

CHAPTER 12

Patents and Technology Transfer

This chapter covers the ARS guidelines set forth for reporting inventions; obtaining patents and Plant Variety Protection Certificates; licensing; and distribution of license income (including awards to inventors). Technology Transfer Agreements with ARS provide access to research information and assist in the development and commercialization of new knowledge and technology.

Abbreviations: See Chapter 22 for commonly used acronyms and abbreviations.

References: P&P 140.1 - Patenting, Plant Variety Protection Certificates and Licensing
P&P 141.1 - Technology Transfer Cooperative Research and Development Agreements
P&P 324.0 - Reimbursable and Trust Fund Agreements
Manual 280.0M - Extramural Agreements Manual
Agreements Training Manual MCI 1996
Booklet - Patents in ARS, A Plain Language Guide
Leaflet - Technology Transfer Agreements with the ARS
Leaflet - Cooperative Research and Development Agreements (CRADA's) Between Industry and ARS
Memo from Richard M. Parry, Jr., Asst. Admin. for Technology Transfer, on "Use of Material Transfer Agreements"
Memo from Floyd Horn, ARS Administrator, on "CRADA Review Procedures"

Cross References: Chapter 16 - Research Management Information System (RMIS)

Points of Contact:

Technology Transfer Coordinator

Dr. Phillip O'Berry
Office of Technology Transfer
National Soil Tilth Laboratory
Ames, IA 50011
Telephone: (515) 294-7762
Fax: (515) 294-8125
E-mail: usdaott@iastate.edu

Patent Advisor

Mr. Curtis Ribando
Nat'l Center for Agric.Utilization Res.
1815 N. University St.
Peoria, IL 61604
Telephone: (309) 681-6513
Fax: (309) 681-6688
E-mail: ribandcp@mail.ncaur.usda.gov

Headquarters:

Dr. Richard M. Parry, Jr.,
Assistant Administrator for Technology Transfer
USDA-REE-ARS-ADMIN STAFF-OTT
WHITTENBG RM 358-A
1400 Independence Avenue, S.W.
Washington, D.C. 20250-0302
Telephone: (202) 720-3973
FAX: (202) 720-7549
E-Mail: rparry@ars.usda.gov

TECHNOLOGY TRANSFER IN ARS

The role of a government scientist has experienced a significant change in the past decade. Historically, expectations were often limited to publication and the exchange of technical information among peers. With the advent of the Technology Transfer Act in the mid 1980's, the goals of federal research programs began a fundamental shift toward the development of tangible benefit for the public.

In this new environment, emphasis has now been placed upon the scientist to create interactive relationships with corporate counterparts, where their research supports such. The thinking is that in many cases the public will not directly (and measurably) benefit from federal research without an industrial champion who will carry the beginning technology through the stages of refinement and marketing, for which the federal lab is both ill-equipped and does not possess an accepted mandate.

IMPACT

At the agency level the goals of technology transfer manifest themselves to the scientist in the form of the RPES, wherein it is requisite that the researchers show the "impact" of their work. Several "tools of the trade" in the technology transfer process are useful in substantiating this "impact" for the scientist. These include patents, licenses, and Cooperative Research and Development Agreements (CRADA's).

Through the experience of the last several years, it has been found that pickup of Agency developments by the corporate sector is critical in order to bring about maximal public use and benefit.

PATENT PROCESSING PROCEDURES

Generally, it is ARS policy not to delay public release of research results because of patents. Instead, scientists are urged to notify Patent Advisors (PA's) of potentially patentable inventions and discoveries at the time they are recognized and preferably no later than when manuscripts are prepared for peer review. This generally allows time for the patent to be filed at the U.S. Patent and Trademark Office before the publication becomes (in patent parlance) a statutory bar.

Refer to "Patents in ARS, A Plain Language Guide", revised October 1997, for general information on patenting in ARS and Directive 140.1, "Patenting and Patent Licensing," for important details.

The formal process begins with an Invention Report (IR) which is submitted electronically on the Agricultural Research Service Inventions Tracking System (ARSITS) via RMIS. The IR proceeds electronically through line management clearance procedures. Send E-mail to Area PAA for alert to process file in RMIS-ARSITS since this program is infrequently used and not monitored daily.

The IR should be submitted as early in the research progress as possible, preferably no later than when a formal scientific manuscript reporting the relevant research has been prepared.

It is important to remember that as a separate act, a hard copy of the IR must be printed, signed and dated by inventor(s), witnessed (signed and dated), and forwarded immediately to your Area Patent Advisor (PA), (address on front page).

Inventors are encouraged to conduct a literature search including both domestic and foreign patents before preparing the IR and, if possible, forward it to the PA with a statement as to how the invention is different from the most relevant known technology and that technology found during the search.

PATENT CLEARANCE PROCEDURES

The Agency decision process with regard to patents is as follows:

1. Scientists should notify their PA as soon as possible after they achieve what they believe to be a patentable invention. While domestic rights are available for one year after a scientist's own disclosing publication, foreign rights for the same invention are less instantaneously with disclosure, - whether oral or written.
2. If the PA agrees that a patentable invention may have been achieved, the PA will request a formal IR and such other written documentation as may be appropriate. The IR, upon entry in RMIS is electronically forwarded through the Research Leader and Center Director to the PA.
3. If after reviewing the information provided, the PA still believes the research achievement may be patentable, the PA will put it on the agenda for the next Patent Committee (PC) meeting. (In urgent cases, the PA may distribute the information immediately to the members of the PC and then poll them by telephone for a recommendation. Another alternative is to request that one of the other PC's meeting earlier be asked to handle the urgent case.) The PA will place each case in one of three categories: APPROVED (recommended for filing a patent application); DEFERRED (to be held until one or more deficiencies are met); or SUSPENDED (recommended for publication in lieu of patenting).
4. After the PC meeting or polling by telephone, the PA will place inventions recommended for patents on the IR docket and send the Area Director, (AD) and Inventor(s) a report of the PC's recommendations and each IR under the AD's jurisdiction.
5. No action is required by an AD who agrees with the recommendations of the PC. If the AD disagrees with any of the recommendations, the AD should contact the Assistant Administrator, OTT (name and address on front). Additional information will be requested, as needed, e.g., from the appropriate NPS members, to make a final decision.

6. When a PA sends a completed patent application forward to the USDA patent attorney for filing in the U.S. Patent and Trademark Office, a copy of the transmittal memo should be sent to the AD of each inventor. After a Serial Number is assigned to the application (usually 6-8 weeks later) a copy of the application will be forwarded to the AD.

PENDING CASES FOR PATENT COMMITTEE MEETING

Patent Committee meetings are now scheduled on approximately a quarterly basis, with one meeting a year done in person and the others handled through telephonic conferencing. Cases needing speedy review may be transferred to another committee or handled on an ad hoc basis.

The following criteria are used by the Patent Committees in assisting PA in evaluating invention reports:

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 large enough to warrant a patent?
3. Would the patent likely play a significant role in transferring the technology to the user beyond what could be achieved through publication?
4. Would a patent on this invention be enforceable, i.e., is the invention drawn to, or does it employ, a unique and readily identifiable material or device which could be bought or sold?
5. Is the invention of sufficient scope to justify patenting?

PATENT LICENSING

ARS no longer favors royalty-free license arrangements. Only those ARS patents licensed previously as domestic, non-exclusive royalty-free and where the licensee is active will be maintained as such until the patent expires or the license is terminated. It has been proven that inventions made available freely to all have been used by only a few.

As a general policy, all patents will be licensed on a fee-bearing basis with some form of an incentive to exclusivity to assure product availability to the public. Patents involving technologies where the industry investment is minimal are sometimes considered on a non-exclusive basis.

ARS inventors will be contacted as a source of expertise by the Agency licensing team when patents are being considered for licensing. Inventors, however, are not allowed to participate in the negotiation process to avoid conflict of interest issues.

License application forms are maintained and distributed to industry by the License Coordinator and Technology Transfer Coordinators. ARS strives to negotiate fair licensing terms and conditions, considering both 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(s).

PATENT LICENSE AWARDS

ARS Inventors of a given invention collectively receive 25 percent of the Agency's share of license income up to a maximum of \$150,000 per inventor per year. In situations with multiple inventors the income is shared equally. Inventors are guaranteed by the Agency a minimum \$300 annual award on licensed inventions.

CONFIDENTIALITY AGREEMENTS

It is important for the scientist to realize that a potential cooperator needs to be given sufficient information so that they can make an informed decision as to whether or not a particular technology is for them. The Confidentiality Agreement, in addition to protecting potential patent rights, should give the scientist a measure of comfort in knowing that by sharing early information, others won't run off with it and either misrepresent it or claim it as their own. The confidentiality agreement does not however create an obligation for the scientist to "tell all". Sometimes being "coy" with critical details is desirable - they may not be necessary for a sound business decision and, if the arrangement breaks down, it is preferable that the party not know enough so as to successfully engineer around our technology.

Copies of the agreement may be reproduced on your letterhead for use. In filling out the form, be specific about what information is to be disclosed. The scientists and engineers may sign this form themselves. If a company provides an ARS scientist or engineer with the company's confidentiality agreement, have it reviewed by the Area Technology Transfer Office before signing it.

MATERIAL TRANSFER AGREEMENTS

In some situations, the exchange of information may include the transfer of material from one party to the other. For these instances, another form of document has been created - the Material Transfer Agreement. This document states that whatever materials that are transferred must be destroyed and/or returned upon completion of their testing; and that no commercial usage may be made of them without permission by the Agency. This should be copied onto your letterhead for use and be signed by the scientist or engineer involved. Again, be specific about the samples provided.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Directive 141.1 "Technology Transfer Cooperative Research and Development Agreements," furnishes policy guidelines and a sample agreement. These multipage agreements are too lengthy to be included here but copies may be obtained by calling the Area Technology Transfer Office.

Chapter 1300 - Guides for Instrument Selection

Instrument Selection Criteria Chart Table 1

	Purpose	Relationship/ Benefit to ARS Programs	ARS Involvement during Performance
Use a Contract When:	Acquiring Service or Property	Direct Benefit/Use	No Involvement
Use A Grant When:	Transferring Anything of Value	To Support or Stimulate a Public Purpose	No Involvement
Use an Assistance Type Cooperative Agreement When:	Transferring Anything of Value	To Support or Stimulate a Public Purpose	Substantial Involvement
Use a Specific Cooperative Agreement When:	ARS is Paying and Mutual Interest and Contributions toward Research Effort Exists	Direct Benefit to ARS In-house Research	Substantial Involvement
Use a Research Support Agreement When:	Procuring Service/Supplies Directly from a SCI*	Direct Benefit to ARS In-house Research	Substantial Involvement
Use a Memorandum Of Understanding When:	Describing Research Work with No Obligation of Funds	Direct Benefit to ARS In-house Research	Substantial Involvement
Use a Technology Transfer Cooperative Research And Development Agreement When:	Receiving Funds Under Federal Technology Transfer Act	Direct Benefit to ARS In-house Research	Substantial Involvement
Use a Reimbursable/ Trust Fund Cooperative Agreement When:	ARS Receives Funds to Perform Research Work	Direct Benefit to ARS In-house Research	Substantial Involvement

*SCI = State Cooperative Institution

Each project involving cooperation must be assessed individually to ascertain the agreement instrument most appropriate for the project. For further information on contracting, contact the PAO.

CONFIDENTIALITY AGREEMENT

THIS AGREEMENT, effective _____, 1999 ("Effective Date"), is by and between _____ of the U.S. Department of Agriculture, Agricultural Research Service (USDA-ARS), and _____ (hereinafter Company) whose place of business is located at _____

WHEREAS, in order for Company to determine if there is sufficient mutual interest to pursue a possible research collaboration or other agreement, it will be necessary for ARS to disclose certain information about _____ (hereinafter Confidential Information); and

WHEREAS, such material is considered by ARS to be confidential;

THEREFORE, Company agrees that any such Confidential Information disclosed to it by ARS in connection with said disclosure, which Confidential Information is specifically identified by ARS as comprising confidential material, shall be maintained in complete confidence and secrecy, and will not be disclosed directly or indirectly to others, except to those working with Company in connection with said determination and who are under an obligation of confidentiality to Company, and that it will not use or make use of said Confidential Information, except in connection with said determination.

For purposes of this Agreement, such Confidential Information shall not include:

1. information already known to Company;
2. information which Company receives from a third party who has not obtained such information directly or indirectly from ARS;
3. information that has become public knowledge through no actions of Company; or
4. information received after the disclosure from a third party having the right to the information and who does not impose a confidentiality obligation on Company.

This Confidentiality Agreement shall be superseded by the confidentiality terms found in any resulting Research or Cooperative Agreement, or stay in effect for three years, whichever is earlier.

USDA/ARS Employee:

For Company:

Employee

Date

Authorized Representative Date

October 31, 1997

SUBJECT: Use of Material Transfer Agreements

TO: All ARS Employees

FROM: Richard M. Parry, Jr.
Assistant Administrator for Technology Transfer

Agricultural Research Service (ARS) employees frequently receive or send research materials to universities or private companies in the course of their work. Usually requests are made by research scientists, but requests may also involve technical and administrative support personnel. If the materials are patented or could be at some future date, the sender will often require that the recipient sign an acceptance statement, sometimes called a Material Transfer Agreement (MTA). This message is being sent to ARS employees to provide general guidance on handling these documents.

Many institutions, both private and public sector, use Material Transfer Agreements to limit use of the material to the specific research at hand and also claim ownership of improvements made during the research. One purpose of a MTA is to convey to the recipient of the materials that, if the material is patented, a license will be needed for commercial development of the technology. The difficulty encountered in exchanging materials between university scientists is described in Science Vol. 278, page 212, 10 October 1997.

It is ARS policy to encourage the free exchange of materials for research purposes whenever possible. To facilitate this, OTT has developed a standard or "generic" Material Transfer Agreement that imposes a minimal burden on the receiving party while still preserving ARS rights. Your Technology Transfer Officer can supply this generic MTA upon request.

ARS scientists may sign Material Transfer Agreements. If the ARS generic MTA is used, then the scientist can be assured he/she is following agency guidelines. However, if a company or university asks an ARS scientist to sign a MTA which differs from the ARS generic format, the document may contain additional provisions regarding restrictions on publication of research results, or rights to improvements made with the material or other limitations that commit the agency's future research and are beyond the authority of the individual scientist. In order to assure that all non-standard agreements are within appropriate bounds for research use, ARS scientists are required to get all non-standard MTAs or similar documents reviewed by a Technology Transfer Coordinator or Patent Advisor. If the proposed agreement deviates from ARS policy, the Coordinator or Patent Advisor may request modifications. OTT has found that institutions sharing proprietary material will often alter the agreement if specific problems are identified and explained.

Exchanging research materials has become more complex because of the commercial value realized from research. The use of OTT staff to assist you in this process will help avoid future problems when you attempt to apply the fruits of your discovery.

(date)

ARS STANDARD MATERIAL TRANSFER AGREEMENT

PARTIES:

PROVIDER SCIENTIST:

PROVIDER:

RECIPIENT SCIENTIST:

RECIPIENT:

PURPOSE:

To provide Recipient with the following Material:

This Material and associated know how is released to you under the following conditions:

1. The Material only shall be used for _____

_____ (give the purpose, i.e., research, evaluation, or testing) purpose(s).
2. The Material shall not be transferred in whole or in part to a third party without express written consent. Any third party requesting a sample shall be referred to the Agricultural Research Service.
3. The Material will not be used for commercial or profit making purposes without an appropriate license or other permission from the Agricultural Research Service.
4. You shall keep the Agricultural Research Service informed of the results obtained through your use of the material and will provide the Agricultural Research Service with any manuscript which describes the work with the material prior to submission for publication and acknowledge our contribution to the work reported.
5. You shall comply with all laws, regulations, and/or guidelines applying to the use of the Material and to assume sole responsibility for any claims or liabilities which may arise as a result of your use of the Material.

6. The Agricultural Research Service gives no warranties or guarantees, express or implied, for the Material, including merchantability or fitness for a particular purpose.
7. Upon completion of the activities performed using the Material, the Material shall be returned, destroyed or otherwise disposed of as instructed by the Agricultural Research Service.
8. You shall meet with U.S. Department of Agriculture representatives to determine inventorship if an invention should arise during your work with the Material.
9. You shall not disclose Material marked "Confidential" or "Proprietary" to anyone else without our written permission to do so.
10. Confidentiality shall be considered null and void if you can demonstrate either that you had possession of the "Confidential" Material prior to it being sent to you by the Agricultural Research Service or the "Confidential" Material became generally available to the public through no fault of your after the transfer or the "Confidential" Material was made available to you by a third party and the third party has lawful possession of the "Confidential" Material.
11. If the parties hereto decide to engage in a cooperative research and development project or program using the Material at some future date, a formal Cooperative Research and Development Agreement must be negotiated and entered into among the parties. That Agreement shall supersede this Material Transfer Agreement.

ACCEPTED FOR THE AGRICULTURAL RESEARCH SERVICE:

Research Leader

Laboratory

Date

ACCEPTED FOR THE COMPANY:

Company Representative

Title

Date

APPROVED:

Technology Transfer Coordinator

Date

April 11, 2000

SUBJECT: CRADA Review Procedures

TO: ARS Administrator's Council

FROM: Floyd P. Horn /s/ Floyd P. Horn
Administrator

At the February meeting of the Administrator's Council, we discussed a proposal for the review of Cooperative Research and Development Agreements (CRADAs). Based on that discussion, the review procedures have been revised (see enclosure). Effective immediately, these procedures should be used for all CRADA documents.

The Office of Technology Transfer has the primary role in negotiating and assuring the timely review of these agreements. However, this can be accomplished with the active participation of ARS scientists, line managers, and the National Program Staff using the outlined procedures. The CRADA program has proven to be a successful mechanism to rapidly develop ARS discoveries into products benefitting agriculture. The CRADA Review Procedures will allow oversight of this process to assure that collaborative research fits within the public mission of the Agency's program.

Enclosure

cc:
Technology Transfer Coordinators

Agricultural Research Service

Cooperative Research and Development Agreement Review Procedures

Cooperative Research and Development Agreements (CRADAs) have provided a valuable mechanism to form partnerships with private sector organizations. This authority has allowed the rapid development and transfer of many Agricultural Research Service (ARS) discoveries to solve critical problems. The success of this program has also led to an examination of the procedures used to review and approve a CRADA and to assure that the public mission of ARS research is not altered through the partnership.

This document describes the current review procedure that is given to each CRADA before approval by ARS. Also, an additional review procedure is described to allow early identification of research areas requiring specific agency policy review. The roles of the ARS Office of Technology Transfer (OTT), National Program Staff (NPS), Area Directors (AD), and other line managers are described.

CRADA Review Procedures: The current ARS CRADA review and approval process involves NPS, AD, line management, and OTT. The ARS scientist and OTT Technology Transfer Coordinator (TTC) discuss the CRADA requirements and the proposed plan of research with the potential cooperator. As these negotiations proceed, the unit Research Leader, other line managers, and the NPS are consulted as appropriate to assure that the collaboration is appropriate to the approved research program and that sufficient resources are available to complete the planned research. 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. CRADAs cannot be used simply as a means to bring in outside funds, nor should they be used to test, develop, or validate a company's product. CRADAs are appropriate vehicles for 1) transfer and/or further development of ARS technology, 2) collaboration using the cooperator's intellectual property, or 3) merging of ARS discoveries with the cooperator's technology. CRADAs are developed by scientists and TTCs, approved by NPS, the AD, and line managers, and signed by OTT on behalf of ARS. Each CRADA also has documented approval by the ARS-425 project clearance procedures.

Additional CRADA Review Procedures: For proposed CRADAs involving plant and animal biotechnology research, the review procedure shall provide 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.). This review process is not designed to censure or limit science, but to allow careful consideration of sensitive issues and to consider the need for additional risk assessment research at an early stage in the development of the agreement.

For any proposed CRADA in the area of biotechnology, information (see below) 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 should provide documentation of the review decisions and recommendations with the documents submitted for final agency clearance.

INFORMATION REQUIRED FOR REVIEW OF A CRADA:

- A. Title, Laboratory, Lead Scientists, Location, Proposed Cooperator.
- B. Summary of Proposed Research: A brief description describing the problem, research objectives, methods, etc.
- C. Criteria to be Considered when evaluating a CRADA:
 - 1. How does the proposed research further the ARS mission?
 - 2. What technology, expertise, financial resources, etc. would be contributed by the cooperator?
 - 3. What are the possible end products of the research?
 - 4. How will the end products be used?
- D. Additional Criteria for a Biotechnology CRADA.
 - 1. Are inventions anticipated and if so, describe the commercial development in all potential fields of use.
 - 2. What are the risks/benefits, either real or perceived, associated with implementing (commercializing) the technology?
 - 3. Have all risk questions been addressed or is additional risk-related research needed?