CONFIDENTIAL

APPLICATION FOR PROGRAMME APPROVAL BY THE REVIEW BIOETHICS COMMITTEE (RBC)

THIS APPLICATION SHOULD BE SUBMITTED IN ELECTRONIC FORM ALSO

An application requirement is that the proposed Programme has secured the necessary funding for its implementation
(Where the application will be submitted before securing funding, detailed reasoning should be provided for the request of the RBC's approval)

The Review Bioethics Committees (RBC) are under the direct supervision of the Cyprus National Bioethics Committee (CNBC). The CNBC has authorized the RBC to study the application submitted and to make a decision. The RBC's decision on this application may be re-evaluated by the CNBC if the applicant disagrees with the decision of the RBC.

To be completed by the Principal Investigator (s) of the Programme (if a Programme has a "Coordinator" then for purposes of this application, the Coordinator is considered the "Principal Investigator")

Date of application		
Date:	**Month:**	**Year:**
Programme title for which the application is submitted		

To be completed by the Cyprus National Bioethics Committee

Date of submission		
Date:	**Month:**	**Year:**
Bioethics Committee Protocol Number		
Person receiving the application on behalf of the Committee		

Note: While completing this form, if any information is requested which does not apply to the Programme in question, please state as "NOT APPLICABLE".

To be completed by the Principal Investigator (s)

Name of Institution to which the Principal Investigator (s) of the project for which the application is submitted belongs (attach a certificate from the representative body certifying that the institution is aware of and consents to the conduct of the study).

Name of the Principal Investigator and full details of the postal and e-mail address.

Title of the Scientific Programme

Full details of the Programme sponsor

Programme Duration / period

If the Institution of the Principal Investigator (S.D.) **is not** in Cyprus, a representative researcher must be appointed by the P.I. whose institution is located in Cyprus
(personal information of the P.I.'s representative in Cyprus, full postal address, telephone numbers, facsimile, e-mail, etc.)

Attach a curriculum vitae (up to 2 pages) for each researcher who will be participating in the Programme.

List all the researchers participating in the Programme and explain the role of each participating researcher.

Summary of the Programme on a single page (to include at least the purpose, reasoning and objectives of the proposed Programme)

Type of Programme (eg pilot, clinical, genetic, multi-centre, etc.). In the case of multi-centre clinical studies, please include the EudraCT Number or the FDA number (fda.gov) of the study.

Describe the population to be studied (number, admission or exclusion criteria, etc.)

Give details of how to recruit individuals (participating patients and/or volunteers) who will participate in the Programme

Attach any forms to be used to recruit people in the Programme (newsletters, advertisements, etc.)

Describe the procedures by which Programme participants (patients and/or volunteers) can submit grievances or complaints. Note: Other than the research group, full details of an individual or authority must be provided (for more information, visit the CNBC website: www.bioethics.gov.cy)

Will people with disabilities participate in the Programme?
YES or NO: …… If YES, complete the following:
Full details of how to obtain legal consent for the participation of these individuals in the Programme.
Full details of why it is considered necessary to involve these people in the Programme

Are there any participants in the Programme who are not capable to give their consent?
YES or NO: ……. If YES, complete the following:
Full details of how to obtain legal consent for the participation of these individuals in the Programme.

Full details of why it is considered necessary to involve these people in the Programme

Will Minors participate in the Programme?
YES or NO: ……. If YES, complete the following:
Full details of how to obtain legal consent for the participation of these individuals in the Programme.
Full details of why it is considered necessary to involve these people in the Programme

Is there a need for access to previous medical records of people who will participate in the Programme?
YES or NO: ……. If YES, complete the following:

Full details as to how to secure permission for access to previous medical records of individuals who will participate in the study (including arrangements with physicians)

Attach it the Programme Protocol **as a whole**, which should include at least the following with references to the protocol pages to which reference is made.	
Subject	Page Number
Type of Programme	
The number of Institutions participating in the Programme	
The total number of people participating in the Programme	
Reasoning for the study	
Background of the Programme	
Research assumptions set by the Programme	
Programme Purpose	
Programme objectives	
Benefit resulting from the Programme	
Programme Design	
Sample size	
Reasoning for Sample size	
Inclusion Criteria	
Exclusion Criteria	
Procedures and methods	
Ways of measuring or estimating results	
Statistical analysis	
Conscious consent for participation in the Programme	
Legal damages to people who will take part in the Programme (who will be responsible?)	
Relevant Compensation for Participants in the Programme or any limitations on their legal compensation	
Reasoning for the use of genetic information	
Details of the personal information that will accompany the Programme's population sample	
Details of the demographic data that will accompany the Programme's population sample	
Disclosure of Personal Information	

Disclosure of Genetic Information	
Disclosure of genetic or other biological samples	
Access to information from participants in the Programme and their relatives	
Storage and destruction of samples and data	
Grievance or complaints procedure	

Where applicable, justify the use of placebo
Details of the treatment currently used
Effectiveness of current treatment
Full reasoning for the necessity to use placebo
Possible risks for patients receiving placebo and lacking the usual treatment
Details of the measures to be taken to reduce the risks (if any) to patients who are receiving placebo
If new medication is to be used, give details of the possible risks and side effects that can be experienced by the people taking it.

ONLY FOR CLINICAL TRIALS
ON MEDICINAL PRODUCTS FOR HUMAN USE

1) Results of preliminary clinical examinations or reasoning for not having performed preliminary clinical examinations.

2) Assessment of risks and disturbances from the administration of the treatment under study.

3) Method to identify / specify any side effects during the clinical trial.

4) Plan on the basis of which the medical care or the updating to the participants in the clinical trial will be continued until the end of the study and/or extended even to after the end of the study.

5) Determine the relationship between individuals (patients and/or volunteers) participating in the Programme and the researcher/physician who will conduct the study.

6) Regulations governing the early termination of the clinical study in a, Institution or the total of Institutions conducting the clinical trial.

7) Attach a summary of the characteristics of the medication to be used. If not attached, detailed explanations should be provided.

8) Attach a copy of the approval of the manufacturer of the medication (if any) stating the purpose of the approval. If not attached, detailed explanations should be provided.

9) In the event that the medication is manufactured in the European Union, attach a certificate from the manufacturer that the premises where the medication is produced operates, at least, in accordance with the standards applicable in the European Union. - If not attached, detailed explanations should be provided.

10) Attach a copy of the medication import license. If not attached, detailed explanations should be provided.

11) Have studies been carried out to ensure the safety of the medication regarding virology?

12) Is there a plan for continuing to administer the drug after the study is completed?

FOR ALL STUDIES / PROGRAMMES

Record (if applicable) previous experience and training of the Institution and of the Principal Investigator in handling Programmes similar to the one proposed in this application.

Record the expected benefit of the participants in the proposed Programme (patients and/or healthy volunteers) and the expected results of the study.

Attach all relevant information and consent forms to be used in the Programme (specifically consent forms EEBK03).

Ensuring the protection of personal and medical data of individuals who will participate in the Programme
Give details of:
1) Administrative Mechanisms *(refer to which individuals will collect which information, whether there will be access codes and if yes, whether there will be classification into different levels of access regarding each member of the research team)*
2) Technical Mechanisms (refer mainly to whether the collected data will be archived anonymously, which members of the research team will have access to the assignment of a code to a participant's name, whether clear procedures of destroying the samples and data collected through the research protocol have been specified)
3) Physical Mechanisms *(refer mainly to the natural security of the material and data collected, how and where storage will take place, whether the site will be locked, which individuals will have access, etc.)*

Funding / Financial Agreements
Give ALL details for the Programme funding
Attach any special contracts in respect of fees or the entire Programme
Please quote below all relevant details regarding:
1) any fees that will be paid to participants (patients and/or volunteers)
2) any financial charges that participants (patients and/or volunteers) may incur
3) fees, indemnities, gifts and/or services being or will be granted to researchers or their associates in relation to the Programme

State whether any person of the part of the sponsor, researchers and their associates may have any future benefits to be derived from the proposed programme

Document all the arrangements that have been made with Organizations, Institutions, Bodies, Laboratories, Ministries and/or individuals who provide specific services or/and approvals necessary for carrying out the proposed programme

Where applicable, please provide details below:
1) How will the Research Team of the proposed Programme will be able to continuously inform the participants of the study (patients and/or volunteers) on security-related issues and their participation in the Programme?
2) How will the rights of researchers regarding possible publications of the results of the Programme will be safeguarded?
3) Have any conditions been set, by the sponsor, in relation to the publications concerning the results of the Programme?

To be completed by the Principal Investigator(s)

Give answers as to whether the Programme includes the following topics:		
Subject	YES	NO
Participation of humans		
Participation of people with disabilities who cannot consent on their own		
Participation of individuals between 16-18 years old		
Participation of individuals under 16 years		
Adult volunteer participation		
Participation of a related Patient Association		
Use of any human biological samples		
Use of human genetic material		
Use of stem cells		
Use of stem cells from human embryos		
Use of stem cells by humans		
Use of embryonic tissue		
Use of human embryos		
Use of human eggs		
Use of human sperm cells		
Use of medication		
Use of placebo		
Known side effects of drugs to be used		
Personal data management		
Medical data management		
Biochemical data management		
Genetic data management		
Management of data that will be used anonymously		
Human cloning		
Attempting human cloning for reproduction purposes		
Creation of human embryos (all stages)		
Intervention for permanent alteration in the human genome (alteration to be inherited)		
Animal Use		
Creation or use of transgenic organisms		
Use of animal stem cells		
Intervention for permanent alteration in the animal genome (alteration to be inherited)		
Use of genetically modified micro-organisms / organisms		
Use of genetically modified plants		
Genetic modification of micro-organisms and/or plants		
Release into the environment of genetically modified micro-organisms and/or organisms and/or plants		

The Principal Investigator of the Programme should list the ethical concerns (if any) underlying the proposed Programme

(A) Statement on Non-Conflicting Interests by Researchers.
All of us, the undersigned, taking part in the Programme as researchers (at all levels) to hereby declare responsibly that we do not have any direct or indirect conflict of interest in relation to the Programme in which we participate.
(B) **Responsible Declaration by Programme Researchers that the information and consent forms attached to the application are binding to ALL** Note: For Cypriot Researchers, original signatures should be placed. For researchers permanently residing overseas, signatures are accepted via facsimile (for more information, visit the CNBC website at: www.bioethics.gov.cy)

Name and Surname	Signature	Date

The Principal Investigator(s) of the Programme signs and commits to not proceed with any changes to the Programme, such as those included in this application. In the event where there are changes, he/she must immediately inform the RBC which will decide whether or not the authorization given is still valid or should be withdrawn.
Name: …… Surname: ……   Date: …….. Signature: ……

If applicable, the representative of the Principal Investigator based in Cyprus, who is a researcher in the proposed programme, signs below.
Name: …… Surname: ……   Date: …….. Signature: ……