United States Department of Agriculture
Research, Education, and Economics

ARS ❑ CSREES ❑ ERS ❑ NASS

Policies and Procedures

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This P&P describes policies, procedures, and responsibilities for technology transfer.

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1. Summary

Successful technology transfer (TT) helps ensure that society benefits from Agricultural Research Service (ARS) program. It responds to the public's right to know how tax-supported ARS research improves their health, the environment, and their quality of life. It meets the requirements of laws that mandate that ARS be proactive in transferring its technology to the private sector, including small businesses. Research is only successful if the information and technologies developed are transferred to those who need it.

ARS has been delegated authority by the Secretary to administer the patent and license programs for USDA. The ARS Office of Technology Transfer (OTT) is assigned the responsibility for protecting intellectual property, developing strategic partnerships with outside institutions, and performing other appropriate functions that enhance the effective transfer of ARS technologies to users. To accomplish this, OTT is organized around broad functional areas. The Administrative/ Headquarters Section conducts the day-to-day operations, coordinates the development of TT policy, and signs licenses and Cooperative Research and Development Agreements (CRADAs). The patent advisors (PAs) and the Patent Section assist the scientist in protecting intellectual property (IP), coordinate Invention Reports (IRs), prepare and prosecute patent applications, and oversee any patent applications prepared by contract law firms. The Licensing Section coordinates targeted marketing for selected ARS technologies and negotiates licenses for ARS IP. The Marketing Section coordinates the dissemination of information on ARS technologies that are available for cooperative work or licensing, provides answers to stakeholder questions on TT in ARS, and ensures that information about the commercial successes of ARS research is made available to the public. These objectives are accomplished via written information, reports to stakeholders, trade shows, the Information Staff (IS), the National Agricultural Library, and electronic media. Technology Transfer Coordinators (TTCs) are located in the field and have overall responsibility to assist in any way possible to facilitate and effectively transfer ARS technologies. They serve as liaison with scientists, line and program managers in ARS, university partners, users, and the private sector, they also negotiate CRADAs, other TT agreements and some licenses.

This Policies and Procedures pertains to: (1) reporting inventions, (2) patents, (3) Plant Variety Protection Certificates (PVPC), (4) licensing, (5) distribution of license income (including awards to inventors), (6) CRADAs, and (7) other agreements used in TT. It sets forth ARS policies, procedures and responsibilities for TT, and includes guidelines for inventors.

2. Authorities and Forms

- AD-416, Research Work Description-Research Resume
- AD-417, Research Work/Project Description, Classification of Research
- AD-421, Research Work Unit/Project Description, Progress Report
- ARS-425, Authorization to Apply for and Use Funds from Outside Sources
- ARS-451, Research Agreement Fact Sheet (Local reproduction)

- Departmental Regulation 5700.01, Patents
- Executive Order 12591, Facilitating Access to Science and Technology
- Presidential Memorandum to the Heads of Executive Departments and Agencies on Government Patent Policy, February 18, 1983
- 7 CFR, 1999 edition, section 2.65(a), Delegations of Authority to the Administrator, ARS, subparagraphs (11), (22), and (58)
- 37 CFR, part 404, Licensing of Government Owned Inventions
- 37 CFR, part 501, Uniform Patent Policy for Rights in Inventions Made by Government Employees.
- 7 USC 450(a), Cooperative Research Projects; Agreements with, and Receipt of Funds From State and Other Agencies
- 7 USC 2321 et seq., Plant Variety Protection Act
- The following parts of the Federal Technology Transfer Act of 1986 (FTTA):
    - 15 USC 3710a, Cooperative Research and Development Agreements (CRADAs)
    - 15 USC 3710c, Distribution of Royalties Received by Federal Agencies
    - 15 USC 3710d, Employee Activities
- 35 USC 200-209, Bayh-Dole Act, Patent Rights in Inventions Made with Federal Assistance

3. Invention Reports and Intellectual Property Protection

In many cases involving ARS research, some form of IP protection is required to justify the cost of commercial development of ARS research by a licensee. Most protection of intellectual property in the Federal Government is done through patents. Utility Patents protect a newly invented product, process, machine, or composition of matter. Plant Patents protect a unique plant variety that is produced vegetatively. Plant Variety Protection Certificates are issued for plants that reproduce sexually (by seeds) or by tubers. Once the patent is issued, protection extends for a period of 20 years from the date the patent application was filed. The first consideration in deciding whether or not to seek a patent is to ask if protection will enhance the likelihood that the technology will be transferred to the private sector. Many excellent original ideas are best transferred to those who need the information by scientific publications or other methods that do not involve patenting, such as electronic media, field days, demonstration projects, or public release.

Policy

ARS policy is to use the patent system to promote the utilization of inventions arising from its research, to ensure that sufficient rights in inventions are obtained to meet the needs of the Government, and to bring the invention to practical application.

ARS recognizes that patents represent documentation of research accomplishments and will consider patents, along with other factors, as evidence of research productivity in evaluating scientist performance under the Research Position Evaluation System.

Under U.S. patent law, a U.S. patent application must be filed within one year after a printed publication, public use or sale, or other enabling public disclosure of the invention. If an invention is to be, or has been made publicly accessible, the PA must be promptly advised so that the PA will have sufficient time to prepare and file the case at the U.S. Patent and Trademark Office (PTO). Most foreign countries require that patents be filed before public disclosure, which may be as simple as talking about it in a meeting with non-ARS personnel.

Inventors shall take prompt action to report inventions made as a direct result of their official duties. To ensure that their inventions are protected in a timely manner, inventors shall submit an Invention Report as soon as there is enough information to evaluate the invention. Waiting to submit an IR until a manuscript disclosing the invention is submitted for ARS clearance for submission to a journal may delay publication of the manuscript to protect the Intellectual Property Rights (IPR).

USDA is entitled to patent ownership of an invention. As a condition of employment, ARS scientists must assign their rights in their inventions to the Secretary of Agriculture who represents USDA. It is the decision of ARS, not individual scientists, as to whether or not inventions are to be protected. ARS does not assign its ownership of inventions to other parties.

ARS shall file for patent protection on those inventions that have been adequately described, have been reduced to practice, and have been evaluated to determine that they appear to have significant commercial potential, and that a patent will speed TT and preserve U.S. Government property rights. Patents should be filed no later than one year from the date that the invention is recommended for patenting by a Patent Review Committee (PRC), provided that information or data necessary to support the scope of the invention is complete and made available to the PA by the inventor.

Patent maintenance fees are required by the U.S. Patent and Trademark Office. These fees are due at intervals of 3 ½, 7 ½, and 11 ½ years during the life of the patent. If the fees are not paid, the patent cannot be enforced or licensed. General ARS policy is to pay the first 3 ½ year maintenance fee, since activities to locate appropriate potential licensees take time. Criteria used to determine whether or not to pay the subsequent fees are the same as those used by Patent Committees for determining whether or not to seek a patent.

If ARS decides not to apply for domestic and/or foreign patents on an invention or to abandon or otherwise not pursue commercialization of a patent, the inventors may be entitled to ownership of patent rights under one or more authorities cited above. If interested, the inventor should seek advice from the USDA Office of General Counsel (OGC), Deputy Assistant General Counsel for Patents (DAGCP), however, returning of patent rights may create a conflict of interest situation that would necessitate the reassignment of the inventor to a different area of research.

ARS policy is to obtain utility patents on plants or transgenic animals on a case by case basis. Primary consideration will be given to whether IPR are necessary to speed transfer of a new plant or animal invention into commercial trade, if protection is necessary to permit widespread

availability of the plant or animal variety, or if protection will enhance international competitiveness of domestic producers. It is ARS policy to ensure that all plant varieties developed by ARS are available for breeding.

Procedures

Reporting Inventions

The ARS scientist who thinks he or she has something to protect starts the process. They should contact their respective PAs for assistance as soon as they believe they have made, or are about to make, a new invention, but definitely no later than when starting preparation of a presentation or scientific manuscript that reports the research leading to the invention.

Early reporting to the PA may save the scientist considerable time by determining whether the invention is patentable, and by giving the scientist advice on what information might be needed to develop a good patent application. The PA can also help the scientist protect his/her IPR by resolving questions as to what would constitute public disclosure of the invention.

The next step is for the scientist to submit an IR using the Invention Disclosure Form located in the Research Management Information System (RMIS). This confidential document is not available to the public and requires approval from line management (i.e., as appropriate) Research Leaders (RL), Location Leader (LL), Laboratory Director (LD), Institute Director (ID) and Area Office (AO). This approval process keeps line management fully informed about discoveries made in ARS laboratories. The IR provides information on the technology, commercial potential, related publications that may affect patentability, advantages over the state of the art, and possible inventors.

As soon as the IR is complete, a hard copy must be printed, signed and dated by the inventor(s), witnessed (signed and dated), and forwarded immediately to the appropriate PA.

Patent Review Committee

The Patent Review Committee (PRC) is an important, and confidential part, of the ARS patent process. It is composed of a PA and several scientists as peers. Individual scientists are invited to serve as voting members because of their scientific expertise. Others, such as the TTC, other members of OTT, and National Program Leaders of National Program Staff (NPS), often sit in and contribute to the discussion, but are generally nonvoting members. PRCs are established by PAs for their geographic region of responsibility, or by subject matter area, such as biotechnology or mechanical/chemical inventions.

PRCs meet periodically, but an individual case should be reviewed within three months after a PA has determined that an invention disclosure is complete. For each case, an in-depth reviewer who is a peer on the PRC, contacts the inventors, line managers, other scientists, etc., to obtain

additional information that might be needed in reaching a decision whether or not to prepare and file a patent application. Several factors are considered by the PRC in reviewing each case in addition to the question of patentability, which is preliminarily assessed by the PA. These include:

- Is there commercial interest or a high probability of commercialization in the future?
- Is the size of the potential market large enough to justify the expense of commercialization?
- Will a patent play a significant role in transferring the technology?
- If granted, will the patent be enforceable?
- Is the invention of sufficient scope to justify patenting?

Several recommendations are available to the PRC based on the answers to these questions: they may approve proceeding with the patent application, suspend further action, or defer further action until the inventors provide additional information or data. Further patenting decisions are made by the Assistant Administrator for TT or the designated official.

Patents

Once an invention disclosure is approved and the necessary information provided to the PA by the inventors, a patent application is prepared. Prompt input from the inventors is critical. Preparing and filing a patent application with the PTO may take up to one year depending on the complexity of the application, the response time of the inventors, and the backlog of applications in OTT. The filing fee of approximately $800-$1,200 is paid by the inventor's Management Unit. All other fees, such as the prosecution fees, issue fee, maintenance fees (every four years) and foreign filing costs are paid by OTT from the patent revenue account (PRA).

When, ARS enters into partnerships with other institutions which result in jointly owned IP, OTT retains the right to prepare and prosecute patents. That right may be waived, at OTT's discretion, to a co-owner of an invention, or to a CRADA partner for an ARS solely owned invention. The other party must request the waiver in writing to the PA responsible at the ARS location involved. After review, the PA may grant the waiver, however, the PA and the USDA DAGCP must both be listed as Agent and Attorney of Record, respectively. The filing party must provide the PA with copies of the application, all documentation, notices from the PTO, and updates on prosecution. ARS retains the right to rescind the waiver if circumstances change and it is no longer in the Agency's best interest to allow the outside entity to continue prosecution.

ARS inventors should not sign any documents relating to intellectual property rights provided by any outside entity or its legal representative without prior review and approval by the PA.

OTT may also determine that contracting patent preparation with an outside law firm is in the best interest of ARS in obtaining a patent. Such a decision is usually based on time constraints or an unusual subject matter area. OTT selects the law firm and requires that a PA and the DAGCP liaison be Agent and Attorney of Record, respectively. Preparation expenses are usually paid by OTT from the PRA, however, the inventor's laboratory may pay in cases where OTT has decided not to pursue patenting of the invention. OTT generally retains authority to prosecute the patent application before the PTO.

Disclosure

Information released about an invention can result in the loss of IPR. Disclosure, for example, can be as simple as publishing an abstract, presenting a poster at a scientific meeting, discussing the discovery at a meeting with non-ARS participants, or putting the information on the Internet (this includes electronic reports in the RMIS that ARS makes available to the public). If there is a disclosure before filing for a U.S. patent, foreign patent rights are ordinarily lost, and U.S. patent rights must be sought within one year of the disclosure. Once the domestic patent application has been filed, there is a one year period from the date of domestic filing to file for foreign rights, provided that there was not a public disclosure prior to the domestic filing. ARS scientists must contact their PA prior to making public presentations or release of materials or technologies that may have associated IP.

Inventorship and Ownership

Inventorship is defined by patent law. Consequences of inaccurate listing of inventors on patents is more severe than the inaccurate listing of authors on manuscripts. Wrongfully including someone on a patent application who is not an inventor, or leaving off someone who is, can result in the challenge and invalidation of the patent. Any doubts about inventorship should be brought to the attention of the PA when an invention is first submitted. The PA will then make a determination of who is actually an inventor after interviews and collection of information on each person's contribution to the invention.

Ownership (rights) is another key issue in patents. USDA, like most organizations whether public or private, requires inventors to assign (transfer) their rights of ownership to the organization as a condition of employment. In ARS, this includes both domestic and foreign rights. The owner, not the inventor, licenses the patent and receives any income generated (see Section 4). IP developed by government researchers is, and remains, Government Property and may only be transferred to others under set procedures. A common misconception is that providing of funds and materials results in ownership. Any document originating from an outside entity that addresses IP or IPR must be reviewed by OTT for conformity with law and ARS policy before signing.

Plant Variety Protection Certificates (PVPCs)

PVPCs cover plant varieties propagated sexually (by seeds) or by tubers (like potatoes). They are prepared by the ARS scientist in consultation with the NPS and processed by the USDA Plant Variety Protection Office, rather than the PTO. PVPCs allow for the use of the variety in breeding programs without permission of the Plant Variety Protection (PVP) holder and also permit farmers and growers to save seeds for their own use. The cost of filing a PVP application is approximately $2,400 which is paid by the breeder's Management Unit. There are no maintenance fees. PVPs apply only to the U.S. but many foreign countries have a system known as "Breeder's Rights" which is similar to PVPs. Laws governing PVPCs do not require identifying breeders, only the owner(s). However, an organization must have a breeder of the variety to be an owner. ARS's policy is to list its breeders on Plant Variety Protection Certificates (PVPCs).

General information needed to obtain PVPCs may be obtained from: The Commissioner, Plant Variety Protection Office, Agriculture Marketing Services, NAL Building, 10301 Baltimore Blvd., Beltsville, Maryland 20705.

4. Patent Licensing

In order for an individual or entity to make, sell, use or have made a patented invention, the right to do so must be licensed from the owner. The USDA patent licensing program grants patent licenses to qualified businesses and individuals who wish to commercialize inventions resulting from federally supported research performed at USDA laboratories and research locations.

The USDA technology licensing program has been delegated to and is administered by OTT. Licenses may be exclusive, co-exclusive, exclusive by field of use or territory, or nonexclusive. They may be broad (for anything covered by the patent) or limited to a specific field of use. Revenues from licenses may include up-front fees, annual minimum royalties (maintenance fees), milestone payments and royalties (usually a percentage of net sales). ARS inventions not made under a CRADA (see Section 7) may be exclusively licensed after notice of the invention's availability for licensing has been announced in the Federal Register. In addition a notice of ARS intent to grant an exclusive license must be published in the Federal Register in accordance with Federal Regulations (37 CFR 404). Other parties who may also want a license have 60 days to submit a written objection to the granting of the exclusive license and must submit a complete license application to support their objection. If there is more than one qualified domestic applicant, then co-exclusive licenses may be issued to all qualified applicants.

Policy

An objective of ARS is to serve the interest of the Government and the public by having ARS inventions developed to the point of practical application. The granting of patent licenses is one procedure to reach this objective.

The licensing of federally owned inventions must be done in accordance with the terms, conditions and procedures prescribed under 37 CFR 404 regulations administered by the Department of Commerce.

The key provisions are summarized as follows:

- Only protected IP, i.e., a patent application, issued patent, or PVPC can be licensed. ARS does not have statutory authority to license non-protected property.

- Application for a license must be addressed to the Federal agency having ownership of the invention. In the case of USDA, applications must be addressed to the Patent Licensing Coordinator, OTT, ARS.

- A license may be granted by the Federal agency only if the license applicant has supplied the agency with a satisfactory plan for the development and marketing of the invention and has provided evidence of capability and intention to fulfill the submitted plan.

- There is a preference for small business applicants if they are equally qualified.

USDA/ARS often has jointly owned inventions, especially with universities. ARS can license the rights to these inventions to the co-owner if it is in the Agency's best interest to do so.

Licensees reimburse ARS for domestic and foreign filing, prosecution, and maintenance costs.

ARS permits its inventors, where practicable, to participate in the development of their inventions by permitting them to provide technical assistance to licensees.

Because of conflict of interest rules, inventors shall not participate in license negotiations to establish fees and royalties. Inventors and RL's may furnish advice on license strategy and negotiations.

ARS strongly supports the principle of the "research exemption" to patent rights. Accordingly, ARS does not in-license technologies or patents for use in ARS research programs, nor does ARS require others to obtain a license for use of ARS technologies in research, or permit a licensee of ARS patented technology to require licenses for research use.

Procedures

37 CFR 404.8 sets forth the information that must be provided by a license applicant. For the convenience of the applicant, USDA has itemized the information needed on Form AD-761, which is included in the Patent License Application Package. The information submitted is used to determine whether the applicant has both a complete and sufficient plan for developing

and marketing the invention and has the necessary manufacturing, marketing, financial and technical resources to carry out the submitted plan. Under the provisions of 37 CFR 404.14, any plan submitted by a license applicant may be treated as privileged and confidential and not subject to disclosure under the Freedom of Information Act (FOIA, 5 U.S.C. 552).

All members of OTT can provide general information regarding the licensing program, and information is also available at the OTT Internet site (http://ott.ars.usda.gov).

Patent License Application Packages are available from:

Coordinator, Technology Licensing Program
USDA, Agricultural Research Service
Office of Technology Transfer
5601 Sunnyside Avenue
Beltsville, MD 20705-5131

Phone: (301) 504-5989
Fax: (301) 504-5060

The Technology Licensing Program Office is available to answer any questions concerning the license application process, how to complete the license application form, and license agreement terms.

5. License Income

Policy

ARS license income is distributed in compliance with the Federal Technology Transfer Act of 1986 (FTTA, 15 USC 3710c) which authorizes specific uses for income from inventions: incentive awards to the inventors; expenses for prior art searches; patent filing costs; costs associated with administration of patent activities; licensing and administration expenses; rewards to employees for TT activities, including the annual ARS TT awards; and activities that increase licensing potential for transfer of technology (salary expenses related to some TTCs, PAs and support positions).

Government inventors shall collectively divide, as an incentive award, the first $2,000 of income received by ARS from each license and 25% of income over $2,000 each year up to a maximum of $150,000 per inventor per year. For licenses negotiated prior to March 7, 1996, the inventors share is 25% of the total income received each year.

This payment shall not affect the entitlement of the inventors to any regular pay, annuity, or award to which they are otherwise entitled or for which they are otherwise eligible or limit the amount thereof. ARS employee(s) who leave ARS receive license income award(s), provided they were an ARS employee at the time the invention was made. Heirs of an estate of a deceased ARS inventor receive decedent's license income award(s).

Procedures

The Legal Instruments Examiner/Licenses (LIE/L) monitors payments of licenses and sends notices to the licensee where needed for royalty income and reports.

The Foreign Patent Specialist monitors domestic maintenance fees and foreign patent filing costs and notifies licensees when reimbursements are due.

When checks are received from the licensee, they are forwarded to the appropriate office in the Financial Management Division (FMD) for deposit in the OTT PRA. Distribution for licenses with single inventors, or licenses with single patents but multiple government inventors are calculated by FMD following standard ratios. When multiple patents and inventors are involved, the LIE/L calculates the income awards due to government inventors and notifies FMD of the distribution to reflect current procedures.

FMD notifies NFC to issue checks to the inventors for their awards.

6. Partnering with Outside Organizations

Agreements with outside organizations, whether public or private, produce many direct benefits. They allow research scientists to obtain expertise, proprietary products, and information that would not otherwise be available to them. Hence, agreements can markedly speed up the research process and greatly shorten the time required to get a problem solution to those who need it. Finally, agreements can bring in outside funds to leverage limited research dollars. TTCs deal directly with the scientists in the field locations to negotiate CRADAs, assist in the patent process, act as liaison with private industry and in some cases negotiate licenses. The selection of the type of agreement to use is important. It is not just a matter of choice, but often a matter of law, regulation, or policy. Different situations require specific types of agreements and actions. Regardless of the type of agreement, the subject area must be within the mission of the specific laboratory entering into the agreement. Sometimes only one type of agreement permits a desired outcome. Discussed below are some of the agreements used in TT.

7. Cooperative Research and Development Agreement (CRADA)

This is the most formal agreement available for cooperative research. It is authorized by the FTTA. Two aspects of a CRADA that make it unique. First, it gives the cooperator the right to negotiate an exclusive license in at least one field of use to any ARS solely owned invention(s) or jointly-owned invention(s) conceived or reduced to practice under the scope of work of the CRADA. Second, it permits ARS, at its option, to keep information developed under the CRADA confidential for up to five (5) years if such information would have been proprietary had it been generated solely by the cooperator. ARS is required to keep confidential indefinitely any proprietary information given to ARS directly by the Cooperator, unless the information becomes publicly available from a source other than

ARS. CRADAs are developed by scientists and TTCs, approved by NPS and line managers, and signed by OTT on behalf of ARS.

Policy

It is ARS policy to implement and take advantage of the authorities provided in the FTTA (15 USC 3710). Scientists and TTCs are authorized to seek out opportunities for CRADAs with Cooperators provided the following criteria are met:

- All parties to the CRADA must have a mutual interest in the CRADA's objectives and the research work must be consistent with the ARS and CRIS Research Management Units' mission.

- CRADAs may or may not have incoming funds, but both partners must actively participate in the research. In addition to intellectual input and proprietary information, such participation may involve contributions of personnel, equipment, supplies, materials, facilities, etc. ARS is not authorized to contribute funds to another party under a CRADA.

CRADAs should not be used simply as a means to bring in outside funds, nor should they normally be used to test, develop, or validate a company's product.

CRADAs are appropriate vehicles for:

- Transfer and/or further development of ARS technology.

- Research combining ARS's and a Cooperator's intellectual property or technology.

- Discovery and development of new and/or improved products and or services.

Inventions arising under the scope of the CRADA that are either solely owned by ARS, or co-owned by ARS and the Cooperator, are offered to the Cooperator for licensing in at least one field of use on an exclusive basis without Federal Register notice. As with any ARS license, the Cooperator must submit a complete and sufficient license application which includes a business plan for commercialization of the invention.

ARS personnel shall handle TT documents expeditiously and appropriate procedures are to be used to protect information identified as proprietary.

ARS scientists/inventors may work closely and directly with Cooperators to help commercialize technology based on the scientists' research.

Procedures

Development of a CRADA

ARS TT opportunities are announced through meetings, symposia, workshops, conferences, and/or in the print or electronic media, and scientists are contacted by potential Cooperators. Formal competition is not required except as deemed necessary by the Assistant Administrator for Technology Transfer.

The ARS scientist and Cooperator identify the area of cooperative research work.

The ARS scientist contacts the TTC and the two consult and receive verbal approval from the RL to proceed with developing the CRADA. If the CRADA concerns a sensitive area such as biotechnology, documentation of NPS approval prior to negotiations is required and approval must also be obtained from the Institute/Laboratory/Center Director and Area Director. (See also Early Review of CRADAs).

The ARS scientist and Cooperator develop a brief description of proposed cooperation and forward it to the TTC.

The current version of the "Generic CRADA" should be used by the TTC in drafting a CRADA for review by all parties. Any special provisions or considerations are incorporated into the text of the document.

The draft CRADA, with supporting documentation, is forwarded, through the AD, to OTT's Authorized Departmental Officer (ADO/OTT) for action.

For CRADAs involving the receipt of funds, the scientists will obtain approval from line management, NPS, and the Ethics Office via normal channels, i.e., forms ARS-425, AD-416, AD-417, and the Research Management Information System Coordinator. A copy shall be forwarded to OTT. If no funds are to be transferred under the CRADA, only the form ARS-425 is required. A CRADA will not be finalized unless these approved documents are in place.

The ADO/OTT obtains other appropriate internal ARS clearances of the final CRADA, checks that the document is complete, sends it to the Cooperator for signature, and upon return of the Agreement makes distribution.

Award Document

The award document consists of:

- The ARS-451 or equivalent.

- The CRADA prepared as described above.

The distribution of the award document is:

- If ARS is receiving funds from the Cooperator, the National Finance Center's Reporting Section No. 4, receives a copy of the award documents.
- Cooperator (manually signed original).
- ADO/OTT Official File (manually signed original).
- ADODR (photocopy).
- ABFO (photocopy), if ARS is receiving funds from the Cooperator.
- TTC (photocopy).
- APAA (photocopy).
- Information Staff (photocopy).
- OTT Marketing Section (photocopy).
- REE Ethics Office (photocopy)

Amendments or Revisions

Proposed amendments or revisions to existing CRADAs are processed by the ADO/OTT in consultation with the ADODR, the Cooperator, the NPS, the AD, and the OTT staff. Procedures are designed to be as expeditious as possible. All amendments must be made in writing. Prior to official amendment, the ADODR will be asked to submit a progress report, a new budget and a revised statement of work.

Administration

The ADODR and Cooperator shall submit work progress reports to each other at the frequency agreed upon in the CRADA and at closeout/termination. Copies are sent to the ADO, who makes further distribution including AAOTT, IS, NPS, OTT Marketing and the REE Ethics Office (final reports only).

The ARS and the Cooperator shall submit invention reports to each other as set forth in the CRADA.

The ABFO will:

- Provide fiscal and accounting support to the ADODR.

- Send the Cooperator an annual financial statement (if required) when funds are received by ARS. A copy is also be sent to the ADO.

- Verify final payment on all valid obligations with the National Finance Center and recommend return of funds not used to the contributor(s).

The ADO/OTT periodically contacts the ADODR and the Cooperator, as necessary, in order to monitor the accomplishment of the CRADA and the ADODR's adherence to his/her duties under the CRADA.

Closeout

The ADO/OTT notifies the ADODR and the REE Ethics Office that a CRADA is due to expire prior to expiration. The notice specifies the documentation necessary to close out a CRADA. Such documentation typically includes:

- Final Technology Report.
- Description of accomplishments (new products or services).
- Report of all inventions.

The ADO/OTT sends closeout files to the Records Retention Center as soon as possible after closeout in accordance with ARS files management procedures. Also sends notification of expiration of CRADA to the REE Ethics Office.

Early Review of CRADAs

For proposed CRADAs involving plant and animal biotechnology research and other sensitive topics, there will be a more formal, extensive, and systematic review early in the agreement development process. In addition to addressing standard evaluation criteria on mission relevance and resources, there also needs to be careful consideration for risk criteria (including human health, environmental effects, social consequences, etc.) and potential legal or public mission issues (national security, access to tool technologies, etc.).

Information, as described in the Administrator's Memorandum dated April 11, 2000, shall be submitted by the TTC electronically to the NPS (the relevant National Program Leader and Associate Deputy Administrator) prior to negotiating the CRADA with the Cooperator. The same information would be made available to line management including the Area Office. If the NPS concurs that the proposed CRADA is appropriate for negotiation, then the Program Leader will inform the TTC by e-mail with a

copy to the ADA and AD. Line management would continue to give approval to proceed with the CRADA development via the ARS-425 procedure. Either line management or NPS could raise additional questions at any point throughout the process. Approval of the final draft would continue to be by NPS, line management, and OTT. The TTC would be responsible for coordinating and tracking the entire CRADA process. The Coordinator shall provide documentation of the review decisions and recommendations with the documents submitted for final Agency clearance.

8. Other Types of Cooperative Agreements

Detailed Policies and Procedures for other types of cooperative agreements are found in P&P 324.0, Reimbursable and Trust Fund Agreements, Chapter 2400 of the Financial Management Manual and the Extramural Agreements Manual Given below are brief descriptions of these agreements as they relate to TT.

Trust and Reimbursable Cooperative Research Agreements

Both of these agreements have incoming funds from the cooperator. In Trust Agreements, ARS receives some or all of the funds at the initiation of the agreement. The Reimbursable Agreement allows for repayment of funds after they are spent. Both agreements are similar to CRADAs but lack the provision for exclusive licensing of ARS inventions. Confidentiality provisions apply to the Cooperator's proprietary material, but information developed by ARS during the agreement can be withheld only to protect IP rights until a patent application is filed, normally no more than one year. The TTC may assist in the negotiation and preparation of these agreements. They are approved by line management and NPS if incoming funds are more than $25,000, and signed by an Authorized Departmental Officer at the location or Area Office.

Memorandum of Understanding (MOU)

The MOU is similar to a Trust Agreement but no money changes hands, although other resources such as personnel, supplies, or equipment may be exchanged. Approval and signatures are the same as for Trust and Reimbursable Agreements.

Material Transfer Agreements (MTAs)

MTAs are used when a scientist desires to provide material to someone outside of ARS but wants to maintain control over the material and also avoid public disclosure (use). A MTA is also used to bring in material from parties outside ARS. This agreement states specifically what the material is, what it can be used for, restricts giving it to a third party without permission, and prohibits commercial use. A standard version is available from the TTC or the OTT homepage. The standard MTA must be signed by the Cooperator's representative and the scientist and RL. The TTC receives the original for post-

approval after signature. When a scientist is asked to sign either 1) an MTA from an outside organization in order to receive material the ARS scientist wishes to use for research, 2) or when the company requests changes to the standard ARS MTA, the MTA MUST be reviewed and approved by the TTC prior to signing to ensure that the provisions are acceptable to ARS.

Confidentiality Agreements (CAs)

A scientist should use a CA when he or she wants to discuss unpublished information or data with someone outside of the Agency that other wise might disclose IP that has patent potential, or if ARS wishes to share a patent application with an outside entity before the patent issues. Discussion of information within ARS is not considered public disclosure and does not require a CA, but colleagues should be cautioned not to discuss or disclose the information to outsiders. Copies of a standard ARS CA may be obtained from the TTC or the OTT homepage. CAs are signed by the cooperator's representative and the ARS scientist and/or RL.

9. Summary of Responsibilities

Authorized Departmental Officer (ADO)

Per their delegated authority, the ADO has responsibility for establishing, administering, and terminating agreements with outside entities on behalf of ARS.

Authorized Departmental Officer, OTT (ADO/OTT)

Conducts the specific responsibilities of the ADO for CRADAs, using the procedures outlined in Section 7.

Authorized Departmental Officer's Designated Representative (ADODR)

ARS employees serving as ADOs and ADODRs on ARS extramural research agreements (Memoranda of Understanding, Grants, Research Support Agreements, Specific Cooperative Agreements, CRADAs, etc.) are responsible for:

- Promptly reporting inventions made under these agreements to the Patent Coordinator.
- Keeping AD and NPL informed of program implementation and progress.
- Developing CRIS documentation and submitting it to the Area Program Administrative Assistant (or equivalent) for action (AD-416/417, and ARS-425).

- Keeping the ADO informed of activities under the CRADA and forwarding copies of required correspondence to the ADO.

- Assuring that confidentiality of the CRADA is honored.

Deputy Assistant General Counsel for Patents (DAGCP), Office of General Counsel (OGC), USDA

- Files and prosecutes selected patent applications.

- Determines ownership of inventions.

- Takes other necessary and appropriate legal actions.

- Gives advice and counsel pertaining to patent license policies, regulations, and statutory authority.

- Determines if rights to a patent are to be waived to the inventor if the invention is not selected for patenting. This determination is made in coordination with line management, NPS and OTT.

Financial Management Division

- Oversees the establishment of funds management and accounting system controls and operations.

- Identifies and tracks royalties and other income received by ARS to be distributed to ARS employee/inventors, field units, Headquarters, and other agencies.

- Deposits checks received to lockbox.

- Initiates distribution of royalty check in coordination with Reporting Section #4 (RS#4).

- Establishes financial plans for the PRA.

- Enters and reconciles obligation and disbursement activity.

- Renders Status of Funds Reports monthly in accordance with P&P 325.1, Funds Control at the Operating Level.

- Reconciles allocations.

- Initiates closeout procedures in coordination with RS#4, NFC and OTT.

Information Staff

- Provides appropriate public information supporting the TT efforts of ARS through the appropriate media.

Line Managers (RLs, CD, LD, ID, ADs)

- Assures that the ARS Patent Program is being used by all ARS employees whose research leads to an invention.

- Assures that inventions and patents are recognized in performance evaluations and RPES writeups.

- Expedites the orderly processing of data to ensure timely reporting of invention disclosures to PAs. Such actions include but are not limited to:

    - Promptly reviewing Agricultural Research Service Invention Tracking System (ARSITS) and taking action on the IR by accessing the signature screen, entering the signer's name or four digit signature code, and entering "A" for approval or "D" for disapproval.

    - Exercising approval authority analogous to that of scientific manuscripts to assure that IRs are of a quality to reflect favorably on ARS and that listed inventors are appropriate, similar to the review of authorship of manuscripts.

Office of Technology Transfer

OTT, a part of the Office of the Administrator, has the delegated responsibility for implementation of the FTTA and Executive Order 12591. In this capacity, OTT manages the ARS Technology Transfer Program. OTT:

Establishes policy and procedures for processing of IRs, patent preparation, and prosecution of patents.

- Makes final determination on Patent Committee recommendations on IRs.

- Consults with NPS on intellectual property protection of plants and animals.

- Coordinates with ADs on the selection of PRC members.

- Assists inventors in TT activities to seek commercialization of inventions through CRADAs and/or licenses.

- Reviews and approves/disapproves any deviation from standard IP clauses in ARS research agreements (Memoranda of Understanding, Grants, Research Support Agreements, Specific Cooperative Agreements, CRADAs, etc.).

In consultation with OGC, formulates USDA patent licensing policy and procedures.

- Negotiates, approves, disapproves, amends, revokes, terminates, and/or reissues patent licenses.

- Administers licenses on (1) inventions made by ARS, (2) inventions made under ARS CRADAs, and (3) inventions made by other USDA agencies.

- Coordinates the public advertisement of USDA's inventions available for licensing.

- Pays patent maintenance fees on ARS inventions determined worthy for continuance.

- Coordinates payment of maintenance fees on inventions by other USDA agencies.

- Prepares required Federal Register Notices relevant to the patent program.

- Negotiates fair licensing terms and conditions with potential licensees, considering applicable Federal Regulations, the interest of the U.S. Government in promoting commercialization of Federal research results and the need to provide a proper reward to the inventor.

- Monitors licenses to assure annual progress reports and fees due are received, maintains patent and license records, and keeps ARS employee/inventors and other USDA agency personnel advised of activities.

- Authorizes patent awards for inventors.

Assures the distribution of patent license income according to the FTTA as amended. Patent license income received by ARS must be obligated by the end of the fiscal year succeeding the fiscal year of receipt.

- Prepares a yearly ARMPS plan for estimated license income and prorates uses of such income (Patent Revenue Account).

- Remits promptly all license income received to the FMD Headquarters Collection official for deposit in an appropriate account with instructions on disbursements.

- Notifies the recipient USDA inventor(s) of the amount of money they will receive, that it is taxable, and that the Internal Revenue Service will be notified.

Has lead responsibility for coordinating the development of CRADAs.

- Works with ARS scientists, managers, and potential Cooperators to develop and process CRADAs.

- The ADO/OTT is authorized to award, administer, terminate, and closeout CRADAs, as is the Administrator, Associate Administrator, and the Assistant Administrator for Technology Transfer. The ADO works closely with each ADODR and follows all applicable laws, regulations, policies, and procedures.

Carries out other activities to promote transfer of USDA technology.

- Coordinates and/or prepares TT awards for USDA inventors through appropriate officials.

- Serves as the focal point and clearinghouse for information concerning TT.

- Advises the Information Staff of developments relating to the implementation of and progress in TT activities.

- Attends trade shows, prepares written materials, and develops marketing plans of ARS technology.

Patent Advisors

- Provides counseling and patent awareness training to ARS inventors in their respective geographic area of responsibility.

- Reviews IRs and assesses patentability.

- Coordinates Patent Committee meetings to review and evaluate the potential economic and technical impact of inventions.

- Prepares and prosecutes patents subject to OGC review.

- Provides timely information to the Coordinator of the Technology Licensing Program about patent applications and patent status.

Patent Review Committee

- Recommends whether or not to patent the invention. (See criteria, Exhibit 2.)

- Recommends whether or not the IR needs further research data to substantiate a patent and to broaden the scope of the invention.

- Recommends whether or not the publication is appropriate to transfer the technology and that a patent application need not be filed.

- Recommends whether or not the IR be given additional evaluation for commercial potential.

Human Resources Division

- Takes action to sensitize ARS management and individuals participating in TT of the need to avoid real or apparent conflicts of interest.

- Develops and administers the ARS Technology Transfer Incentives and Awards Program.

- Ethics review of CRADAs

Scientists (Inventors)

- Become familiar with the TT process through attendance at a OTT training and other means.

- Use permanently bound research notebooks, preferably Form ARS-1. Specific instructions are in the front of the notebook. Notebooks are available from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Road, Landover, Maryland 20785. To order, use CFPDC-1, Request for Forms and Publications.

- Meet critical dates in patent law due to statutory deadlines that must be met to avoid loss of valuable patent rights for both foreign and domestic applications.

- Protect intellectual property through invention reporting, CAs, and MTAs.

- Forward IRs, through appropriate channels, to the PA as soon as possible but, in any case, no later than the time that a manuscript disclosing the invention is submitted for ARS clearance for publication.

- Prepare material relative to the IR sufficient for evaluation and/or preparation of a patent application. The material submitted should include a search report in the technical field of the IR with copies of references found.

- Report the publication of an invention to the PA as soon as possible. Publications include: scientific journals, trade journals, newspaper articles; abstracts distributed at professional society meetings; CRIS reports; interpretive summaries; and/or manuscripts distributed upon request.

- Not disclose an invention in a publication, presentation, or other means prior to filing a patent application in the PTO, if the invention has foreign commercial potential. Disclosure prior to filing is an immediate bar to obtaining foreign patent protection in most countries.

- Strive to avoid disclosing inventive concepts by exercising discretion when preparing meeting abstracts, CRIS reports, and interpretive summaries by focusing on the "what" and "so what" of the research rather than critical details of the "how." Check with the PA when in doubt.

- Conduct a thorough search before preparing the IR and, if possible, forward to the PA a copy of the search with the IR. State specifically how the invention is different from the most relevant known technology found during the search.

- Provide advice to the PA to help ensure that the breadth of the claims of the patent application claims do not exceed reasonable scientific predictability.

- Assist the PA in the ongoing prosecution of the patent application by reviewing and commenting on PTO Official Actions and the references cited by the PTO Patent Examiner, IN A TIMELY MANNER, to avoid monetary penalties or loss of intellectual property protection.

- Submit requests for consideration of a PVPC to the Associate Deputy Administrator for Plant Sciences.

Technology Transfer Coordinators

- Represents ARS in CRADA, license, and other TT negotiations.

- Approves MTAs, negotiates non-standard MTAs and Confidentiality Agreements.

- Provide advice to area Administrative Management staff regarding intellectual property rights and confidentiality issues in Trusts, SCAs and MOUs.

- Provides training and advice to scientist regarding TT issues.

- Serves as non voting member of Patent Committee. Provides advice to Patent Committee regarding commercial potential of reported inventions.

- Works with scientists and OTT Marketing Staff to market ARS inventions.

10. Glossary

ABFO - Area Budget and Fiscal Office.

AD - Area Director.

ADO - The individual in ARS having written delegation of authority by the Administrator of ARS to enter into, administer, and close out agreements with organizations outside of ARS.

ADO/OTT - The Authorized Departmental Officer of OTT granted a written delegation of authority from the Administrator of ARS to enter into, administer, and closeout CRADAs.

ADODR - An individual (usually the lead ARS scientist of the research) who is granted a written limited delegation of authority to represent the ADO in the administration of a CRADA. This individual provides ongoing administrative oversight of activities that occur under the CRADA and provides scientific or technical interactions with the Cooperator on behalf of ARS.

AMS - Agricultural Marketing Service

ARMP - Annual Resource Management Plan.

ARSITS (Agricultural Research Service Invention Tracking System) - A computer database tracking system on the RMIS which allows all interested parties to track the progress of IRs, patent applications, patents, and licenses.

BPMS - Budget and Program Management Staff.

CA - Confidentiality Agreement.

CD - Center Director.

Co-Exclusive License - The licensing of an invention to a limited number of licensees (two or more).

Cooperator - Need definition.

CRADA - A joint agreement between the Federal Government and industry, foundations, or universities to collaborate in a research project as authorized by the Federal Technology Transfer Act (15 USC 3710).

CRIS - Current Research Information System.

DAGCP - Deputy Assistant General Counsel for Patents.

Exclusive License - The licensing of an invention to only one licensee.

FMD - Financial Management Division.

FTTA - Federal Technology Transfer Act (15 USC 3710).

FR - Federal Register.

ID - Institute Director.

IP - Intellectual Property.

IPR - Intellectual Property Rights.

IS - Information Staff.

Invention -An invention is any process, art, method, machine, manufacture, design, composition of matter, or any new and useful improvement thereof, or any variety of plant or other biological entity which is or may be patentable or otherwise protectable under the laws of the United States.

IR - Invention Report.

License - A written authority granted by the owner of a patent to another person empowering the latter to make or use the patented article for a limited period or in a limited territory and to make, use, or sell articles embodying the patented invention.

License Income - The fees and royalty income paid to the owner of an invention by the licensee. Royalty income is based upon commercial use (e.g., percentage of sales of an invention-based product). In addition, ARS licensees typically pay an execution fee (when the license is first put into effect) and an annual maintenance fee (while the licensee is developing the product for marketing).

LD - Location Director.

MOU - Memorandum of Understanding.

MTA - Material Transfer Agreement.

NAL - National Agricultural Library

NFC - National Finance Center.

Nonexclusive License - The licensing of an invention to more than one licensee without restriction as to the number of licensees.

NPL - National Program Leader.

NPS - National Program Staff.

OGC - Office of the General Counsel.

OTT - Office of Technology Transfer.

PA - Patent Advisor.

Partially Exclusive License - A license granted occasionally to a very limited number of licensees, e.g., for specific fields of use or in a specific geographic area, or both.

Patent - (1) Statutory protection granted for inventions in the United States under Title 35 of the USC; (2) similar protection for inventions granted in foreign countries; and (3) protection granted in the U.S. and elsewhere for other types of inventions and discoveries such as new plant varieties, including PVPC.

Patent Maintenance Fee - A fee required by the U.S. Patent and Trademark Office.

PRC - Patent Review Committee.

PTO - Patent and Trademark Office.

PVPA - Plant Variety Protection Act (7 USC 2321 et seq.).

PVPC - Plant Variety Protection Certificate issued under the Plant Variety Protection Act.

RL - Research Leader.

RMIS - Research Management Information System.

RPES - Research Position Evaluation System.

TT - Technology Transfer.

TTC - Technology Transfer Coordinator.

USC - United States Code.

W. G. HORNER
Deputy Administrator
Administrative and Financial Management

EXHIBIT 1

Committee Guidelines

The Committee will make a recommendation whether or not to patent the invention report based upon the following criteria:

1. Is there current commercial interest in the invention or a high probability of commercialization in the future?

2. Is the magnitude of the market relative to the costs of commercialization in the future?

3. Would the patent likely play a significant role in transferring the technology to the user?

4. Would a patent be enforceable, i.e., is the invention drawn to, or does it employ a unique and readily identifiable material or device which could be brought or sold?

5. Is the invention of sufficient scope to justify patenting?