Plant Germplasm Release and Distribution Policy and Procedures
College of Tropical Agriculture and Human Resources (CTAHR)
University of Hawaii at Manoa, January 2007

Replaces "Distribution of New and Improved Cultivars" found in Section 2 of the CTAHR Farm Manual, 1995

The vision for the College of Tropical Agriculture and Human Resources (CTAHR) is that we will actively help Hawaii diversify its economy, ensure a sustainable environment, and strengthen its communities, and we will be the premier resource for tropical agricultural systems and natural resource management in the Asia-Pacific region. The pursuit of new technologies, including plant breeding and biotechnology, for enhancing farming, food quality and safety, and the environment is consistent with this vision and will enable Hawaii to participate in the benefits of current and future technological innovations. CTAHR operates in the public domain and receives funding from public and private sources for its education, outreach, and research programs. The public funds include annual appropriations, grants, and contracts from the federal and state governments.

For Hawaii's farmers and growers to be successful in a highly competitive marketplace, improved and unique plant materials must be rapidly and widely used if the breeding efforts of CTAHR are to have their greatest impact on Hawaii's agriculture. The development of new plant germplasm is a natural output of research activities in a land-grant university. However, new plant germplasm does not benefit Hawaii unless it is released fairly and efficiently. CTAHR's policy establishes a uniform procedure for the release of plant materials consistent with documents developed by the Experiment Station Committee on Organization and Policy (ESCOP) of the National Association of State Universities and Land Grant Colleges (published November, 1988; http://policy.nrcs.usda.gov/scripts/lpsiis.dll/M/M_190_NPMM.pdf, Exhibit 540-29, See page 540-135), the Plant Patent Act (http://www.uspto.gov/web/offices/pac/mpep/mpep_e7r1_1600.pdf), and the Plant Variety Protection Act (PL91-577; http://www.ams.usda.gov/science/PVPO/PVPO_Act/whole2.pdf). The objective of this release policy is to facilitate an orderly and equitable release of plant material whether by seed or vegetative propagation.

The following are fundamental to this policy:

1) Plant material discovered, created, or developed by CTAHR personnel is the property of the University of Hawaii and is entrusted to CTAHR, with the exception stipulated under the Executive Policy E5. 500, Section IV.
2) Because of Hawaii's isolated agricultural sector, worldwide competition, fragile markets, and the large input of state and federal appropriations to support CTAHR, the activities of CTAHR in the development and distribution of new and

improved plant germplasm must support Hawaii growers and producers first and foremost.

3) CTAHR reserves the right to recover any costs of development, production, and/or maintenance of any improved plant germplasm if CTAHR laboratories or research stations were used in the process. If CTAHR facilities or research stations serve as repositories for improved germplasm, costs of maintaining these plants should be included in any distribution or licensing fees.
4) CTAHR, through specific plant germplasm distribution agreements, approved by the dean and director of CTAHR and the University of Hawaii, reserves the right to license to and grant exclusivity of improved plant cultivars or germplasm to bona fide, nonprofit commodity organizations or for-profit organizations, as appropriate. CTAHR reserves the right to limit the distribution of improved plant cultivars or germplasm to only Hawaii growers for a period of time as negotiated in the specific agreements. As a public institution, CTAHR will make every effort to encourage equitable distribution of its improved plant cultivars and germplasm to its growers. These agreements may include rights to license, market, and/or propagate improved plant materials while the University of Hawaii retains ownership.
5) Ownership rights of the newly developed plant cultivars or germplasm are vested in the University of Hawaii. Ownership rights to UH are established using the following categories of effort (See Appendix 1):
    a. Sponsor-Supported Efforts: Efforts in which the sponsoring agency waives or is silent on ownership or intellectual property rights.
    b. University-Assigned Efforts: Efforts funded by the University of Hawaii, the University of Hawaii Foundation, or the Research Corporation of the University of Hawaii are considered University-Assigned Efforts.
    c. University-Assisted Efforts: Efforts in which use of university facilities, including but not limited to research stations and laboratories, support staff, and telecommunications services are considered University-Assisted Efforts.
6) Intellectual property rights and income derived from intellectual property are to be shared between the university and the inventor(s)/originator(s), in accordance with University of Hawaii policies as established, unless it can be determined that the intellectual property was derived solely as an individual effort. (See Appendix 1 for definitions). University policies related to intellectual property rights can be found at the following Web site: http://www.mic.hawaii.edu/faculty/policies.html.
7) The Office of Technology Transfer and Economic Development (OTTED) serves as the agent for the university and its faculty and staff in developing and managing all licensing and material transfer agreements, invention disclosures, and patenting of new material. CTAHR and the inventor(s)/originator(s) are encouraged to assist OTTED in identifying potential licensees. All potential agreements developed by OTTED and related to distribution of plant materials must be reviewed and approved by the dean and director of CTAHR.

Release of Plant Germplasm for Testing (Prior to Formal Release)

If the experimental material is proposed for release as germplasm, it must possess at least one inherited trait that can be utilized by plant breeders in crosses to develop superior cultivars. Experimental evidence must be provided that the experimental plant possesses the desired trait that justifies the proposed release of the plant material. Evidence for the trait must be documented and the originating plant breeder or developer of new germplasm (hereafter the "principal investigator" or "PI") should describe how to utilize the trait in a breeding program. The principal investigator will decide when it is desirable to advance-test new crop materials with non-university cooperators. The purposes of advanced testing prior to naming and/or formal release are (1) to improve the evaluation of new materials under different environmental conditions, and (2) to minimize risk to the industry, which will make a substantial investment in planting new cultivars or crops. Advanced testing will be offered through, but not restricted to, the appropriate commodity organization. However, the organization will be kept informed of all such tests. The transfer of any plant genetic resource, whether produced by seed or vegetative means, that allows for the establishment of plant material for evaluation must be accompanied by a Materials Transfer Agreement (MTA) between the cooperator and the University of Hawaii (See Figure 1. flowchart). For more information about creating MTAs, visit the UH Office of Technology Transfer and Economic Development Web site (http://www.mic.hawaii.edu/faculty/mta.html). This agreement shall be reviewed and approved by the CTAHR principal investigator, the cooperator, the department chair, and the dean and director of CTAHR and signed by OTTED. It is the duty and responsibility of the principal investigator to monitor the plant material distributed under these agreements. Any deviations from the agreement should be reported to the dean and director of CTAHR and to OTTED. It is expected that the data collected from these collaborative arrangements will be summarized and then reviewed by the Plant Materials Review Committee in their peer review of any proposed germplasm release.

Selection of growers to serve as cooperators for testing will be made by the principal investigator with the cooperation of the appropriate specialists or county agents for that commodity. Private sector cooperators will be selected based upon the following criteria:

1. Experience as a commercial grower or propagator.
2. Past experience as a cooperator or interaction with UH and CTAHR.
3. Location geographically in the current or potential growing area.
4. Willingness to carry out the responsibility of a cooperator including:
    a. Following prescribed cultural practices and providing performance information to CTAHR upon written request;
    b. Keeping data on quality, yield, etc. of selections;
    c. Permitting periodic visits by researchers, specialists, and county agents and organized visits by other growers interested in the performance of selections and;
    d. Agreeing that plants under test are the sole property of the University of Hawaii, and therefore will not be discarded or propagated without the written consent of CTAHR.

All materials transferred to the cooperators for the testing purposes and the results of testing shall be the property of CTAHR unless the Materials Transfer Agreement provides otherwise or unless CTAHR releases its right to the cooperator after the testing is completed. CTAHR reserves the right to make a determination with respect to disposal of the materials transferred and tested.

Scientific Exchange of Plant Materials

In general, no distribution of plant materials shall be made outside the state of Hawaii before distribution is available within the state. Exceptions may be made where it will mutual benefit of the CTAHR scientists and cooperating scientists, breeders, collectors, or institutions. A Materials Transfer Agreement (MTA) between CTAHR and the other individual or institution must be approved before such transfer can take place. Once the Materials Transfer Agreement is approved, the PI notifies the research station or facility manager, who will arrange to obtain and prepare the materials for transfer. Mutually beneficial exchange of material, especially for unselected progeny, may be exempt from an MTA at the discretion of the PI with the notification and approval of the dean and director of CTAHR.

Protecting Plant Materials

If the new plant germplasm is to be protected, the first step is an invention disclosure (see Figure 2 flowchart). The PI completes the Invention Disclosure Form (http://www.mic.hawaii.edu/faculty/disclosure.html) through UH-OTTED. The disclosure must be reviewed by the PI's department chair and the CTAHR dean and director. The dean and director may refer the disclosure to the Plant Materials Release Committee (see below) for review. Any disputes to inventorship are referred to the university Patent and Copyright Committee (PCC) for resolution (University of Hawaii Executive Policy, Administration E5.500, Administration of the Patent and Copyright Policy, http://www.mic.hawaii.edu/faculty/execpolicy.html). UH may seek a plant or utility patent or protection under the Plant Variety Protection Act. As part of the invention disclosure process, the department chair must sign the disclosure form and verify, to the best of their knowledge, the accuracy of the information presented in the disclosure.

Plant Release Procedures

The release of any new or improved plant material (e.g., variety, cultivar, in-bred line, population, seed, or germplasm, hereafter referred to as "germplasm") imposes the obligation of providing reliable information regarding the value of the material and its potential use, and at the same time safeguarding the agricultural producers and industry and consumers of the state. Improved germplasm shall be eligible for release only after it has been recommended as meriting release by a Plant Materials Release Committee (hereafter referred to as "Committee"). This is a seven-member committee with three-year rotating terms and is appointed by the dean. Through scientific peer review, the committee is advisory to the dean and director of CTAHR. Membership on the committee

should include representatives of the various plant breeding programs within CTAHR, and/or county extension faculty representing those commodities, a representative of the CTAHR Faculty Senate, and/or industry representatives, as appropriate.

If the principal investigator believes that a new or improved plant germplasm is ready for distribution to the public at large, the PI applies to the chair of the Committee for review and approval. The originating plant breeder or the Principal Investigator will submit in writing, via the department chair or county administrator, to the Committee a case for release of the improved materials. If the Committee has questions regarding the release, the Committee can request a formal presentation to the Committee to discuss justification of proposed release of new germplasm. The request must provide supporting information and documentation for use by the Committee as follows:

1) A statement concerning the origin of the germplasm and the breeding and selecting used in its development.
2) A detailed description of the morphological, physiological, cytological, molecular changes, methods of propagation, or other novel characteristics that may distinguish the subject germplasm from other materials.
3) Evidence of performance must include data obtained by experimental and statistical procedures with appropriate interpretations by the originating plant breeder. The performance should be evaluated in replicated experiments over an appropriate period of time or number of growing seasons. Performance also should be evaluated in different environments or locations whenever feasible or not limited by resources. Alternative evidence such as molecular analysis can be used as evidence for early release of materials.
4) Performance data for a germplasm release may include, but are not limited to, the following:
    a. Novelty and uniqueness of the new material compared to existing germplasm.
    b. Yielding ability in comparison with one or more varieties or cultivars of current economic importance.
    c. Pest and disease resistance where appropriate; statements such as “moderately resistant” and “showing some tolerance,” etc., should be avoided unless expressed relative to an industry standard, or specified to be preliminary, or if the language is a descriptor for a quantified scale.
    d. Crop quality measures including such factors as color, weight, shelf life, oil, protein, sugar, fiber properties, tenderness, palatability, longevity, novelty, or others where appropriate.
    e. Seed characteristics (tolerance of mechanical injury, seedling emergence, storage life, resistance to environmental stresses, etc.).
    f. A statement on the suggested uses of the new germplasm, specifically the plant materials it is to replace and the soils or cropping systems for which it is best adapted. Performance information for plant material proposed for release as germplasm should include a description of the useful traits and experimental documentation of its value in breeding new plant materials.
5) Included in the request should be some information related to need for the new germplasm. Information related to industry priorities or the cultural impacts of the release can assist the Committee in judging the merit of the release.

6) Should the Committee recommend *against* release, the committee shall notify the PI and provide, in writing, reasons for not recommending release of the improved germplasm. The PI may appeal the decision by addressing concerns raised by the committee and by providing additional supporting data and re-applying for release. After additional review, should the Committee again recommend against release, a final appeal may be made to the dean and director.
7) Should the Committee recommend *in favor* of release, the committee shall inform the PI in writing, with copies to the department chair and Dean and Director's Office for filing. Upon approval, the PI shall follow procedures outlined in the Distribution of Improved Plant Materials section of the policy (below).
8) Upon approval of release and/or availability of improved germplasm, the CTAHR shall announce the release or availability of the improved germplasm via appropriate vehicles, e.g., a CTAHR publication, press release, or other announcement to the public and/or growers.

Distribution of Released Plant Materials

Distribution of a released plant material depends on whether it has been filed for PVP or plant patent. OTTED handles patented plant materials distribution according to the established UH procedures. Non-patented plant materials will be handled by CTAHR and distributed by the process described below (see Figure 3 flowchart). CTAHR reserves the right to release non-patented plant materials using the same process as patented plant materials, when an out-of-state party wishes to have access to these plant materials.

Public distribution of germplasm shall be through bona fide, nonprofit commodity organizations, for-profit organizations, or hobby organizations. Preference will always be given to Hawaii grower organizations. These organizations will submit to CTAHR a distribution plan that may be accepted, amended, or rejected by the PI and CTAHR. Of major concern is that the distribution system used by an organization be equitable to all qualified and interested commercial propagators and growers and not result in exclusion or favoritism. CTAHR reserves the right to terminate distribution rights in cases of discriminatory distribution practices. Distribution plans should be for a fixed duration.

The commodity organization for distribution shall be recognized as such by CTAHR if: (1) its membership consists of commercial growers and propagators in Hawaii and is open to all commercial growers and propagators of the state, and (2) it agrees to allow access to plant materials to nonmember growers and propagators in the state who request material. Commodity organizations assume the responsibility for the materials upon acceptance from CTAHR.

Commodity organizations may charge a fee to recover their costs of propagating the plant materials for distribution or actual distribution costs. These fees are over and above any charges to the commodity group or royalties collected, and fees should be established in the plant distribution agreement negotiated with CTAHR. Commodity groups may also solicit donations to support the breeding program or other research and/or extension programs in CTAHR, but such donations must be strictly voluntary and not in any way given for something in exchange, such as plant material. Such donations

will not specify any amount nor in any manner be represented as payment for past and future considerations.

All proceeds from the sale of improved germplasm or CTAHR's share of licensed germplasm, as established by Plant Distribution Agreements or licensing agreements with growers, shall be received by the CTAHR Dean and Director's Office. It will then be distributed to accounts of the principal investigator(s) and/or programs initiating the improved germplasm. These proceeds are for the purpose of recovering costs of production and to support ongoing programs of crop improvement.

In general, no distribution of plant materials shall be made outside the state of Hawaii before distribution is available within the state. Exclusive rights to distribution within and outside Hawaii can be negotiated with the commodity organizations through the execution of a Plant Distribution Agreement. This may include establishing a length of time that the plant materials are exclusively available to Hawaii growers before the materials are distributed out of the state.

Once the Plant Distribution Agreement is executed, the principal investigator, working closely with the county administrator or department chair and/or research station or facility manager will ensure that there is a sufficient amount of the material available to the commodity group at the scheduled time of distribution. Grant resources or biological determinants may limit the amount of material available for certain releases; CTAHR is under no obligation to meet a minimum number of propagules.

CTAHR shall keep records of identification, source, and amount of all plant materials distributed, as well as the organization to which it is distributed. Receiving organizations will likewise maintain records of their own distribution and report these distributions to CTAHR. Records shall be housed in the CTAHR Dean and Director's Office, the county administrator's or county agent's office and the farm manager's office from where the plant materials originate, if applicable. A signed copy of the Plant Distribution Agreement, licensing agreement, and/or the MTA must be in hand before any plant materials can be shipped, distributed or delivered.

In some cases, breeding research may result in materials that may be unusual or novel and for which a market or production facility does not yet exist. Such materials may be most suitable for release to organized hobby growers. CTAHR reserves the right to release materials, as available, to organized hobby groups following approval by the Committee. It is recommended that a Material Transfer Agreement be executed with the organized hobby growers or groups before the material is released. Such material can still be named and published by a peer-reviewed vehicle.

Naming Plant Materials

A new germplasm should be given an official designation at the time it is released. The International Code of Nomenclature for Cultivated Plants and ESCOP Policy provides guidance for the naming of cultivars and other plant materials. It is recommended that this source be consulted with respect to new cultivar names.

Under no circumstances should germplasm be distributed under more than one name, nor should the same name be used more than once in a given crop. Once established, a legitimate cultivar name should not be changed. Exceptions could occur when marketing issues arise, such as ability to sell a cultivar with a certain name in a

specific country, or other inadvertent objections, or as difficulties arise over time. Names that are misleading or identical or similar to brand names or trademarks associated with agricultural products should be avoided, as there may be an implied association of the cultivar and trade names or trademarks. To avoid conflicts in proposed names, appropriate federal and state organizations' registers should be referenced. The PI proposes a name for the improved plant germplasm; final approval rests with the CTAHR dean and director.

As part of the release process, the PI will publish a description of the plant germplasm including its origin, characteristics, and availability. Publication may be in a professional journal (e.g., *HortScience*); a trade journal (e.g., *Fruit Varieties Journal*); or a CTAHR publication. The PI working with the appropriate research station manager and county administrator shall also ensure that plant material is maintained at its repository. An approved plot allocation should be in place to cover these activities.

Permanent records of all named germplasm shall be stored in the CTAHR Dean and Director's Office. In no case may plant material be distributed for commercial production prior to its approved release date or distributed informally in any way other than in accordance to the procedures described by this policy statement.

Release of Transgenic Materials

Policies governing release of transgenic plant materials shall follow the policies stated above in addition to any other policies, guidelines, or statutes mandated by state and federal law.

Use of transgenic plant materials may involve licensing and marketing of gene constructs developed and patented by CTAHR scientists, or the utilization of gene constructs licensed from other persons, agencies, or commercial interests. To utilize this technology, UH may have to enter additional legally binding agreements with cooperators which may be at variance with the stated release policy for traditionally-bred plant materials described above.

Federal, state and local agencies have or may establish policies and procedures for developing and employing transgenic materials. For U.S. Laws and Regulations, consult the United States Regulatory Agencies Unified Biotechnology Website: http://usbiotechreg.nbii.gov/lawsregsguidance.asp.

Disclaimer

CTAHR is unable to guarantee that plant materials will be free of diseases and pests, nor does it guarantee taxonomic accuracy. Further, CTAHR is unable to guarantee that the plant materials will continue a specific long-term performance or marketplace success. Receivers of plant materials assume all risk and responsibilities for materials received.

Appendix 1

Definitions

A. Sponsor-Supported Efforts: Sponsored project agreements often contain specific provisions with respect to ownership of intellectual property developed during the course of such work, in which case the terms of the sponsored project agreement shall establish ownership. When the sponsored project agreement is silent on the matter, all rights of intellectual property shall vest in the University of Hawaii. Income, if any, from such intellectual property shall be shared; subject to sponsor's requirements and University of Hawaii Executive Policy, Administration E5.500, "Administration of Patent and Copyright Policy" (March 1985), and appropriate contractual agreements.
B. University-Assigned Efforts: Ownership of intellectual property developed as a result of assigned university effort shall reside with the university. Works supported by funding from the University of Hawaii, the University of Hawaii Foundation, or the Research Corporation of the University of Hawaii shall be considered assigned efforts. Income, if any, from such intellectual property developed from University-Assigned Efforts shall be shared between the university and the inventor/originator as established by University of Hawaii Executive Policy, Administration E5.500, "Administration of Patent and Copyright Policy" (March 1985), and appropriate existing contractual agreements.
C. University-Assisted Individual Efforts: Ownership of intellectual property developed by university personnel through an effort that makes use of the university shall be shared with the inventor/originator and the university. In general, the university shall not construe the provision of office space or access to library resources and off-line office computers as constituting use of university resources. Use of university resources shall include, but not be limited to: use of research funding; use of university-paid time within the employment period; use of support staff; use of telecommunication services; and use of facilities (laboratory and experiment station facilities) other than office or library facilities. Income, if any, from such intellectual property developed from University-Assisted Individual Efforts shall be shared as established by University of Hawaii Executive Policy, Administration E5.500, "Administration of Patent and Copyright Policy" (March 1985), and appropriate existing contractual agreements.

D. Individual Efforts: Ownership of intellectual property developed by university personnel shall reside with the originator/inventor of such intellectual property provided that:
    a. There was no use of university resources in the creation of such intellectual property; and
    b. The intellectual property was not developed in accordance with the terms of a sponsored project agreement; and
    c. The intellectual property was not developed by faculty, staff, or students as a specific university assignment.

    It shall be the responsibility of the originator of the intellectual property to demonstrate that this classification applies. The university shall relinquish all rights to the originator/inventor, if the invention or discovery is adjudged by the Patent and Copyright Committee (PCC) to have been made:
    - by the inventor independently of any contractual obligations to the university
    - and without using university equipment, facilities, or funds provided by the university or outside sponsor,
    - or the invention or discovery was made with the aid of university facilities or funds, but the PCC, with the written approval of the UH president or designated agent decides to waive the university's rights therein.

    Individual efforts may not include inventions or plant materials developed by faculty outside the university but that are closely related to the faculty member's UH research or extension program(s).

The University of Hawaii Patent and Copyright Committee (PCC) shall be vested with authority to administer this policy and address all matters pertaining to this policy as established by University of Hawaii Executive Policy, Administration E5.500, "Administration of Patent and Copyright Policy" (March 1985).

Figure 1. Flow chart for plant germplasm performance testing

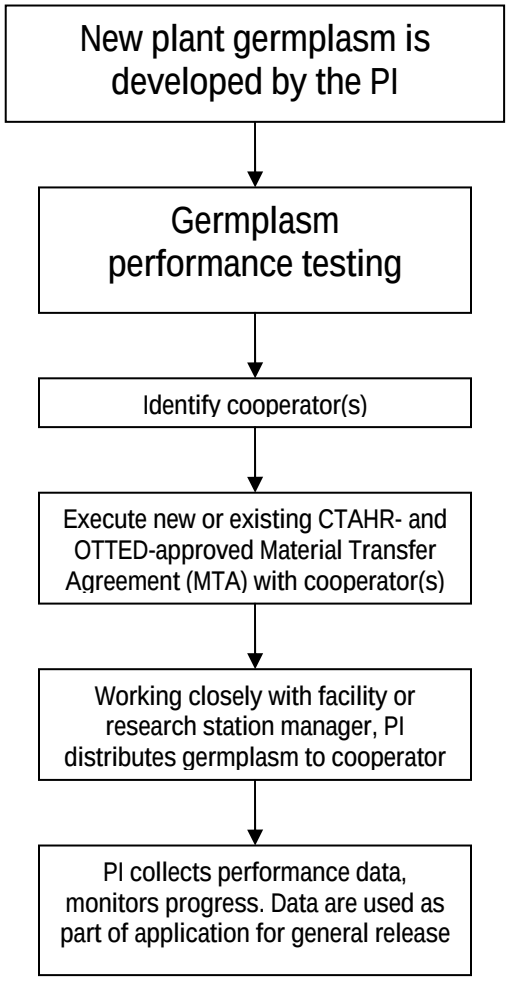

Figure 2. Flow chart for new plant germplasm seeking intellectual property rights protection

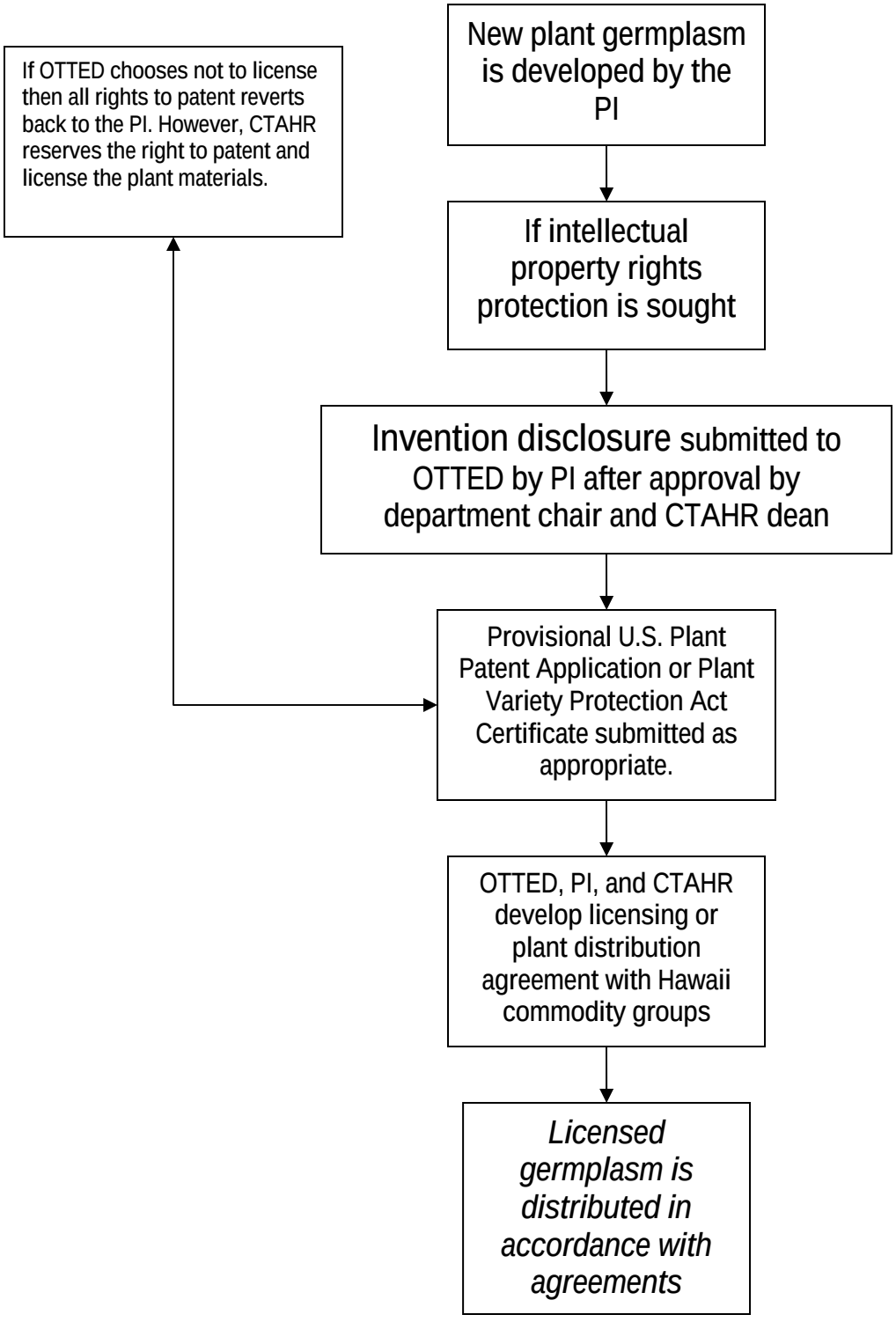

Figure 3. Flow chart for new plant germplasm not seeking intellectual property rights protection