- Protect the rights of inventors and the university regarding inventions, discoveries (including biological materials), trademarks, copyrights, and software.
- Assist researchers in preparing invention disclosures.
- Evaluate the potential to protect the technology and to generate commercial interest.
- Promote transfer of technology to industry through negotiations of intellectual property issues related to sponsored research, material transfer agreements, or licensing.
- Distribute royalties and other income to inventors, departments, and the university.

**What actions can prohibit filing a patent application in the United States?**

A public (nonconfidential) disclosure of the invention

- The invention may not be described in a printed publication in the United States or a foreign country or in put into public use or on sale in the United States more than 1 year before the date of the application for patent in the United States.
- If a U.S. patent application is not filed within 1 year of public disclosure, no patent protection is available.

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What actions can prohibit filing a patent application outside the United States?

An inventor initially has the potential to obtain worldwide coverage as long as there is no public disclosure. However, once the technology has been publicly disclosed, only a U.S. patent application may be filed within 1 year.

What is considered a printed publication?

- theses
- presentation handouts
- manuscripts
- poster presentations
- information on the Web
- grant proposals (once awarded and published)

What else do I need to consider when patenting biological material?

Some countries require us to deposit samples of certain biological materials with the American Type Culture Collection (ATCC) prior to filing any patent application. Examples of these materials include algae, plant and animal viruses, bacteria, bacteriophages, cell lines, cloned genes, hybridomas, plant tissue cultures, recombinant DNA materials (plasmid and phage vectors, libraries, etc.), seeds, and yeasts.

For patenting purposes, deposits must be made with the ATCC. Deposits in other repositories may not satisfy requirements of patent law.

Can we license material that is not covered by a utility patent, plant patent, or plant variety protection certificate?

Biological material can have commercial value even if it is not covered by some form of intellectual property protection. This is the case if the material could be purchased more quickly and easily than it could be created independently. We can license germplasm, plasmids, monoclonal/polyclonal antibodies, viral isolates, cell lines, etc.

When do I need a confidential disclosure agreement (CDA)?

A CDA is a contract for the protection of proprietary information. Such a document is necessary before any transfer of proprietary information is made from one party (e.g., university investigator) to another (e.g., corporate scientist). Without this agreement, the individual or company to whom the information is disclosed is free to use and transmit this information to others. Such activity may significantly reduce or eliminate the value of intellectual property related to the information.

When do I need a material transfer agreement (MTA)?

An MTA is a contract to control the use and further distribution of research materials, including biological materials. Without this agreement, the recipient of the material is free to use the material for commercial purposes and further distribute the material to others. An MTA should be executed every time material is transferred to someone outside of K-State.

When K-State receives material from another party, the contract may be specific to a particular individual. In these cases, the specified materials may not be freely distributed to others at K-State or elsewhere.