

MIDWEST AREA
STANDARD OPERATING PROCEDURES
MANUAL

TECHNOLOGY TRANSFER

Created by
Program Administrative Support Task Group

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SUBJECT: Changes to Increase the Efficiency of the Technology Transfer Process

TO: Research Leaders/Center Directors
Location Administrative Officers
Secretaries

FROM: Steven R. Shafer
Director

After consulting with the ARS Office of Technology Transfer (OTT), I am implementing several changes in Midwest Area (MWA) policies and procedures to increase the efficiency of the technology transfer process. The procedures described below are effective immediately. Please contact Renée Wagner, Technology Transfer Coordinator, MWA, Renee.Wagner@ars.usda.gov, if you have any questions.

Cooperative Research and Development Agreements (CRADA)

Letters of Intent (LOI) will no longer be required **for CRADAs and CRADA amendments** (LOIs will still be required for all other forms of agreements specified in the original LOI policy for the MWA). The following steps now initiate a CRADA.

1. ARS scientist contacts Renée Wagner to discuss the concept of the CRADA and if appropriate, gets confirmation that a CRADA is the correct type of agreement for the proposed interaction.
2. Researcher provides Renée with preliminary project information. (The format for this will be posted on the MWA Technology Transfer Website in the near future, but can be obtained from Babette Davis until that time.)
3. Renée shares preliminary information with the MWA Office, obtains clearance, and informs the scientist accordingly.
4. Scientist or the Research Leader (RL) contacts the NPL to discuss the concept of the CRADA. (We recommend that this contact with NPS is done with a telephone call. NPS has expressed a strong interest in hearing about CRADA opportunities directly from researchers or RLs. Renée herself will no longer pre-clear CRADAs with NPS unless the proposed collaboration warrants special attention.)
5. Scientist prepares the detailed SOW with Renée's assistance, with input from the Cooperator as necessary
6. The remainder of the CRADA process remains unchanged.

Note: OTT has a new database and reporting system, which will record when the first SOW is drafted and allows for internal tracking of CRADA development.

Material Transfer Agreements (MTA)

Procedures for MTAs involving the following are UNCHANGED:

Transfer of animal or plant pathogens that are classified as BSL2, BSL3, high consequence pathogens, or Select Agents.
Any MTA involving the National Animal Disease Center (NADC).

ALL OTHER MTAs are to be initiated as follows. (The approved formats for incoming and outgoing MTAs may be downloaded from the OTT website or, alternatively, may be requested from Babette Davis.)

If the providing or receiving party asks for changes to the standard ARS language, or if they request use of their own format, this must be cleared with Renée before signing.

1. ARS scientist provides three (3) originals of each MTA signed by himself/herself, the RL and the agent of the receiving/sending party to Babette Davis, Technology Transfer Assistant.
2. Renée signs the three (3) originals and sends a copy back to the scientist, retaining one original for OTT files, and transmitting the other fully executed original to the sending/receiving party.
3. Prior to shipping BSL1 materials, the receiving party provides the ARS scientist an APHIS or CDC permit **(or import permit, if required)**.
4. Scientist may send or receive the materials.

If a researcher prefers that OTT handle the MTA process, he/she may request such assistance from Babette Davis.

PATENT PROCESS

1. SY completes the Patent Disclosure.
 - Title
 - Answer 4 questions

2. MU Secretary enters the Patent Disclosure into ARIS LICENSES/INVENTIONS.
 - Work
 - Inventions – Patent Dockets
 - This will create a form for signature and issues the Docket No. on the top left of the form. (ex. 0099.09)
 - Send original signed copy to appropriate Patent Advisor.
 - Keep a copy for the file

3. The replenishment form will notify user that an application has been file.
 - Request an abstract from the SY
 - Enter a ARIS Research Doc 115
 - Journal: 03590 Patent Application
 - Publication Type: Z - Patent Application

4. Another way to know that it is time to enter the 115:

When the application has been files with the Patent & Trademark Office, the Office will send a pink carbon form entitled, “Authorization for Replenishment of Patent Office Deposit Account 50-2132.” This form indicates that an AD-700 is needed for the patent fees. PLEASE NOTE: The Patent Office does not need the AD-700. This form authorizes the Patent Office to ask NFC to transfer funds from Unit’s account to Patent Office account.

- If BRDC or other collaborator processes the patent application, the secretary will not receive this form.
- The Patent Committee only meets 3 or 4 times a year, and the process could take a long time before the patent application is actually filed.

5. Sheri Whitehurst is your Patent Office contact.

- Phone: 309-681-6513
- E-mail: sheri.whitehurst@ars.usda.gov

CRADA Process

- 1) ADODR discusses project with potential Cooperator and Research Leader.
- 2) ADODR discusses project with Technology Transfer Coordinator. Is a CRADA the best mechanism for the project? Based on the information known at that point, is there anything that would prevent us from using a CRADA? If CRADA will be used, TTC provides forms to ADODR. If CRADA will not be used, ADODR submits a Letter of Intent (LOI) to the Area for a different type of agreement.
- 3) ADODR develops abbreviated Statement of Work and budget; provides additional info to TTC.
- 4) TTC does IP review of SOW and additional information; TTC requests additional information from Cooperator and discusses any questions with ADODR.
- 5) TTC discusses project specifics with Area Director for approval.
- 6) ADODR and/or RL contact NPL (and Center Director, if applicable) for approval of the project and cooperator; ADODR contacts TTC when approval received or to discuss any concerns of the NPL.
- 7) If approved by NPL, TTC sends generic CRADA language to Cooperator for review by Cooperator and negotiation (if needed) with TTC.
- 8) ADODR, Cooperator and TTC finalize detailed SOW and budget; TTC does final IP evaluation.
- 9) TTC requests an ARS-425 by ADODR based on final SOW and budget.
- 10) TTC and Cooperator finalize negotiation of the terms of the rest of the CRADA.
- 11) TTC sends complete negotiated draft CRADA to Cooperator and ADODR/RL for final review and approval; TTC requests Conflict of Interest form and financial disclosure form to be completed by ADODR.
- 12) When all forms (COI and FD) complete and sent by ADODR, the ARS-425 is approved at the RL/CD level and all parties agree on the terms of the CRADA, TTC sends CRADA to Headquarters for final review and approval and signature.
- 13) Headquarters reviews CRADA and sends any comments to TTC; HQ talks to NPL about project for approval; HQ checks with Ethics to be sure that COI and FD forms are received and that there are no conflicts of interest.

14) Headquarters signs CRADA and sends to Cooperator for signature. HQ sends email to ADODR to let them know.

15) Headquarters receives signed CRADA from Cooperator and sends ADODR letter and final CRADA to ADODR. ADODR meets with TTC to discuss responsibilities and requirements of the Agreement.

16) ADODR signs ADODR agreement and sends it back to HQ; TTC requests initiation of 416/417 if needed.

17) CRADA begins.

Because of the intellectual property rights granted in a CRADA, Specific Cooperative Agreements are rarely used in conjunction with a CRADA. However, if an SCA is needed, ALL proposed SCA's under a CRADA should be identified as early in the process as possible and must be approved by the TTC and the Cooperator in advance before submitting an LOI to the Area Office for this purpose.

If a CRADA is proposed with a foreign organization, additional steps are required. The CRADA must have Department of Commerce clearance and ARS must advertise a generic description of the project for 30 days to allow U.S. companies to express interest in pursuing the collaboration.

More information may be found here:

<http://www.ars.usda.gov/business/docs.htm?docid=771>

Plant Variety Invention Report

1. Was this variety developed in cooperation with a university experiment station or other organization? What resources were contributed by the cooperator (e.g. technicians, breeders, land, facilities, services, test data, etc.)? List all cooperator employees who were directly involved in the breeding and selection of this material.
2. Enter the complete draft text of the proposed release notice.
3. Who is expected to use the released plant material and how they will use it? What public or private organizations have requested this material for research, breeding or testing purposes? Have you consulted with any commodity groups?
4. List any publications and/or public use of this plant material. Has the material been provided to anyone outside of USDA for field-testing purposes? Have seeds, cuttings, fruit or other materials been sold by cooperators? If so, give dates(s).
5. Explain how protection will facilitate technology transfer that would otherwise not occur if the variety is publicly released. Does the variety have any special characteristics that would make protection desirable (e.g., niche market use, transgenic, incorporates proprietary technology, incorporates third party IP)
6. Is there an international market for this variety? If so, in what countries? Have you sent the variety to anyone outside the U.S. for testing or breeding? If so, provide country (s) and date(s).

CONFIDENTIALITY AGREEMENTS

Confidentiality Agreements (CAs) are used when confidential or proprietary information is to be provided, received or exchanged prior to, in development of, or during execution of 1) cooperative research projects or 2) licenses for ARS inventions. CA's are **NOT** used to provide or receive Materials. If you have any questions about whether a CA is needed or appropriate, please contact Renée Wagner, Technology Transfer Coordinator in the MWA Office of Technology Transfer.

Standard ARS CAs: The standard ARS CA's found on the ARS Office of Technology Transfer website may be completed and signed without review *if* these formats are used ***without any changes to the terms of the Agreement.*** All information should be complete (including the topic of discussion) before signing the Agreement. Original signatures should be obtained on 3 copies of the agreement; one for your records and one for the Cooperator. The third copy should be provided to the MWA Technology Transfer Office at 1815 N. University St., Peoria, IL 61604 for tracking and reporting purposes.

There are 3 different ARS formats for CA's, depending upon who is providing the Confidential Information: 1) for ARS providing information, 2) for ARS receiving information, and 3) for exchange of confidential information:

All are available on the OTT website at:

<http://www.ars.usda.gov/Business/docs.htm?docid=2075>

Please check this website *each time* you initiate a new CA; changes are made frequently to address changes in the law or for the purpose of clarification.

Hints for an effective ARS CA:

- ▶ Include all ARS employees (and their associated contact information) who will have access to information.
- ▶ Include complete contact information for the Cooperator, including those who will receive the information as well as those who will sign the agreement.
- ▶ Define the topic of discussion accurately and specifically to reflect the scope of the discussion.
- ▶ Term of the agreement for 2 years or less.

If you would prefer, the MWA TT Office would be happy to prepare and execute any Confidentiality Agreements for you or to review those you have initiated before you send them out for signature. Just contact Babette Davis, the MWA Technology Transfer Assistant, by phone or email.

If you OR the Cooperator wish to change *any* part of the standard ARS agreement, please send the proposed changes to Babette or refer the Cooperator to her for review of

the modifications. In addition, if you need a multiple-party CA, please contact Babette.

Confidential Agreements from non-ARS organizations: If the Cooperator wishes to use their own institutional format, the institutional agreement should be sent to Babette for review prior to signature, to ensure compatibility and compliance with federal law and USDA and agency policies.

Copies of *ALL* final signed CA's should be sent to Babette for the official files. This information will be included in a Headquarters-based database, from which monthly and annual reports are developed for the Agency, National Program Staff and the Area Offices, as well as the Annual Technology Transfer Report to Congress. This will also help us to identify potential licensees or commercialization partners for ARS technologies, and will also assist us in responding to inquiries when the MWA Technology Transfer Office is contacted by RPES panels regarding technology transfer activities and impact.

Contact information:

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