Material Transfer Agreements

(background reading for Exercise 1C)

What is a Material Transfer Agreement[1]

A Material Transfer Agreement (MTA) is an agreement by which an organisation which has biological materials provides those biological materials to another organisation for certain purposes.

Those purposes, ordinarily, are limited to:

(a) providing the biological material to a researcher for research, non commercial purposes, as a free service to the research community, and

(b) providing the biological material to a prospective commercial partner, to enable the prospective commercial partner to evaluate and conduct tests in relation to the material.

Material Transfer Agreements and Confidential Information

Almost always, when biological material is provided by one organisation to another, there is also disclosure of Confidential Information.

You will therefore see that the Material Transfer Agreement Builder closely follows the Confidentiality Agreement Builder, and reflects the same principles that are contained in NTU's Confidentiality Agreement Builder.

What is Biological Material

Biological material is all forms of biological material.

It includes molecules, compounds, reagents, cell lines, antibodies, proteins, peptides, enzymes, clones, and all other biological materials.

What is Confidential Information?

Confidential information is all information about which secrecy needs to be maintained. It includes, in relation to biological materials:

1. scientific information about the characteristics or properties of the material

2. inventions and discoveries, whether or not intended to be the subject of a patent application concerning the biological material

3. technical information.

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[1] Source: Charles Darwin University, Casuarina, Darwin, Australia, http://eagle.cdu.edu.au/ntu/apps/ntuinfo.nsf/WWWView/Procedure_1016.

Why have a Material Transfer Agreement?
A Material Transfer Agreement is necessary whenever you intend to

1. provide biological material owned by NTU

2. receive another party's biological material.

The biological material and any accompanying confidential information may be valuable Intellectual Property, and therefore needs to be protected by obligations restricting the use of the biological material, and the secrecy of the Confidential Information, and to ensure that the Recipient of the material and Confidential Information does not make improper use of it, nor provide or disclose it to unauthorised persons.

Doesn't the law already require a recipient to keep material and anything disclosed secret?

Yes.

However, the law will only impose obligations of confidentiality and restricted use if certain legal technical requirements are met.

A written Material Transfer Agreement meets all those legal technical requirements for you.

If you provide material or make a confidential disclosure without a written Material Transfer Agreement, you run the risk that NTU will be unable to meet those legal technical requirements, and so be unable to enforce restrictions on use, and confidentiality.

That may well adversely impact upon, or make impossible, NTU' success in seeking patent protection.

Material Transfer Agreements and Patenting

A patent is the right to exclusively commercialise intellectual property that is a new discovery or invention. It is a very valuable asset for NTU.

A patent can only be granted in relation to something that is *not* in the public domain.

If it is in the public domain, no patent will be granted.

If you provide material on an unrestricted basis, and make a disclosure of confidential information, without a Material Transfer Agreement, you may preclude NTU from being able to apply for a patent, or preclude a patent being issued to NTU.

A written Material Transfer Agreement allows material to be provided, and a disclosure to be made before a patent is applied for, without putting at risk the ability to apply for a patent.

Do I have to Use a Written Material Transfer Agreement?
Yes.

On every occasion that you intend to provide material that

1. is not in the public domain; or

2. is an invention or discovery; or

3. might be the basis of an application for a patent; or

4. is in the public domain but is not generally known; or

5. NTU would regard it prudent to require restrictions upon use, or obligations of confidentiality,

6. is encompassed in a patent application or granted patent

you must use a written Material Transfer Agreement.

If you are unsure whether a Material Transfer Agreement should be used, you should seek assistance from the Commercialisation Officer.

Even where there is a patent application or a granted patent, the use of the Material Transfer Agreement is necessary, as it is effectively a license over that patent application or granted patent.

Material Transfer Agreements are Tools

Material Transfer Agreements are tools to help facilitate commercial relationships.

These agreements are not intended to contain clauses over which parties haggle.

Material Transfer Agreements which contain provisions which are objectionable might scar a relationship that is sought to be formed, and not promote the building of that relationship.

The Material Transfer Agreement Builder will build for you a Material Transfer Agreement with these objectives.

When Do I seek the signing of a Material Transfer Agreement?

Before any material whatsoever is provided.

What is the Material Transfer Agreement Builder?

The Material Transfer Agreement Builder is a Material Transfer Agreement which you prepare.

It has choices about alternative clauses to make the agreement appropriate for the particular transaction you are concerned with. It also has text to help you decide which choices should be made.

Its objectives are that:

1. a Material Transfer Agreement is prepared that is flexible enough to be responsive to the needs of the transaction with which you are concerned, and the needs of all the parties to it, not just NTU

2. a Material Transfer Agreement is prepared that is consistent with the way all NTU Material Transfer Agreements are prepared.

Can I depart from the clauses in the Material Transfer Agreement?

No.

You can make choices where these are prompted in the Material Transfer Agreement Builder.

You cannot add anything else. Nor can you delete anything that is not the subject of a choice.

If to meet the needs of the transaction you are concerned with you believe that something should be removed, or that something should be added, you should consult with the Commercialisation Officer.

How long will it take me to generate a Material Transfer Agreement using the Builder?

The first few you do might take up to 10 minutes or so.

Once you become familiar with the Builder, it should take you no more than 2 or 3 minutes to generate a Material Transfer Agreement.

When can I provide NTU's biological material?

You must not provide biological material to any person until the Commercialisation Officer notifies you that the signed Material Transfer Agreement has been received back from the other party.

Can I use Another Party's Material Transfer Agreement

Sometimes the other party will inform you that it requires use of its own form of Material Transfer Agreement, instead of NTU' Material Transfer Agreement.

When NTU is a ***recipient*** of another party's biological material, this requirement is not necessarily unreasonable, but nevertheless, NTU' preferred position is that its own form of Agreement be used. This preferred position will not always be acceptable to the other party, and so on these occasions you will need accept that the other party, as the owner of its own material, is entitled to submit its own preferred form of Material transfer Agreement.

Where NTU is the ***provider*** of its own biological material, NTU's preferred form of material transfer agreement must be used. Only the Commercialisation Officer can approve otherwise, and this approval will not be given except in very exceptional circumstances.

If the other Party insists on using its own form of agreement you need to bear in mind the following:

1. NTU will need to obtain legal advice about the other party's form of Material Transfer Agreement. This can take from a few days to up to a week to obtain. You should bear this time frame in mind.

2. NTU will incur legal expenses of $200.00 to $400.00 or more to obtain that advice, which it prefers to avoid incurring.

There are obvious advantages to the other party agreeing to use NTU' form of Material Transfer Agreement, namely that there is no need to obtain legal advice beforehand, in that way accelerating the signing procedure.

NTU encourages you to persuade the other party of the advantages of using NTU' form of Material Transfer Agreement.

If the other party insists on using its own form of Material Transfer Agreement, you will need to

1. obtain a copy at as early a time as possible

2. refer it to the Commercialisation Officer as quickly as possible.

MTA for Germplasm Requested from the SPC RGC[2]

Policy statement for use with Material Transfer Agreements of the Regional Germplasm Centre

The SPC RGC holds germplasm from the Pacific Island countries which it distributes to third parties for agricultural research, and it also utilises that germplasm in its own research. Following the entry into force of the United Nations Convention on Biological Diversity on 29 December 1993, the SPC RGC recognizes the specific rights of the original source country of the germplasm in its germplasm release policy. This policy will also apply to germplasm collected, and maintained prior to the Convention on Biological Diversity. This policy duly reflects the concerns of original source countries and of their farmers who have been improving the material over historical time.

The SPC RGC therefore adopts the following policy:

1. In any transfer of germplasm, whether material is in the form in which it was maintained or whether it has been modified in any way through research carried out by the SPC RGC but without making warranty as to the genetic make-up of the transferred material, the SPC RGC will notify the recipient of the identity of the country or countries from whom the material was obtained.
2. The SPC RGC will require the recipient to (a) acknowledge the source of the material in any publications reporting on its use or descriptions of marketed varieties thereof and (b) to issue to the SPC RGC a report on evaluation results.
3. The SPC RGC will require that the recipient does not transfer the material, its products, or results derived from research using the material to another party other than to farmers through NARS.
4. Depending on the categorisation of the material requested the SPC RGC will either require Prior Informed Consent of the **(original source country)** and/or the committee as to its release, or will inform the **(original source country)** of the release of that germplasm. Where the latter applies, source countries will be advised of releases over a specified period. The SPC RGC will track the destination of released germplasm to the recipient, and will provide the source country with evaluation data obtained from that recipient.
5. The SPC RGC will not claim intellectual property rights over germplasm maintained by them, whether in the original form received by the **(original source country)**, or whether in a form modified through research by the **(original source country)**.
6. The SPC RGC will require that the recipient does not claim intellectual property rights over the material itself, and that any such claim on products or results derived from research using that material must be preceded by consultation with the source country and the SPC RGC.
7. The SPC RGC will advise the recipient that the material is subject to the conditions set out in the Convention on Biological Diversity and that, in case

[2] Source: TaroGen, http://users.bigpond.net.au/grahame/MTA.html.

of successful commercialisation of the material or products or research derived from the material, the recipient is subject to an obligation to provide a reasonable share of the net profits to the source country in a form to be agreed upon between the recipient and the country. The SPC RGC will assist the source countries in negotiations on profit sharing as necessary.

8. Where relevant all obligations, but especially (6) and (7) will also apply to genes derived from the material.
9. This policy statement is part of the MTA which all potential recipients of material will receive prior to the dispatch of any material. Therefore it is an essential component of the MTA.

Germplasm Access Agreements for Use by the SPC RGC

1. Material Transfer Agreement (MTA) for Distribution of Genetic Material for Use by the SPC RGC

The materials stated on the Plant Propagule Request Form are released under the following conditions:

1. This material, as described on the Plant Propagule Request Form, is or derives (in part or total) from material collected in or provided to the SPC RGC by **(the original source country)** and is subject to those rights as defined under the United Nations Convention on Biological Diversity.
2. In case of commercialisation of either the genetic material, its products or results derived from research using the genetic material, the **(recipient)** is required to negotiate an equitable benefit sharing agreement with the **(original source country)** in accordance with the Convention on Biological Diversity. This could be through payments, training assistance, technology transfer, or other forms of collaboration. When requested, the SPC RGC can assist in these negotiations**.** If the **(original source country)** is not known then the **(recipient)** is required to negotiate with the SPC RGC so that some form of benefit is made available to the region.
3. The SPC RGC is notifying the **(original source country)** as to this transfer.
4. The **(recipient)** will provide the SPC RGC with the results of any evaluation trials it may perform on the material. This information will be made available by the SPC RGC to the **(original source country).**
5. The **(recipient)** shall not obtain any form of intellectual property protection on this material or parts thereof.
6. The **(recipient)** cannot pursue intellectual property rights protection on any products or results derived from research using the genetic material without consultation with the **(original source country**) and the SPC RGC.
7. The **(recipient)** can only transfer this material, products of this material or results derived from research using the genetic material to farmers through NARS. Requests from any other body have to be referred back to the SPC RGC.
8. The SPC RGC makes no warranty as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, availability, or

purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine/biosafety regulations and rules as to import or release of genetic material.

9. The material is supplied expressly conditional on the **(recipient's)** acceptance of the terms of this agreement. No material will be exchanged until this form and the attached Plant Propagule Request Form are signed.

I/we agree to comply with the conditions above in the use of the material requested on the Plant Propagule Request Form:

Name of Person representing Institute

Name and Address of Importing Institute

Date

2. Plant Propagule Request Form

Crop:

Please enter the accessions required:

Accession Name /Number Variety Number of tubes and/or plants required

Intended Use or Uses of the Material:

If requested for use in a project please state title:

I agree to comply with the conditions as specified in the attached policy statement and material transfer agreement.

Name Signature
Date

Institute/Organisation:
Address

Approved by:

Prepared by

Date:

3. Germplasm Acquisition Agreement (GAA) for Use by the SPC RGC

1. **(Country)** grants germplasm to the SPC RGC under the following terms and conditions.
2. **(Country)** warrants that the germplasm originates from within its territory and, if it does not, that it is legally free to provide the germplasm to the SPC RGC.
3. The SPC RGC will hold the material, place it in its genebank, maintain it, periodically regenerate it, duplicate it for security reasons and provide state-of-the-art long-term conservation, whenever applicable.
4. The SPC RGC will make the material available to any user for research and education purposes, under an agreement as described in the attached policy statement, with terms intended (a) to indicate to the recipient that the **(original source country)** may have rights as specified under the Convention on Biological Diversity, (b) to restrict the recipient from obtaining intellectual property rights on the material itself, and (c) to require the recipient to consult with the **(original source country)** and the SPC RGC prior to the pursuit of intellectual property rights on products or results derived from research using the material.
5. The SPC RGC will not seek any form of intellectual property right protection on the material held in trust, nor on related information.
6. The SPC RGC is free to improve and breed with the material in any fashion. Should the SPC RGC develop advanced varieties or separate genes from the material, it will not seek intellectual property protection on these, and it will consult with the **(original source country)** as to conditions governing the release of this material.

1/We agree to comply with the conditions of this agreement as detailed above:

Name of Curator of RGC

Date

Name of RGC

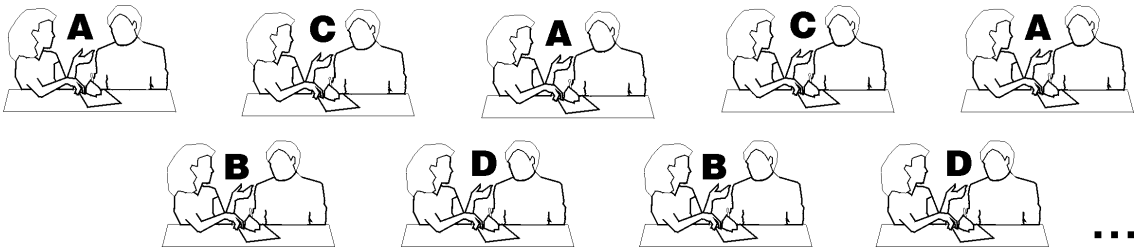
Source Country Representative
Date

Exercise 1C. Accessing Genetic Resources from an *ex Situ* Genebank

(work in pairs)

The objective of this exercise is to consider a request for germplasm and to come to a decision using the information provided, taking into account all of the legal and policy issues that are relevant.

1. Form a pair with your neighbour. (5 minutes)



Phase 1. Work in pairs (25 minutes)

2. The trainer assigns letters A, B, C, D and E to the pairs, repeatedly, until all pairs have a letter.
3. Carefully read the hypothetical case below and work on the questions assigned to your pair to complete step 3 of this exercise.

A national institution from a country outside of the Pacific requests selected accessions of yam. Yams are important for their food security, and their local varieties are currently succumbing to a virulent form of anthracnose. The yams you are conserving have shown good resistance to anthracnose. The original material was collected prior to the entry into force of the CBD. The requesting country is party to the CBD and the IT.

The genebank is an important component of a regional organization, which, as such, is signatory to neither the CBD nor the IT. However, all of the germplasm conserved within the genebank originated from countries that have signed the CBD. The only country within the Pacific to have signed the IT is the Marshall Islands and this is not the country from which the desired yam germplasm originated.

The regional genebank operates using an MTA (see Handout 1C.1.)

4. Respond to the question assigned to your pair: Pretend you are the curator for the regional genebank in the Pacific.

   PAIR A. What factors would be relevant to determining your response to the request in this hypothetical case?

   PAIR B. How would you respond if the national institution requesting the germplasm is within the Pacific region?

PAIR C. How would you respond if the requesting institution is a private one (a) within the region (b) outside the region?

PAIR D. How would you respond if the requesting institution wishes to use the material commercially?

PAIR E. How would you respond if the requesting country is a non-party to the IT but has a large public *ex-situ* genebank?

Phase 2. Reporting and discussion (40 minutes)

5. The trainer invites rapporteurs from the A, B, C, D and E pairs to present their results to the audience. (20 minutes)

6. The trainer invites other pairs who had different responses to share and discuss their results. (10 minutes)

7. The trainer distributes handout 1.C.8 to the participants, analysis practical considerations for this exercise, provides feedback on the context of the presentations and closes the session. (10 minutes)

Exercise 1C — Worksheet

PAIR A

Question:

What factors would be relevant to determining your response to the request in this hypothetical case?

Exercise 1C — Worksheet

PAIR B

Question:

How would you respond if the national institution requesting the germplasm is within the Pacific region?

Exercise 1C — Worksheet

PAIR C

Question:

How would you respond if the requesting institution is a private one
(a) within the region
(b) outside the region?

Exercise 1C — Worksheet

PAIR D

Question:

How would you respond if the requesting institution wishes to use the material commercially?

Exercise 1C — Worksheet

PAIR E

Question:

How would you respond if the requesting country is a non-party to the IT but has a large public *ex situ* genebank?

Practical Considerations for Exercise 1C

(to be distributed after the exercise has been completed)

As a curator of a genebank, you have responsibility for making decisions regarding germplasm exchange. Requests for germplasm can be varied, and often have to be considered in the light of numerous agreements, both national and international. After doing this exercise, participants are able to consider a request for germplasm and to come to a decision using the information provided, taking into account all of the legal and policy issues that are relevant.

General Considerations

The IT does not apply even though yams are one of the crops in Annex 1 and the country requesting the yam germplasm has signed the IT. The original supplier of the yam germplasm to the regional genebank has not signed the IT.

All Pacific island countries have signed the CBD but none have national legislation in place.

The regional genebank operates using an MTA, which does acknowledge sovereign rights as in the CBD. But could the actual country of origin be determined? There is a lot of commonality with PGRFA in the Pacific.

Is the Pacific self-sufficient in PGRFA? Could the genebank in the requesting country provide germplasm to the Pacific that would be of interest/use? It is possible that they have other species of yams and aroids that might be of interest to the Pacific.

The information obtained from this country in evaluating these yams could be useful to the Pacific: perhaps they also have different ideas for processing yams, which could be of benefit to the Pacific region. In addition to sharing germplasm, information could also be shared. This is an opportunity for promoting mutually beneficial cooperation.

Under what conditions did the regional genebank obtain the yam germplasm? The information states that it was collected before the CBD. Can the genebank distribute without PIC? What are the terms and conditions within the MTA? In the SPC RGC Germplasm Release policy it states: *This Germplasm Release Policy Statement and its associated Material Transfer Agreement . . . . will apply to all germplasm maintained by the SPC RGC unless a country prefers a different arrangement to govern distribution of material originally collected there.*

Is there an existing yam network? If not, would it make sense to have a yam network to promote germplasm exchange within the network by its members?

Specific considerations

How would you respond to the following if you are the curator for this regional genebank in the Pacific?

In the situation as described, if conditions for use are within those specified within the MTA, you would provide access to the yam germplasm using a standard MTA, assuming that the genebank has the approval of the countries to do this. If not, the genebank would have to consult the country of origin and ask for PIC. Regional genebanks would encourage the country to grant access to its germplasm on the basis that we are all interdependent on PGRFA and that this is a request for a food-security crop. It is likely that informal discussions would have taken place between curators as to what in this specific case would be mutually beneficial: exchanging germplasm and/or information.

If the national institution requesting the germplasm is within the Pacific region, you would provide access if the conditions in which the germplasm was given to the RGC allow this. If not, consult the country of origin for PIC. There could be a case here for having a yam network to facilitate the sharing of germplasm. Evaluation information obtained from sharing this germplasm could be very useful.

If the requesting institution is a private one (1) within the region or (2) outside the region, first, why does the institution require this germplasm? Is it for research, breeding, evaluation and production in accordance with the terms of this agreement, as the MTA states? Is the request in line with the conditions of the MTA? The response would also depend on whether there was a policy for distributing to private institutions. There is no mention of one. The MTA does cover what should happen when there is the possibility of commercial use. In both cases, the genebank would discuss the situation with the country of origin and seek PIC.

If the requesting institution wishes to use the material commercially, this is outside the conditions of the MTA, so the genebank would have to consult the country of origin. Because of the commonality that exists with PGRFA in the Pacific, then consultation with other yam-producing countries would also be recommended. It is likely that a bilateral agreement would have to be established. Transaction costs would have to be taken into account.

Whether the requesting country is a non-party to the IT or has a large *ex situ* genebank would not make any difference because the country donating the germplasm to the regional genebank is also a non-party to the IT. Why does the institution require this germplasm? Does it fall under the conditions stated by the MTA? As an *ex situ* genebank, will it further distribute this germplasm and is it in a position to obtain a commitment to the conditions of the MTA from any subsequent recipient?