



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

June 0, 2017

Reference: Assurance Approval for:
F16-00178 (A5755-01)
BioGenes GmbH

Dr. Alexander Knoll
Managing Director/CEO
BioGenes GmbH
Koepenicker Str. 325
D-12555 Berlin
Germany

Dear Dr. Knoll:

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) reviewed and approved your institution's Animal Welfare Assurance. The Assurance is key document in defining your relationship with the Department of Health and Human Services (HHS), the Public Health Service (PHS), and the National Science Foundation (NSF). It sets forth the responsibilities and procedures of your institution regarding the care and use of laboratory animals.

Your Assurance, identification number **F16-00178 (A5755-01)**, became effective on **June 1, 2017** and will expire on **May 31, 2022**. Please include the Assurance number on all correspondence to OLAW or with any funding component of the HHS (BARDA), PHS, or the NSF. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

Thank you for your cooperation in submitting an Assurance in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), revised in 2015. If I may be of any further assistance, please do not hesitate to contact me.

Sincerely,

6/6/2017

X Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S

for Eileen Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare

cc:
Dr. Claudia Keil
Ms. Dagmar Schwertner-Knoll

Animal Welfare Assurance for Humane Care and Use of Laboratory Animals by Foreign Institutions

Name of Institution: BioGenes GmbH
Address (*street, city, state, country, postal code*):
Koeppenicker Str. 325, D-12555 Berlin, Germany

_____BioGenes GmbH_____*[Name of Institution]* hereinafter referred to as Institution, hereby states that, in reference to the Public Health Service Policy on Humane Care and Use of Laboratory Animals, it will comply with laws, regulations, and policies regarding humane care and use of laboratory animals of the jurisdiction in which the research will be conducted.

I. Applicability

This Assurance is applicable to all research, research training, and biological testing activities involving live, vertebrate animals supported by the Public Health Service and conducted at this Institution, or at another Institution as a consequence of the sub-granting or subcontracting of a PHS-supported activity by this Institution. *[List all entities, such as hospitals, separate institutes or centers that will be covered by this Assurance] (Must complete this section)*

BioGenes GmbH

II. Institutional Commitment

This Institution is guided by the *International Guiding Principles for Biomedical Research Involving Animals* developed by the Council for International Organizations of Medical Sciences (CIOMS). This Institution will comply with all applicable provisions of the following laws, regulations, and policies governing the care and use of laboratory animals. *[List titles of all governing laws, regulations, and policies for your jurisdiction in English] (Must complete this section)*

- DIN EN ISO 9001:2008
- European Union guidelines 2010/63/EC of 22.09.2010 and resulting German guideline for protection of animal trials and other for scientific purposes used vertebrates (TierSchVersV)
- German Guidelines according to § 8a Animal Welfare Act (TierSchG) of 18 May 2006 (BGBl.I p. 1206)
- NIH/OLAW Animal Welfare Assurance #A5755-01

This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Animal Welfare Assurance. As partial fulfillment of this responsibility this Institution shall make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with all applicable laws, regulations, and policies pertaining to animal care and use.

Check one: (Must complete this section)

- This Institution is accredited by AAALAC International.
- This Institution is not accredited by AAALAC International.

Check one: (Must complete this section)

- This Institution is accredited by Canadian Council on Animal Care.
- This Institution is not accredited by Canadian Council on Animal Care.

III. This institution agrees to notify OLAW when contact information changes. This information can be emailed to OLAWDOA@mail.nih.gov or sent by fax to: +1 (301) 915-9465. Include Foreign Animal Welfare Assurance number in all correspondence.

IV. Institutional Endorsement and PHS Approval of Statement

A. Authorized Institutional Official (*Must complete this section*)

Name: Dr. Alexander Knoll

Title: Managing Director/CEO

Address (*street, city, state, country, postal code*):

Koepenicker Str. 325, D-12555 Berlin, Germany

Phone: +49 30 65762396

Fax: +49 30 65762397

Email Address: service@biogenes.de

Signature:



Date: 31 May 2017

B. PHS Approving Official (*to be completed by OLAW*)

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL1, Suite 360 – MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Signature:



Date: 06/06/2017

Animal Welfare Assurance #: F16-00178 (A5755-01)

Effective Date: 06/01/2017

Expiration Date: 05/31/2022

- V. Two additional Institutional Contacts (**Must complete this section**)
Examples include: Chair, Animal or Review Committee, Institutional Representative, Regulatory Official, Veterinarian or Grants Official.

Contact #1	
Name: Dr. Claudia Keil	
Title: Head of Quality Management	
Address (<i>street, city, state, country, postal code</i>): Koepenicker Str. 325, D- 12555 Berlin, Germany	
Phone: +49 30 65762348	Fax: +49 30 65762397
Email Address: Claudia-keil@biogenes.de	

Contact #2	
Name: Dagmar Schwertner-Knoll	
Title: Director Marketing/Sales	
Address (<i>street, city, state, country, postal code</i>): Koepenicker Str. 325, D-12555 Berlin	
Phone: +49 30 65762380	Fax: +49 30 65762397
Email Address: d.schwertner@biogenes.de	

Note: Please notify OLAW at OLAWDOA@mail.nih.gov when contact information changes.

VI. *The Guide for the Care and Use of Laboratory Animals*

The Guide for the Care and Use of Laboratory Animals, 8th Edition pre-publication copy (2010), is available in English as a PDF – [click here](#) to download (893 KB).