ANNEX 2

AUTHORISATION FOR THE TRANSFER OF SAMPLES FROM THE PROVIDING INSTITUTIONS TO THE HERACLES-BIOBANK

AGREEMENT FOR THE TRANSFER OF BIOLOGICAL MATERIAL TO BE HOSTED IN THE BIOBANK "HERACLES"

Full name of the clinical trial: HERACLES— Human cystic Echinococcosis ReseArch in CentraL and Eastern Societies

Summary of the project: Human cystic echinococcosis (CE), one of the most widespread helminthic zoonoses, is a chronic disease caused by infection with the larval stage of the tapeworm Echinococcus granulosus. This disease is highly endemic in some southern (Spain and Italy), eastern (Bulgaria and Romania) European countries and associated (Turkey) countries, where it still represents a major health and economic problem. In endemic areas the annual incidence of CE ranges from 1 to 200 per 100,000 inhabitants and 2-3 million cases are globally estimated. Case series and small clinical trials show a mortality rate of 2-4% for CE, but this increases markedly with substandard treatment and care. The diagnosis of human CE is mainly based on imaging techniques and serological confirmation. Clinical decision making is difficult and the natural history of the cyst is still poorly known. CE is chronic, complex and still neglected. For these reasons the main objectives of HERACLES are:

• Identify by ultrasound screening the population affected by CE in endemic rural areas of CEE countries;

• Create CEE national registries for surveillance of CE;

• Establish a representative bio-bank of genetic Egc isolates and blood/serum/plasma samples;

• Validate new molecular-based POC-LOC kits for immunological surveillance, diagnosis and follow-up;

• Identify factor/s associated with CE response to therapy or lack thereof through investigation of host-parasite interplay (parasite virulence vs human immunity);

• Increase drug bioavailability in an in vivo model, decreasing the length of antiparasitic (ABZ based) treatment of CE and synthesize a new enantiomeric drug based on ABZ.

The project stakeholders, especially the rural populations in which CE is endemic, as well as SMEs, will be engaged as an integral part of the project. Special events to increase general awareness of CE and training activities for local health care providers will be organized.

By this agreement, the institution sending the biological material and associated clinical data (CONSIGNOR) requires the CONSIGNEE institution (HERACLES biobank, hosted at the IRNASA, CSIC, Spain) to agree on the below terms, before sending the biological material in a quantity and for an use defined in the corresponding protocols of HERACLES, to be dispatched to the address of the CONSIGNEE institution: **IRNASA, CSIC**, **Cordel de Merinas, 40-52, 37008 Salamanca, Spain.**

1. Delivered Biological materials shall be used only for the above-mentioned purposes or for secondary purposes which are priorly approved by the CONSIGNOR institution.

2. CONSIGNEE can provide the biological material to third parties, FOLLOWING THE LAW AND MODE OF USE OF SAMPLES HOSTED IN A BIOBANK, usually after approval of the Ethical and the Scientific committees of the Biobank.

3. Biological materials shall be dispatched by the CONSIGNOR to the CONSIGNEE without the identity information of the individuals.

4. CONSIGNEE shall use the biological materials in accordance with the United Nations Human Genome rules and the Universal Declaration of Human Rights.

5. Prior to the dispatch of the biological materials to the CONSIGNEE, informed volunteer consent forms approved by the Ethics Committee of the CONSIGNOR Institution should have been signed by each of the persons that have provided samples and associated data to the CONSIGNOR.

6. CONSIGNEE acknowledges and agrees that the biological materials to be dispatched under this agreement shall be utilized for research purposes and have some hazardous characteristics associated with their usage. CONSIGNOR institution shall not be held responsible for the matters specified in this article.

7. CONSIGNOR and CONSIGNEE shall mutually determine and agree on their rights relating to a joint publication or a patent right that may arise and other rights regarding commercial developments at the beginning of the clinical trial.

8. This agreement shall be terminated in the event of the realization of either one of the following two provisions:

a. If the clinical trial has been terminated,

b. Within 30 (thirty) days as of the delivery of the written notice of any of the parties sent to the other party Other than noncompliance with the agreement clauses, violation of patent rights or risks that may cause hazardous effects on health, in case this agreement is terminated by the written notice of either party as per clause 8 (b), the investigator who provides the material may set a date when the agreement is going to be terminated within a period of up to 1 (one) year upon the request of the CONSIGNEE for not hindering CONSIGNEE's research.

9. CONSIGNEE agrees to return or dispose of all materials and to evidence such acts accordingly in the event of termination of the agreement.

10. Sponsor and the managers of the CONSIGNEE and CONSIGNOR shall be responsible from the execution of this Agreement and performances hereunder. In case of conflict, both countries of the parties' courts are authorized to intervene.

INFORMATION REGARDING THE INSTITUTION SENDING THE BIOLOGICAL MATERIAL (CONSIGNOR)

Name Surname and Title:	
Specialization:	
Institution:	
Address:	
Phone:	
Fax:	
E-mail:	

INFORMATION REGARDING THE CONSIGNEE RECEIVING THE BIOLOGICAL MATERIAL

Name Surname and Title:	**Mar Siles-Lucas, Dr.**
Specialization:	**Senior Researcher, Parasitologist**
Institution:	**IRNASA, CSIC; HERACLES BIOBANK**
Address:	**Cordel de Merinas, 40-52. 37008, Salamanca, Spain**
Phone:	**0034923219606**
Fax:	**0034923219609**
E-mail:	**mmar.siles@irnasa.csic.es**

I read and understood the terms under this agreement. I hereby agree and undertake that I will act in accordance with the terms of this agreement with respect to the dispatched materials.

In Handwriting	**Consignor**	**Consignor Legal Representative**	**Consignee**	**Consignee Legal Representative**
Name and Surname				
Title				
Date				
Signature				