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Project leader

OP

Title: OP for project leader

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	Name	Signature	Date
Produced by	RIZ Management-Team		
Verified by	RIZ Management-Team		
Approved by	Maren von Köckritz-Blickwede		

1. Content

2. Introduction

Aim of this SOP is to introduce new project leader of the RIZ to regulations in Germany.

3. Contact

President/official operator:	Prof. Dr. Klaus Osterrieder Tel no.: 8000 Email: praesident@tiho-hannover.de
Director for Scientific Administration and Biosafety	Prof. Maren von Köckritz-Blickwede Tel no.: 8787 Email: Maren.von.Koeckritz-Blickwede@tiho-hannover.de
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Biological Security Officer (BBS):	Prof. M. von Köckritz-Blickwede Tel no.: 8787 Email: Maren.von.Koeckritz-Blickwede@tiho-hannover.de Dr. Katja-Branitzki-Heinemann Tel no.:6913 Email: Katja.Branitzki-Heinemann@tiho-hannover.de

Management technician biosafety:	Vera Meier Tel no.: 6111 Email: bbs-RIZ@tiho-hannover.de vera.meier@tiho-hannover.de
Company doctor:	*Dr. Michael Glüer Tel no.: 8150*
Representative for working safety:	*Bastian Schäfer Tel no.: 7874*
Representative for fire protection:	*Bastian Schäfer Tel no: 7874*
Dangerous goods safety advisor:	*Dr. Andreas Gassner Tel no: 7871*
24 hours emergency service:	
Technical standby service:	*Tel no.: 7997*
Scientific head on duty:	*Tel no.: 7998*

4. Overview of the procedures

4.1 General lab safety (important for all!):

(a) Introduction of each project group member

(b) Generation of risk assessments ("Gefährdungsbeurteilungen")

(c) Register all chemicals in DaMaRis

4.2 Does the project work with biological substances e.g. microorganisms or cell cultures?

If yes, follow the next topics:

(d) Protection against infections ("Infektionsschutzgesetz")

(e) Protection against bioorganisms ("Biostoffverordnung")

(i) Targeted ("Gezielt")

(ii) Non-targeted ("Nicht gezielt")

(f) Genetically modified organisms ("Gentechnisch veränderte Organismen")

(g) Epizootic diseases ("Anzeigepflichtige Tierseuchenerreger/ Meldepflichtige Tiererkrankungen")

4.3 Does the project work with human samples or animals?

If yes, follow the next topics:

(h) Human samples ("Ethikkommission")

(i) Animal welfare ("Tierschutz")

4.4 Others

(j) Documentation and quality control

(k) Inactivation procedures

(l) Export of bioorganisms

(m) Import of bioorganisms

(n) Pregnant coworkers

5. Detailed procedures

5.1 General lab safety

(a) Introduction of each group member

Each project leader has to make sure, that every group member is receiving

(1) a proper general introduction to RIZ through RIZ management based on SOP "General operating instructions",

(2) all appropriate e-learning safety instructions, touching the work for this group member based on the RIZ-Moodle course

(3) an introduction to all equipment needed through the RIZ-technicians,
(4) an annual general safety instruction through the BBS and
(5) a special hands-on introduction to the respective floor plan by the PI or a representative person.

The management needs to be informed about every update regarding the floor plan. Every two years the floor plan will be revised by the respective project leader.
Long-term group members (more than 4 weeks) have to visit the Company doctor Dr. Glüer prior to starting to work in the labs (see General SOP!). Short-term visitors (less than two weeks) have to be kept under continuous supervision by the project leader or responsible person and need to be registered by the management (see General SOP!).

New coworkers need to be supervised continuously until the project leader decides that the person can work independently.

For S3** and higher biosafety level please contact the biosafety management.

(b) Generation of risk assessments ("Gefährdungsbeurteilungen")

Each project leader must proofread the risk assessments ("Gefährdungsbeurteilungen") for the working area he/she and the group members will work at:
G:\tiho\Gefährdungsbeurteilungen\Muster Gefährdungsbeurteilungen
These "risk assessments" will be public to every member in the RIZ on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\ Gefährdungsbeurteilungen

This risk assessment has to be updated when needed, but latest every two years.
The BBS need to be informed about every update (bbs-RIZ@tiho-hannover.de).

(c) Register all chemicals in DaMaRIS

Every group member has to register all their chemicals in the DaMaRIS system (https://damaris.tiho-hannover.de/) and keep the list up to date. Furthermore, it has to be made sure that all group members have access to the DaMaRIS system via a computer in the lab. Rouwen Stucke is the responsible person for DaMaRIS. Dr. Andreas Gassner manages new access authorizations.

5.2 Does the project work with biological substances e.g. microorganisms or cell cultures?

Bioorganisms (general lists)

The project leader has to update continuously the organism lists:

(1) RIZ-ZZ BIOSTOFFE_RAUMLISTE; (2) RIZ-ZZBIOSTOFFE GEZIELT; (3) RIZ-ZZ BIOSTOFFE UNGEZIELT;
(4) RIZ-ZZ BIOSTOFFE Personenliste (5) RIZ-ZZ Biostoffe S3 zwei Stern
A modifiable list is available at:
G:\riz\Projektleiter Biosicherheit ZZ
G:\riz\Projektleiter Biosicherheit ZZ\S3 zwei Stern

The project leader has continuously proofrad/update the organism lists for work in **RIZ FI in agreement with RIZ-management:**

1) RIZ-FI BIOSTOFFE Raumliste; (2) RIZ-FI BIOSTOFFE Personenliste; (3) RIZ FI BIOSTOFFE Raumliste

A modifiable list is available in the Projektleiter Biosicherheit FI Folder on:
G:\riz\Projektleiter Biosicherheit FI

An updated pdf-version with the date of update will always be available on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\Biostofflisten**.** The BBS and RIZ management (bbs-RIZ@tiho-hannover.de) need to be informed when updates have been made. A good time point for an update will be after a new Biostoffanzeige.
All RIZ members will be informed by e-mail (by BBS) about new available Gefährdungsbeurteilungen.

(a) Protection against infections *("Infektionsschutzgesetz")*

This is a two-step procedure:

(1) For the registration of human pathogens, a **personal permission of each project leader** is needed (**Erlaubnis nach § 44 Infektionsschutzgesetz**). This needs to be obtained by the respective "Gesundheitsamt" of place of residency ("Wohnsitz"). In Hannover, it is the same

authority as given under (2). The permission costs 122 Euro per person. An application including information about the pathogens and the planned work, a criminal record certificate ("polizeiliches Führungszeugnis Belegart 0") and certified copy of your University Certificate ("Beglaubigte Hochschulabschlusszeugnis") as well as a letter from a person with § 44 allowance stating that you have worked for min 2 years with human infectious diseases under his/her supervision.

(2) With the permission, each project leader has to register the infection agents that he/she will use for the project at the *Fachbereich Gesundheit, Region Hannover* **30 days before starting** the work (**Anzeige der Tätigkeiten mit Krankheitserregern nach § 49 IfSG**). Send application including § 44 permission, copy of GMO registration of RIZ and information on the work to:

Region Hannover, Fachbereich Gesundheit, Team 53.01
Weinstraße 2, 30171 Hannover

For more information see:
G:\riz\Projektleiter Biosicherheit ZZ\Infektionsschutz\Vorlagen
For S3 Pathogens:
G:\riz\Projektleiter Biosicherheit FI\Infektionsschutz\Vorlagen

A copy of all documents has to be send to BBS and RIZ management (bbs-RIZ@tiho-hannover.de) and saved on G:\riz\Projektleiter Biosicherheit ZZ\Infektionsschutz
or G:\riz\Projektleiter Biosicherheit FI\Infektionsschutz

(b) *Protection against bioorganisms ("Biostoffverordnung")*

Each project leader must register the level 2 bioorganisms (living microorgansims, cell cultures, primary cells, tissue) that he/she will use for the project at the respective authority **30 days before starting** the work (Anzeige gemäß § 16 BioStoffV). Use the following document for registration:

Anzeige BioStoffV Muster. More Infos are found on:
G:\riz\Projektleiter Biosicherheit ZZ\Biostoffverordnung\Vorlagen: Anzeige BiostoffV Muster.

For Level 3 Bioorganims the project leader have to use the document: „Biostofferlaubnisantrag"
G:\riz\Projektleiter Biosicherheit FI\Biostoffverordnung\Vorlagen: Erlaubnisantrag BiostoffV Muster.
Starting the work is not allowed until the authority send the permission.

All documents (separated into targeted and non-targeted work) have to be filled out and send to Vera Meier. If everything is filled out correctly, she will send the documents via Dr. Gassner to the respective authority (Staatliches Gewerbeaufsichtsamt Hannover).
Additionally, a copy of the signatured Biostoffanzeige/or Biostofferlaubnisantrag
will be saved by Vera Meier on:

G:\riz\Projektleiter Biosicherheit ZZ\Biostoffverordnung
G:\riz\Projektleiter Biosicherheit FI\Biostoffverordnung

Furthermore for respective risk assessment and documentation at TiHo, the four documents provided by Dr. Glüer G:\riz\Projektleiter Biosicherheit\Biostoffverordnung\Vorlagen\Vorlagen-Biostoff-V-GfdB need to be filled out, signed and send as original to Vera Meier and the digital version to (bbs-RIZ@tiho-hannover.de).

A copy of these signed documents will be saved by Vera Meier on:
G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\ Gefährdungsbeurteilungen
All RIZ members will be informed by e-mail (by Vera Meier) about new available Gefährdungsbeurteilungen.

(c) *Genetically modified organisms ("Gentechnikgesetz")*

Each project leader must register the work with level 2 genetically modified organisms (GVO) (microorgansims, cell cultures, animals) as well as the storage of GVO that he/she will use for the project at the respective authority. With obtaining the permission or at the end of a period of **45 days** the work can be started (Anzeige gemäß Gentechnikgesetz).

Cave: For pathogens or work not registered by ZKBS (Zentrale Kommission für Biologische Sicherheit) yet, the time can be longer and starting work is not allowed!

For level 3 the permit of the authority is obligatory (Genehmigung gemäß Gentechnikgesetz). Please contact the biosafety management.

More info is found on
G:\riz\Projektleiter Biosicherheit ZZ\Gentechnikgesetz\Vorlagen\leere Vorlagen
G:\riz\Projektleiter Biosicherheit FI\Gentechnikgesetz\Vorlagen\leere Vorlagen

All documents have to be filled out and send to Vera Meier. She will send it to the BBS and then via Mr. Dr. Gassner to the University president and finally to the respective authority (Staatliches Gewerbeaufsichtsamt Hannover).

For documentation: See Documentation and quality control (below).

Level 1 GMO work must be documented similar to S2 work. No special allowance/registration in RIZ is needed for that.

In case that a project leader is leaving the TiHo, a new project leader has to be defined in agreement with the BBS, the RIZ management and the president (via Dr. Gassner).
Otherwise, all GVO have to be eliminate by the project leader.

(a) *Epizootic diseases ("Anzeigepflichtige Tierseuchen") and animal diseases ("meldepflichtige Tierkrankheiten")*

A classification has to be done by each project leader based on the lists "gezielte und raumbezogene Biostofflisten".

See the lists at G:\riz\Projektleiter Biosicherheit ZZ or FI
(1) RIZ-ZZ BIOSTOFFE_RAUMLISTE; (2) RIZ-ZZ BIOSTOFFE_GEZIELT; (3) RIZ-ZZ_BIOSTOFFE_UNGEZIELT;
(4) RIZ-ZZ BIOSTOFFE Personenliste (5) RIZ-ZZ Biostoffe S3 zwei Stern
(6) RIZ-FI BIOSTOFFE Raumliste; (7) RIZ-FI BIOSTOFFE Personenliste

The TiHo as public facility has a general allowance to work with animal pathogens ("**meldepflichtige Tierkrankheiten**"). The work with them only needs to be documented. See the list here: https://www.bmel.de/DE/Tier/Tiergesundheit/Tierseuchen/_texte/MeldepflichtigeTierseuchen.html

General work and the specific pathogens with "**anzeigepflichtige Tierseuchen**" must be registered with the responsible authorities (here: LAVES) (Anzeige gemäß Tierseuchenverordnung): See the list here: http://www.bmel.de/DE/Tier/Tiergesundheit/Tierseuchen/_texte/AnzeigepflichtigeTierseuchen.html
Registration: http://www.gesetze-im-internet.de/tierseucherv/BJNR021230985.html
Registered/responsible persons at RIZ: Prof. Maren von Köckritz-Blickwede.

Inform them and the BBS (bbs-riz@tiho-hannover.de) about all used pathogens prior to start the work.

Furthermore, the pathogen list "Anzeigepflichtige Tierseuchenliste-LAVES_Raum"on G:\riz\Projektleiter Biosicherheit FI\Tierseuchen anzeigepflichtig needs to be updated and send to LAVES via Mail by the BBS (bbs-riz@tiho-hannover.de).

Storage and Experiments with Epizootic diseases needs to be documented according to the "Tierseuchenerregerverordnung" (Tierseuchenerregerverordnung, TierSeuchErV).
The documentation according to § 9 has to be done immediately and continuously.
The documentation must be reliably and verifiable.
All Epizootic diseases and bioorganisms need to be registered by LabControl ID.
This LabControl ID needs to be documented in the Epizootic diseases documentation.

Authorities:
Dezernat 31 – Tierseuchenbekämpfung und Beseitigung Tierischer Nebenprodukte

Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES); Postfach 3949
26029 Oldenburg; Tel: +49(0)441/570 26-260; Fax: +49(0)441/570 26-179
Mail: jonas.guese@laves.niedersachsen.de

A copy of all documents has to be saved on
G:\riz\Projektleiter Biosicherheit FI\Tierseuchen anzeigepflichtig and send to
bbs-RIZ@tiho-hannover.de.

Just for information: Frau Dr. Doil, Veterinäramt, is not responsible for allowance, but for controlling/inspection.

5.3 Does the project work with human samples or animals?

(a) Human samples ("Ethikkommission")

Each project leader which needs to work with human samples needs an ethical permission prior to start of the work. Please contact "Ethikkommission der MHH" (https://www.mh-hannover.de/3371.html).

If human fresh blood from healthy volunteers is needed please contact Prof. Dr. Maren von Köckritz-Blickwede.

(b) Animal welfare ("Tierschutz")

For all issues regarding experimental work with animals the head of the animal facility of RIZ (Tierhaltung-RIZ@tiho-hannover.de) and the *Tierschutzbeuftragte* need to be contacted.

See more information on: http://interner-tiho-bereich/kommissionen-gremien-ausschuesse-beauftragte/tierschutzbeauftragter/

Informationen zur Projektdurchführung am RIZ

5.4 Others

(a) Documentation and quality control

Each project leader is responsible for proper quality control (purity of organisms) and documentation of lab work of all group members.

Storage of GMO needs to be documented according to the "genetic-recording-regulation" (Gentechnik-Aufzeichnungsverodnung, GenTAufzV). The documentation according to § 3 Abs. 7 GenTAufzV has to be done immediately and continuously. Before beginning of genetic work, the project leader initiates a document according to GenTAufzV (e.g. on basis of the blank form Z) and finally confirms the accuracy by his signature.

All GVO and bioorganisms need to be registered by LabControl ID associated with the according number of the GVO and name of project leader. This LabControl ID needs to be documented in the Z-form/documentation.
The form Z are stored on

G:\riz\Projektleiter Biosicherheit ZZ\Gentechnikgesetz.
G:\riz\Projektleiter Biosicherheit FI\Gentechnikgesetz.
BBS and RIZ management will control the documentation and have the right to delete samples without proper labelling.

For traceability it is strongly required to use the same individual ID in the Z-form, the lab book and LabControl for every particular sample.

The identity and purity of the used organism needs to be regularly confirmed. For this purpose, a regular testing for e.g. mycoplasma contamination in cell cultures or PCR-based testing of specific genes is necessary. The usage of new donors, recipients and vectors justifies a new genetic work, which needs to be separately registered with the authorities.

(b) Inactivation procedures

Each project leader is responsible for proper inactivation of their samples and the respective documentation (including quality control) prior to transfer of inactivated bioorganisms to another lab or disposal of organisms.

S2: Reference-based inactivation is ok. However, for GMO work special official allowance by Gewerbeaufsichtsamt is required for each project.

S3: Prior to disposal / shipping of S3 ** or S3 organisms or the transport of these organisms from the S3 ** / S3 laboratory to another laboratory, permission must be obtained from the BBS, the RIZ manager for each individual process. The authorities (Gewerbeaufsichtsamt) need to be involved (3-fold validation is required if no proper literature is available).

Some general information is here:

G:\riz\Projektleiter Biosicherheit ZZ\Inaktivierungsmethoden.

All approved inactivation methods of S3 area are found here:

G:\riz_RIZ_FI\approved inactivation methods_RIZ FI

(c) Export/ transfer of bioorganisms

Prior to export/ transfer of bioorganisms to another lab (even another TiHo institute), the respective project leader has to make sure that the recipient agrees to comply with all applicable laws, regulations, policies, and guidelines in its storage and use of the receiving biological material (see letter draft “letter to receive biological material from RIZ”) in “Projektleiter Biosicherheit\Import Export” folder.

Every export/ transfer needs to be registered in the list: import export samples. All concerning documents needs to be stored in the group specific Export and Import folders. Both is located on G:\riz\Projektleiter Biosicherheit ZZ\Import-Export and G:\riz\Projektleiter Biosicherheit FI\Import-Export

(d) Import of bioorganisms

General sample deliveries:

All import processes are requested through bbs-RIZ@tiho-hannover.de.

The project leader must be stated on the deliveries as contact person and needs to take care that only instructed and trained co-workers open the deliveries. Samples, that are delivered from outside into the RIZ and are assigned as biological security level 2 or higher need to be unpacked under a bio-safety bench in ZZ and for level 3 in FI-Building. During that you need to wear always the personal protective equipment. After unpacking the outer package needs to be disinfected and/ or autoclaved before disposed. The sample needs to be transferred into a new and clean primary container and can afterwards be stored or processed. This procedure serves to avoid transfer any infectious contaminations of the packaging material into the laboratories.

Every import needs to be registered in the list: import export samples.
All concerning documents needs to be stored in the group specific Import and Export folders.
Both is located on G:\riz\Projektleiter Biosicherheit ZZ\Import-Export.
For Import in the FI Building on G:\riz\Projektleiter Biosicherheit FI\Import-Export.

Official procedure for Non-EU samples stepwise:

(1) Generally there is an allowance for the import of samples of category 1 and 2 for diagnostic/ scientific samples in RIZ available (Number DE 03 201 0043 21, AZ 42300_2_TiHo, vom 16.02.2016, Fachbereich Öffentliche Ordnung, Gewerbe- und Veterinärangelegenheiten, Dr. Gabriele Doil, Tel. 0511-168-31154).
(2) In addition, prior to import, it needs to be asked for a separate allowance for the import of all respective samples (“Einfuhrgenehmigung”) at the respective institution depending on the state (“Bundesland”) of arrival:

Niedersachsen: Dr. Andrea Berkenhoff, LAVES Niedersachsen: andrea.berkenhoff@laves.niedersachsen; Tel. 0511-28897-916) or Ms. Gühl (Tel 0511-28897-912).

NRW (delivery via airport): Landesamt für Natur-, Umwelt- und Verbraucherschutz NRW, Fachbereich 87, Leibnizstrasse 10, 45659 Recklinghausen; Tel.: 02361-305-3265; E-mail: einfuhr-nrw@lanuv.nrw.de

The following information needs to be sent for permission: number and volume of samples, all information available e.g. animal species, inactivation procedure, etc.; flight number, place of origin, sender/user with addresses.

(3) When all permissions have been received, the allowance (*Einfuhrgenehmigung*) and the filled GVDE document ("Gemeinsames Veterinärdokument für die Einfuhr") needs to be sent to the respective boarder control ("Grenzkontrolle") minimum 24 h prior to arrival.
(4) Depending on the permission, finally the "Amtstierarzt" Ms. Dr. Doil needs to be informed about the arrival of samples.

(e) Hausapotheke

If medical products for treatment of animals are needed, the respective SOP "Hausapotheke" needs to be considered. The "Hausapotheke" is exclusively allowed to be used for official business reasons, not for private reasons. Medicinal products are only allowed to be handled after consultation of one of the respective officially registered veterinarians from RIZ for RIZ-Hausapotheke. The responsible person is Dr. Henrieke Meyer Sievers. For usage of official narcotics "Betäubungsmittelgesetz" special permits are needed under the responsibility of Prof. Dr. Maren von Köckritz-Blickwede.

(f) Weekend work

Weekend work and work after 8pm is only allowed after agreement with the project leader. In case of emergency the project leader or a representative person need to be available as contact person. The access to RIZ building after 8pm or before 6am and at weekends needs to be documented at the security service in the foyer of the building 231.

(g) Accidents

In case of all accidents, the project leader needs to inform the DWL directly. dwl-riz@tiho-hannover.de

A biohazard accident report needs to be written and handed out to the BBS and RIZ management.
This report needs to include the following information: Date, time, room, microorganisms involved, equipment involved, decontamination procedure, injured person, first aid procedure, causative reason, level of training of persons involved, steps taken afterwards to avoid accidents in the future.
A template is available on**:** G:\riz\Projektleiter Biosicherheit\Unfallberichte Accidents

(h) Pregnancy of a coworker

In case of pregnancy of a coworker please contact immediately the medical doctor "Betriebsarzt" Dr. Glüer and the representative for working safety ("Beauftragter für Arbeitssicherheit") Mr. Schäfer, as well as the BBS and RIZ management.

A riks assessment for RIZ is avalialbe here:

G:\tiho\Gefährdungsbeurteilungen\80 Research Center for Emerging Infections and Zoonoses\Mutterschutz

See more information at: http://www.tiho-hannover.de/interner-tiho-bereich/arbeitssicherheit-gesundheitsschutz-suchtberatung-und-umweltschutz/betriebsaerztlicher-dienst/

(i) Project leader meetings

There is a project leader meeting in the RIZ-FI seminar room together with the scientific manager, RIZ management and the BBS once per month, where general biosafety issues are discussed.
The meeting is obligatory for all project leader and updates regular on safety issues need to be given.

If PIs cannot attend, they have to inform themselves about the given information by reading protocols.

(j) Consultation of BBS for new GMO approvals

The following procedure will be done for new GMO approvals:

1. PI fills out all required documents or description of biosafety questions. Contact BBS to receive all documents
2. Send documents to BBS: bbs-RIZ@tiho-hannover.de
3. Proof of documents by BBS
4. If needed: consultation meeting with PI and BBS to discuss open questions
5. Final corrections, print out (2 versions) and signature of all documents by PI
6. Send documents to Vera Meier/BBS
7. Vera Meier will arrange signatures by BBS and president via Dr. Gassner
8. Dr. Gassner will send documents to authorities

6. Further questions

For further assistance please contact the BBS or RIZ management.

See general information here: Informationen zur Projektdurchführung am RIZ