

CASE STUDY ON ACCESS & BENEFIT-SHARING FOR NON-COMMERCIAL ACADEMIC RESEARCH IN LATIN AMERICA AND THE CARIBBEAN

BRAZIL

BR3

Clone, expression and purification of *Leishmania braziliensis* proteins: Use in serology and vaccine studies

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Region: Rio de Janeiro State, Brazil

Field of research: Parasitology

Research goal:

Search for new *Leishmania spp.* antigens to be used in diagnosis, prognosis and vaccine

Commercial purpose:

Non-commercial, but the product can become commercial depending of the results of the experiments.

Resources accessed: The protozoas

Provider of resources: *Leishmania* Collection (CLIOC) from Fiocruz.

User of resources: Researchers

Governing body regulating access: Genetic Heritage Management Council (CGEN)

Utilisation of resources during the project: Genetic, biochemical and immunological analysis.

Utilisation of resources after project completion:

The resource is preserved in an institutional collection (CLIOC/Fiocruz) that is recognized by CGEN as Faithful Trustee Collection.

Paragraph from the Provisional Act 2.186-16 regarding Faithful Trustee Collection: "A representative sub-sample of the accessed genetic heritage component shall be deposited in ex situ condition at an institution accredited as trustee (Faithful Trustee Collection), as provided for in item "f" of Paragraph IV of Article 11 of this Provisional Act, in accordance with complementary legislation."

Utilisation of generated information after project completion: Scientific publication and patent.

Negotiation procedures:

There is no negotiation yet because the research is still in the basic research phase*.

*Research types under Brazilian law:

- Basic research: taxonomy, epidemiology, ecology
- Scientific research: research that does not involve taxonomy, epidemiology, ecology, see Resolution 21 (http://www.mma.gov.br/estruturas/sbf_dpg/_arquivos/res21cons.pdf).
- Bioprospecting: an exploratory activity that aims to identify genetic heritage components and information on associated traditional knowledge, with potential for commercial use (Provisional act 2186).
- Technological development: the systematic research, based on the already existing knowledge, that aims the production of specific innovation, the elaboration or modification of already existing products and processes, with economical application (Technical Orientation nº 4, CGEN, without English version).

And see annex for part of MTA content.

Negotiation duration from the time of permit application: Non applicable

Information on Prior Informed Consent (PIC) &/or Mutually Agreed Terms (MAT) when available:

Non applicable

Factors of success of the application procedure:

Non applicable

Non-monetary & monetary benefits shared:

Public benefits such as development of diagnosis test or vaccine.

Awareness of benefits shared:

There will be public benefits nationally and internationally with the development of diagnosis test or vaccine for the Brazilian population as well as population from countries that suffer with leishmaniosis.

Continuation of benefits sharing:

Non applicable – too early in the research process

Other comments:

Information required with the application for the status as “Faithful Trustee Collection”

Veja abaixo a relação dos documentos que devem ser anexados a este formulário:

1. Comprovação de que:
 - a. é instituição pública constituída sob as leis brasileiras; (indicar/apensar a lei que a criou);
 - b. exerce atividades pesquisa e desenvolvimento nas áreas biológicas e afins. (relatório de atividades, produção científica na área);
 - c. possui infra-estrutura disponível e capacidade para conservação, em condições ex-situ, de amostras de componente do Patrimônio Genético.
 - d. possui capacidade da equipe técnica responsável pelas atividades de conservação. (Curriculuns, lista de publicações... p.ex)
2. Descrição da metodologia e material empregado PARA A CONSERVAÇÃO das amostras de componente do Patrimônio Genético sobre as quais a instituição assumirá responsabilidade na qualidade de fiel depositária.
3. Indicação da disponibilidade orçamentária para manutenção das coleções. (especificar os montantes previstos para manter as coleções, sendo eles institucional ou valores adquiridos com a aprovação de projetos de pesquisa vinculada à coleção)
4. Cópia do Ato que delega a competência do Representante Legal da instituição solicitante ou o instrumento de procuração com poderes específicos quando solicitação for feita por procurador.

ANNEX

Part of MTA for *scientific* research

“The signatory institutions, through their duly established representatives, bearing in mind the provisions of the Convention on Biological Diversity, Provisional Act No. 2,186-16, dated August 23, 2001, Decree No. 3,945, of September 28, 2001, as amended by Decree No. 4,946 of December 31, 2003, and Genetic Heritage Management Council Resolution N° 20, of June 29, 2006, undertake to use the sample(s) of the genetic heritage components transferred among themselves pursuant to the following conditions:

The received material must only be used by the receiving institution for non-commercial scientific research purposes.

In cases of any subsequent interest in making use of the samples of the genetic heritage components transferred under this MTA for the purposes of bioprospection, technological development, or the request of a patent, the Receiving Institution shall inform the Sending Institution, which shall in turn inform the Genetic Heritage Management Council or an institution accredited under the terms of Article 11(IV)(e) of Provisional Act No. 2,186, dated August 23, 2001.

Undertaking the activities mentioned in the previous paragraph without complying with the relevant legal provisions, and in particular without prior authorization from the Genetic Heritage Management Council, is prohibited.

Samples of genetic heritage components may not be transferred to third parties by the Receiving Institution unless a new MTA has first been signed between the original Sending Institution and the new Receiving Institution, in accordance with the provisions of Resolution N°. 20 from Conselho de Gestão do Patrimônio Genético, 2006.

Receiving Institutions shall abide by the terms of the MTA and shall not be considered providers with respect to the material received.

Any publication resulting from the use or study of shipped samples of genetic heritage components shall expressly acknowledge the origin of the material and credit the Sending Institution, to whom a copy of the publication in question must also be sent.

The Receiving Institution will facilitate access and transfer of technology to the Sending Institution or to another institution indicated by this, as a means of promoting the conservation and sustainable use of the genetic heritage transferred.

The Sending Institution is wholly responsible for identifying and properly packing the material, and for complying with specific shipment procedures related to biological risk assessment and for the containment of the organism or material transferred, observing all relevant official recommendations, international standards and specific legislation of the Receiving Country.

The Receiving Institution commits itself to:

not claiming any intellectual property rights over the genetic heritage components or parts thereof transferred under the MTA, without prior access authorization issued by the Genetic Heritage Management Council;

informing the Sending Institution, in writing, of any adverse effects observed when handling the genetic heritage components under the MTA.

Failure to comply with the procedures set forth in this Agreement shall subject offenders to the penalties established in existing legislation.

The competent forum for settling disputes among institutions with respect to this MTA shall be the head office of the Sending Institution.

The commitments related to the material transferred under this Agreement shall remain valid for an indefinite period of time, regardless of whether or not the Agreement has been renewed.