

NIH Technology Transfer Training



This training is mandatory for the following groups at NIH:

- All Principal Investigators (Senior Investigators, Investigators, Adjunct Investigators, Senior Scientists/Clinicians, and Assistant Clinical Investigators)
- Fellows
- Graduate Students
- Staff Scientists/Staff Clinicians

Material Transfer Agreements

What is a Material Transfer Agreement (MTA)?

MTAs are used to document the exchange of research materials.

What should I do if I want to exchange materials?

- Contact your institute's [technology transfer office](#)
- MTAs are usually used to transfer materials between NIH and non-profits or academic institutions
- Transferring materials to a company may require a different type of agreement, such as a license

Why are MTAs important to an NIH Researcher?

- Documents the source of the research materials
- Protects a researcher's ability to publish results from use of the materials
- Protects a researcher's ability to do investigator-initiated research
- Protects the researcher from being held personally liable to an outside party
- Helps to protect confidential, unpublished information



MTAs – Material Examples

Examples of materials that may be transferred under an MTA:

- cell lines
- plasmids
- proteins/peptides
- mice
- compounds
- antibodies
- genomic DNA
- software
- stem cells
- blood samples
- equipment



MTAs – Special Attention Materials

Certain materials require **SPECIAL ATTENTION!**

Make sure to work with your institute's [technology transfer office](#) to establish an MTA for these materials.

You want the Special Attention to be on the MTA – not on YOU!!

Examples of Special Attention materials:

- Materials directly obtained from humans (which include: blood, tissues, genomic DNA, primary cells)
- Materials derived from humans (which include: human cell lines, recombinant DNA clones of human genes, and isolated infectious agents from humans)
- Human stem cells and human induced pluripotent stem cells (iPS cells)

NOTE: Data associated with human materials may also require Special Attention (personally identifiable information, limited data sets, etc.)

Your [technology transfer office](#) can help! Contact them!

MTAs – Requirements

Requirements for an NIH Researcher and his/her laboratory under an MTA may include:

- Controlling access to the material (i.e., don't share with your buddy down the hall)
- Providing acknowledgement of the source of the material in publications
- Allowing the material provider review of pending publications/abstracts
(NOTE: this review will not impede your rights to publish)
- Confidentiality obligations
- Limitations on the use of the materials for a specific project/purpose
- Disposition of the materials after use (i.e., return to the provider or destruction)

What if I receive an MTA from another organization?

Call your [technology transfer office!](#)

Who may sign an MTA?

If you have not been provided *explicit, written authority* to sign MTAs, then you do NOT have the authority to sign MTAs.

Contact your friendly [technology transfer office!](#)

MTAs – Data & Confidential Information

Data and Confidential Information

MTAs may contain confidentiality terms that impose restrictions or obligations regarding certain data and information.

Alternatively, a separate confidentiality agreement may be used for the same purpose. These agreements may be called Confidential Disclosure Agreements (CDAs), Non-disclosure Agreements (NDAs), or similar.

You should strongly consider using a confidentiality agreement if sharing unpublished data outside of NIH.

If you need or receive a confidentiality agreement, call your [technology transfer office](#).

MTAs – Quiz #1

QUIZ TIME!

At a recent scientific conference, Professor Clever from a nearby university asks to use a cell line that was published in your recent paper. Another colleague from the WeCan Company overhears your discussion and asks for the same materials. You want to send your colleagues the cell line and a plasmid used to create the cell line. What do you do? (ANSWERS ON THE NEXT SLIDE)

1. Send the plasmid and cell line to Prof. Clever and WeCan Company with a handshake.
2. Send the plasmid and cell line to Prof. Clever and WeCan Company and take care of the MTAs later.
3. Contact your technology transfer office to arrange for appropriate agreements for each of your colleagues.
4. Tell Prof. Clever and WeCan Company that you don't want to share materials with them.



MTAs – Quiz #1 Answers

ANSWERS

1. Send the plasmid and cell line to Prof. Clever and WeCan Company with a handshake.

Not correct. Without a written agreement like an MTA in place, you and the NIH will not be afforded the protection it provides, which could impact publication and research related to the materials. An MTA may not be the appropriate agreement to use with a Company. Contact your [technology transfer office](#).

2. Send the plasmid and cell line to Prof. Clever and WeCan Company and take care of the MTAs later.

Not correct. You will not be afforded the protections of an MTA until it is fully executed. It has been the experience of the NIH that a recipient of materials has little incentive to execute an MTA after he/she has received the material.

3. Contact your technology transfer office to arrange for appropriate agreements for each of your colleagues.

Correct. Your [technology transfer office](#) will work with you to determine the appropriate agreements that are needed with Professor Clever and the WeCan Company.

4. Tell Prof. Clever and WeCan Company that you don't want to share materials with them.

Not correct. It is the policy of NIH that research materials funded by NIH be made as widely available as possible for research use. If the material is not available and/or sharing places an unreasonable burden on your laboratory, please contact your [technology transfer office](#) for further guidance.

MTAs – Quiz #2

QUIZ TIME!

Life University wants to send you human plasma samples for your research. The University has sent you their template MTA in advance of sending the materials. What should you do? (ANSWERS ON NEXT SLIDE)

1. Sign the MTA; you have read it carefully and it looks OK.
2. Contact your technology transfer office.
3. Tell Life University that you don't need an MTA because the Institutional Review Board (IRB) has approved the clinical protocol.

MTAs – Quiz #2 Answers

ANSWERS

1. Sign the MTA; you have read it carefully and it looks OK.

Not correct. MTAs coming from an outside party and/or involving human materials require review by your technology transfer office. Contact your [technology transfer office](#) for guidance.

2. Contact your technology transfer office.

Correct. Your [technology transfer office](#) reviews MTAs from outside organizations. They will be able to provide guidance on transferring these samples. You may also need other approvals to transfer human materials.

3. Tell Life University that you don't need an MTA because the Institutional Review Board (IRB) has approved the clinical protocol.

Not correct. MTAs coming from an outside party and/or involving human materials require review by your technology transfer office. MTAs document the actual transfer of materials, while IRBs and clinical protocols ensure other human subjects compliance. Your [technology transfer office](#) can provide guidance on transferring human samples.



CRADAs

During your tenure at the NIH, you may have an interest in carrying out a collaboration that would be most appropriately handled with a Cooperative Research and Development Agreement (CRADA). You should start this process by contacting your [Technology Transfer Office](#).

What is a CRADA?

- A CRADA is an agreement between one or more NIH laboratories and one or more non-Federal parties in which the parties will collaborate to achieve a mutual research goal.

What can be provided under a CRADA?

- Under a CRADA, the parties involved may provide research funds, personnel, services, facilities, equipment or other resources to conduct the specified research plan.

What distinguishes a CRADA from other collaborative agreements?

- A CRADA is the only agreement by which the NIH can offer a license option to intellectual property arising under the CRADA to a collaborator, and it is also the only collaborative agreement type by which the NIH can receive research funds.



CRADAs – Intent

- CRADAs are authorized only with collaborators who will make significant, intellectual contributions to the research project undertaken, or will contribute essential research materials or technical resources not otherwise reasonably available to NIH.
- A CRADA is not intended to be a general funding mechanism to support directed research in an NIH laboratory. They are to be used only to defray the cost of the project specified in the CRADA. The sole purpose of a CRADA cannot be to obtain funds.
- A CRADA cannot:
 - Restrict a lab's research objectives or compromise the NIH mission;
 - Restrict or constrain scientific interaction or the dissemination of research findings; or
 - Create an actual or perceived conflict of interest. Conflict of interest issues must be addressed in the review of the proposed CRADA.



CRADAs – Document Contents

The CRADA document consists of several parts:

- the Research Plan, which describes the project being undertaken and defines the scope of the research;
- a description of the financial and staffing contributions of the parties; and
- a description of the terms and conditions under which the project will be conducted such as how intellectual property rights will be allocated, and how confidentiality, data sharing, and other issues will be handled.



CRADAs – Questions

Questions you may be asked by your Technology Transfer Office before beginning a Collaboration

- Who is the proposed collaborator?
- What is the proposed research?
- Will the collaborator be actively participating in the research plan?
- Will you need money, material, equipment or personnel from the collaborator?
- Does the collaborator expect rights in any potential inventions?
- Does the project involve a clinical trial, human materials or human data?



CRADAs – Roles & Responsibilities

Roles and Responsibilities

Principal Investigators for NIH and Collaborator

- Participate in drafting the Research Plan with your Technology Transfer Office. The Research Plan describes in detail the work to be done under the CRADA, which party will perform the work, and what resources will be brought to the collaboration by each party.

Institute Technology Transfer Office

- Negotiates the legal and financial terms of the CRADA with the Collaborator. Routes the CRADA through NIH for review and signature.

NIH CRADA Subcommittee

- Reviews the CRADA for compliance with the law and NIH policies. May recommend modifications before recommending approval by the NIH Deputy Director.



CRADAs – PI Responsibilities

Your responsibilities as the NIH Principal Investigator:

Remember that, as the Principal Investigator, you are responsible for your CRADA when approved.

- Keep accurate records on equipment, personnel, expenditures, etc.
- Prepare and submit, in a timely fashion, all reports required by the CRADA.
- Report potential inventions to your technology transfer office for possible patent filing by NIH and licensing by the Collaborator.
- Manage any CRADA funds

Your [Technology Transfer Office](#) will inform you of your duties and responsibilities under the CRADA.



CRADAs – Types

3 Most Common Types of CRADAs

- Materials CRADA
 - typically used for the transfer of proprietary material(s) into the NIH when there will be no significant collaboration on the research project.
- Standard CRADA
 - typically used for a collaborative study involving basic or preclinical research.
- Clinical Trial CRADA
 - typically used for collaborative studies which include a clinical trial.

How do you know what type of CRADA to use?
Contact your [Technology Transfer Office](#)

CRADAs – Quiz #1

QUIZ TIME!



Melanoma, Inc., a major pharmaceutical company, has heard about your new discovery, gro44. They are very interested in collaborating with you. They tell you that they are not set up to carry out the research themselves but would like to fund the research in your lab. In return for providing funding, they want you to report your findings to them. Additionally, they would like an exclusive license to any discoveries that come out of the project. Is this an appropriate collaboration for a CRADA? (ANSWERS ON THE NEXT SLIDE)

1. Yes, because they are helping you to achieve your research goals, consistent with the Federal Technology Transfer Act.
2. Yes, because they are providing funding to the laboratory.
3. No, because they are not making an intellectual or essential material contribution to the research.
4. No, because they want an exclusive license to certain discoveries that come out of the CRADA Research Plan.



CRADAs – Quiz #1 Answers

ANSWERS



1. Yes, because they are helping you to achieve your research goals, consistent with the Federal Technology Transfer Act.

Not correct. This collaboration does not satisfy the criteria for a CRADA collaboration, because Melanoma, Inc. would not be making an intellectual or essential material contribution to the research.

2. Yes, because they are providing funding to the laboratory.

Not correct. Only providing funding to the laboratory would not satisfy the criteria for a CRADA collaboration. Intellectual and/or essential material contributions by both parties are required for a CRADA collaboration.

3. No, because they are not making an intellectual or essential material contribution to the research.

Correct. A CRADA is not intended to be a general funding mechanism to support directed research in an NIH laboratory.

4. No, because they want an exclusive license to certain discoveries that come out of the CRADA Research Plan.

Not correct. A CRADA would be appropriate because they offer an option for an exclusive license to certain discoveries that come out of the CRADA Research Plan.



CRADAs – Quiz #2

QUIZ TIME



Question:

You are approached by two companies, company A and company B. Company A would like to collaborate with you on developing antibodies to the recombinant protein encoded by the gro44 gene. Company B would like to collaborate with you to develop a DNA-based diagnostic test using the gro44 gene. Can you enter into CRADAs with both companies, or with only one? (ANSWERS ON THE NEXT SLIDE)

1. No, because there is a potential conflict between the projects (they both involve the use of the gro44 gene).
2. No, because the companies are fierce competitors.
3. Yes, as long as you don't work on the projects at the same time.
4. Yes, as long as the CRADA research plans are carefully drafted so that there is no overlap in work scope or rights and the PI is careful to keep the projects separate and distinct.

CRADAs – Quiz #2 Answers



ANSWERS

1. No, because there is a potential conflict between the projects (they both involve the use of the gro44 gene).

Not correct. If the projects are very focused and the scope of the research well defined, conflicts between projects can be avoided. This may not be possible for all projects.

2. No, because the companies are fierce competitors.

Not correct. It does not matter if the companies are competitors or not.

3. Yes, as long as you don't work on the projects at the same time.

Not correct. This might not be practical and could slow or impede research progress.

4. Yes, as long as the CRADA research plans are carefully drafted so that there is no overlap in work scope or rights and the PI is careful to keep the projects separate and distinct.

Correct. If the projects are very focused and the scope of the research well defined, conflicts between projects can be avoided. This may not be possible for all projects. The P.I. should be aware that there is an added responsibility of keeping these projects completely separate. This includes not sharing data or resources of one company with the other. Contact your Technology Development Coordinator to initiate the CRADA process.



Clinical Trial Agreements

What is a Clinical Trial Agreement (CTA)?

- An agreement between NIH and another party to conduct clinical research.
- Can be used for single-site or multiple site studies.
- Can be used to obtain clinical agents or clinical devices for research.

Please note:

CTAs are not the appropriate mechanism if NIH will be receiving collaborator funding for the clinical trial or if the collaborator requires an option to license potential NIH inventions resulting from the conduct of the trial.



CTAs – Quiz

QUIZ TIME



Question:

You are an Intramural staff clinician, and a company has contacted you about participation in a multi-site clinical trial. The company is providing their proprietary drug and funding to all participating sites for the conduct of the clinical trial. They have provided you with their standard Clinical Trial Agreement (CTA). Would this be the appropriate agreement for your scenario? (ANSWERS ON THE NEXT SLIDE)

1. Yes, because the proposed collaboration meets the criteria for a CTA.
2. No, because funding is being provided by the company.



CTAs – Quiz Answers

ANSWERS



1. Yes, because the proposed collaboration meets the criteria for a CTA.

Not correct. While the proposed collaboration involves a clinical trial, funding from a collaborator cannot be provided under a CTA. Contact your [Technology Transfer Office](#) to establish a Clinical CRADA.

2. No, because funding is being provided by the company.

Correct. Funding from a collaborator cannot be provided under a CTA. Contact your [Technology Transfer Office](#) to establish a Clinical CRADA.

Patents and Inventions

What is a Patent?

A patent is analogous to a contract between the inventor and the Government:

- Inventor must fully disclose everything about the invention
- The Government grants the right to block others from doing what is detailed in the patent claims for up to 20 years

To be patentable, the invention must be:

- “Novel” (never before made/done/disclosed anywhere),
- “Not Obvious” (*different enough* from prior inventions), and
- “Useful” (at least one specific use)

Only certain things can be patented:

- A machine, a chemical composition, an “article of manufacture” (catch-all), or a process (e.g., method of making, method of using)
- Not patentable: math, physics, items found in nature, text
- *Even a Nobel prize-winning discovery might not be patentable!*



Patents and Inventions – Beware

Traps for the Unwary

Disclosures

- As a rule, disclosing an invention before a patent application has been filed may jeopardize the patent rights
- Nearly **any** kind of disclosure to nearly **anyone** outside NIH counts, unless protected by a written agreement
- Dates matter: keep track of your communications

Co-Inventorship vs Co-Authorship

- An inventor is any person who “conceived” of the complete and operative invention
- Co-inventorship is a complex legal determination based on specific laws, court cases, and facts
- Not all co-authors are co-inventors, and vice-versa
- Co-Inventorship is not an appropriate tool to share academic credit or otherwise reward others

Keep good lab notes!



Patents and Inventions – Federal Labs

Patents in Federal Labs

- Nearly anyone working in a federal lab must, *by law*, report and assign any inventions they make relating to their official duties or with government resources.
 - The decision whether or not to apply for a patent on a discovery made by NIH personnel will be made by the NIH.
 - Applying for patents is an expensive and complicated process, taking years to result in an issued patent.
- Note: even if certain discoveries are not deemed patentable, and even if a potentially patentable invention is not suited for patenting, *report anything that might be an invention.*
 - Better to report something that turns out not to be patented than to fail to report something that would have been valuable!

Patents and Inventions – Procedures

Patent Procedures

To report an invention, the inventor will complete an [Employee Invention Report \(“EIR”\)](#).

- Attach any draft manuscripts, any relevant information, and any articles relating to the general topic of the invention

Your institute’s [technology transfer office](#) will review the EIR. If the decision is to file a patent application, the inventor likely will have to work with a patent attorney to draft the patent application and to respond to the US Patent Office’s actions.

Patents and Inventions – Why Care?

Why should you care?

Because:

- Your good ideas will not be used unless, sooner or later, a company invests in developing it into a product
 - Without a patent, companies will not invest
- Patenting is a viable way to share information with the public, sometimes the only effective means
- Inventors who assign their inventions to the NIH share in royalties the NIH collects through licensing

Patents and Inventions – Quiz #1

QUIZ TIME



Question:

If an invention appears obvious to you, the patent office will also deem it to be obvious and a patent will not be issued on it. (ANSWER ON THE NEXT SLIDE)

1. True
2. False

Patents and Inventions – Quiz #1 Answer

ANSWER



1. True.
2. False. **Correct.** The word “obvious” in patent law does not mean the same as common usage. “Obviousness” in patents is a legally defined standard for whether an invention, as it is described in a patent application, is sufficiently different from what came before. This analysis takes into consideration the state of the scientific field, the precise wording of the patent, and other factors. In fact, your discovery may be truly amazing and yet the patent application still be deemed “obvious” (because, as written, it over-claims). An experienced patent attorney or patent agent may be able to give some indication of the likelihood of whether or not the Patent Office will find a claimed invention “obvious”, but that is not an easy determination to make, and reasonable people can differ.

Contact your [Technology Transfer Office](#) for further guidance.



National Institutes
of Health

Patents and Inventions – Quiz #2

QUIZ TIME



Question:

Which of these events, occurring before the NIH has filed a patent application on your invention, may destroy patent rights? (ANSWERS ON THE NEXT SLIDE)

1. A conversation with a journalist about your new discovery.
2. A discussion with a company interested in commercializing the invention.
3. A talk at the NIH that is open to non-NIH attendees.
4. An e-mail to a trusted university colleague.
5. All of the above.



Patents and Inventions – Quiz #2 Answer

ANSWER



1. A conversation with a journalist about your new discovery.
2. A discussion with a company interested in commercializing the invention.
3. A talk at the NIH that is open to non-NIH attendees.
4. An e-mail to a trusted university colleague.
5. All of the above.

Correct. It is important keep the invention confidential until the NIH has filed a patent application, because if you disclose it to anyone outside the NIH in any manner, then the opportunity to pursue a patent may be lost. ***An invention should be reported as soon as the idea is complete and at least as soon as the invention is actually carried out.***

Licensing

- Each year, hundreds of new inventions are made in NIH laboratories. NIH Institutes or Centers (ICs) transfer these inventions – through licenses – to the private sector for further research and development and eventual commercialization.
- [Institute's Technology Transfer Offices](#) are responsible for negotiating licenses to NIH technologies. Patented technologies, as well as unpatented technologies that include materials, may be licensed for commercial or internal use.
- Hundreds of products have been developed through licenses to NIH technologies; these include FDA-approved therapeutics, diagnostics, vaccines, and devices, as well as research reagents and consumer products.



These products are just a sampling of the dozens of OTT success stories about brainstorms-turned-breakthroughs by NIH inventors.

Licensing – Basically...

- Once you inform your [technology transfer office](#) about a new technology from your lab, they will file a patent application, classify the technology as an unpatented research material, or decide not to seek a patent and recommend that the scientists disseminate the technology to the public via publication or otherwise.
- If a patent application is filed, your technology transfer office will seek to market the technology for licensing. You may be asked to review abstracts or technology briefs describing your invention.
- You, as the scientist, are often the best resource for identifying potential licensees and for making the business community aware of the technology through scientific publications and presentations at meetings. You should let your [technology transfer office](#) know of any recent publications or presentations relating to the technology, or of any companies that may be working in this area.
- In the event that your technology is a research material, it may be provided for commercial use under a license. If you are asked to provide a research material to a commercial entity, contact your [technology transfer office](#).



Licensing – Responsibilities

- Potential licensees will contact your technology transfer office for more detailed information and/or to submit a license application. In some cases, a potential licensee may contact you directly. In such cases, you should limit discussion to the scientific aspects of the technology, and no confidential information should be discussed unless a Confidential Disclosure Agreement (CDA) is in place; CDAs are negotiated by your technology transfer office.
- Questions regarding licensing or patenting should be referred to your technology transfer office. You should not be involved in the actual negotiation of a license, or undertake any activity that would create a conflict of interest, or even an apparent conflict of interest; when in doubt, consult your [Ethics Office](#). However, your technology transfer office may ask you for technical input on development plans and timelines; such information should be treated as confidential and not disclosed to any other party.
- If a licensee has requested materials from your laboratory, your technology transfer office will contact you before the license is executed to verify the materials are available. You should not provide materials to a licensee until requested to do so by technology transfer; this includes samples for testing.

Licensing – Quiz #1

QUIZ TIME



Question:

Super Drug Co. called you to discuss their interest in licensing a cell line created in your NIH laboratory. What kind of information can you discuss with Super Drug regarding the cell line? (ANSWERS ON THE NEXT SLIDE)

1. You can discuss technical/scientific information with the company that is publicly known.
2. You can discuss your latest, unpublished results.
3. You can discuss previous licenses NIH has negotiated for this cell line.
4. You should refer the company to your technology transfer office for information about obtaining a license.



Licensing – Quiz #1 Answers

1. You can discuss technical/scientific information with the company that is publicly known.



Correct. It is appropriate to discuss such information. You should also refer the company to your technology transfer office for licensing information.

2. You can discuss your latest, unpublished results.

Not correct. You should contact your IC technology transfer office to determine whether a Confidential Disclosure Agreement (CDA) may be appropriate. In addition to protecting your unpublished results, a CDA will also preserve the potential to file for patent protection on any inventions arising from your research.

3. You can discuss previous licenses NIH has negotiated for this cell line.

Not correct. Previous licensing interest in your technology is confidential information and should not be shared with anyone.

4. You should refer the company to your technology transfer office for information about obtaining a license.

Correct. Your technology transfer office will be able to provide licensing information to Super Drug. It is also appropriate for you to discuss technical or scientific information that has been published or otherwise disclosed publicly.



Licensing – Quiz #2

QUIZ TIME



Question:

A company has called you expressing an interest in a gene therapy vector for gro44, which you developed in your laboratory (and which is the subject of a pending patent application). They tell you that they are interested in an exclusive license for all fields of use, and that they think that the upfront fee for such a license should be about \$10,000. Then they ask for your opinion. What do you do? (ANSWERS ON THE NEXT SLIDE)

1. Provide your opinion on the upfront fee and agree that an exclusive license for all fields of use seems reasonable.
2. Tell them that it would be more appropriate for them to talk to your technology transfer specialist, then contact your technology transfer office and tell him/her that you would accept \$10,000 only if they also agreed to do a collaboration.
3. Tell the company that it would be more appropriate for them to talk to your technology transfer office.
4. Call your former colleague who now works at a local biotech company and ask what she thinks the technology is worth.

Licensing – Quiz #2 Answers

ANSWER



1. Provide your opinion on the upfront fee and agree that an exclusive license for all fields of use seems reasonable.

Not correct. You should not be involved in licensing negotiations. Refer the company to your technology transfer office.

2. Tell them that it would be more appropriate for them to talk to your technology transfer specialist, then contact your technology transfer office and tell him/her that you would accept \$10,000 only if they also agreed to do a collaboration.

Not correct. You should not be involved in licensing negotiations, even indirectly.

3. Tell the company that it would be more appropriate for them to talk your technology transfer office.

Correct. This would avoid any appearance of conflict of interest.

4. Call your former colleague who now works at a local biotech company and ask what he thinks the technology is worth.

Not correct. You should not be involved in licensing negotiations, and you should not disclose the company's interest to your former colleague (or to anyone), as this is confidential information. Refer the company to your technology transfer office.



Royalties

Royalty income received by the NIH under licenses for NIH technologies is collected by NIH's Office of Technology Transfer (OTT) and distributed by the NIH Office of Financial Management (OFM) to inventors and to the IC(s) where the technologies arose.

- OFM typically distributes royalty income to the inventors twice per year; in June for income received in the first half of the Fiscal Year, and in November for income received in the second half of the Fiscal Year.
- Payments are transferred electronically to each inventor's bank account of record.
- Portions of royalty income designated in license agreements as reimbursement for patent expenses are transferred directly to the IC. (Inventors do not receive a share of this income.)

Since inventors are paid even after they leave employment with the NIH, it is important that you keep OFM informed of your current address and banking information. Form SF-3881 can be obtained from the [OTT Website](#), completed, and sent to OFM with the new information.

More information about royalties can be found [here](#).



Royalties – Distribution

For income received under a given license in a given Fiscal Year, Federal law and NIH policy provide the inventors, as a group, with the sum of the first \$2,000 of income received, 15% of income between \$2,000 and \$50,000, and 25% of income above \$50,000 (the "Inventors' Share").

- No inventor may receive more than \$150,000 in total royalty income in a given year. Individual inventors receive their shares from the total Inventors' Share based on the inventorship of each licensed biological material or patented/patent-pending invention.
 - Inventors who worked at the NIH at the time the invention was made may receive royalty income.
 - Co-inventors outside the NIH may not receive royalty income from the NIH, unless they have assigned their rights to the NIH.

The default distribution formula treats each NIH inventor equally for each technology (patent family or unpatented material) in the license agreement. If the inventors as a group believe their individual contributions to the licensed patents are not equal, they may request that their institute's [Technology Transfer Office](#) alter the distribution formula.

After the inventors are paid, any remaining portion of the royalty income is distributed to the ICs where the invention arose. ICs may use this income to pay technology transfer expenses, provide technology transfer awards to employees, and to support research or programmatic initiatives within the IC's mission.



Royalties – Quiz

QUIZ TIME



Question:

You and two other collaborators invent a new drug for treating rheumatoid arthritis that reduces inflammation by inhibiting the production of IL-12. The NIH has patented this invention and licensed its rights exclusively to Big-Pharma, Inc. At the time the invention was made, you were working at NIAMS, one collaborator was at NIAID (but has since left NIH), and the third collaborator was at Ivy League University and assigned her rights to them. NIH will distribute the royalties it receives under this license to:

1. Just you, since you are the only inventor left at NIH.
2. You and the investigator from NIAID, since you both worked for the NIH.
3. All three inventors.
4. No one, because the technology is owned by the NIH.



Royalties – Quiz Answers

ANSWER



1. Just you, since you are the only inventor left at NIH.

Not correct. The current location of an inventor has no bearing on whether he or she receives royalties from NIH.

2. You and the investigator from NIAID, since you both worked for the NIH.

Correct. Inventors who worked at the NIH at the time the invention was made may receive royalty income. Co-inventors outside the NIH who have not assigned their rights to the NIH may not receive royalty income from the NIH.

3. All three inventors.

Not correct. Inventors, such as the inventor at Ivy League University, who have not either worked at the NIH or assigned their patent rights to the NIH may not receive royalty income from the NIH. They may, however, have an arrangement to receive royalty income from their university.

4. No one, because the technology is owned by the NIH.

Not correct. The NIH distributes royalties to NIH inventors for any royalty-bearing license. However, since the collaborator from Ivy League University did not assign her rights to the NIH, she would not receive any royalty income from the NIH.



Ethics

As stewards of the public trust, Federal employees must always be aware of practicing ethical behavior. NIH scientists must be vigilant in ensuring that they are not using public resources for private gain. This is particularly important for NIH scientists participating in technology transfer activities.

Ethical issues surrounding technology transfer can be a complex subject involving many variables. Therefore, it is recommended that you consult with your [Technology Transfer Office](#), [Ethics Coordinator](#), or [Deputy Ethics Counselor](#) to seek advice.



The End

Thank you for completing the NIH Technology Transfer Training.

Please print this slide and present it to your supervisor.



Please contact your [Technology Transfer Office](#) for any questions and for all Technology Transfer matters!



National Institutes
of Health