

FLI Compliance Management System – Annual Report 2021

Executive Summary

In a continuation of the measures taken to deal with the problem situations that arose at the FLI in 2016 (animal house crisis) and 2017 (GSP crisis), the FLI Executive Board established a Compliance Management System (CMS) in 2019. On the one hand, this incorporated processes at the FLI that were already efficiently guiding rule-compliant work in research. On the other hand, it initiated a process that put existing mechanisms to the test and, where necessary, implemented meaningful optimizations. The efforts expended on the FLI-CMS, which were communicated both internally and externally, repeatedly conveyed the importance of compliant behavior to employees and documented the high priority that the institute's management attaches to this issue.

In the further expansion of the CMS, common areas of interest are to be identified among cooperation partners in the Jena research environment (FSU, UKJ, Jena Leibniz Institutes, etc.) in order to exploit the potential of regionally coordinated solutions (e.g., activities of ethics committees and ombuds committees, staff training, etc.).

The CMS is coordinated by a **Compliance Board**, which reviews, optimizes, and documents all compliance-relevant processes and interactions with authorities and reports to the Executive Board. It meets every two months for a *jour fixe*. Selected compliance experts are invited to report on relevant issues in their compliance areas; the Executive Board of the FLI also participates. In case of acute necessity, the Compliance Board also meets on an extraordinary basis at the invitation of the Compliance Coordinator. A confidential compliance report is prepared annually for submission to the FLI Board. This serves as the basis for reporting to supervisory and advisory bodies. Excerpts may be published on the FLI intranet and internet. The compliance report is written in German and then translated into English.

Eight compliance-relevant topics have been identified for the research-related processes of the FLI (see Fig. 1). Each of these compliance areas is supervised by a **compliance expert** who instructs, trains, and advises employees.

In the calendar year 2021, the meetings of the Compliance Board were replaced without exception by meetings of the **Corona Planning Unit**. The Corona Planning Unit was composed of the members of the Compliance Board, supplemented by responsible persons from internal departments. The Corona Planning Unit formulated all FLI measures and policies required to address the challenges of the Corona pandemic (see Chapter 4).

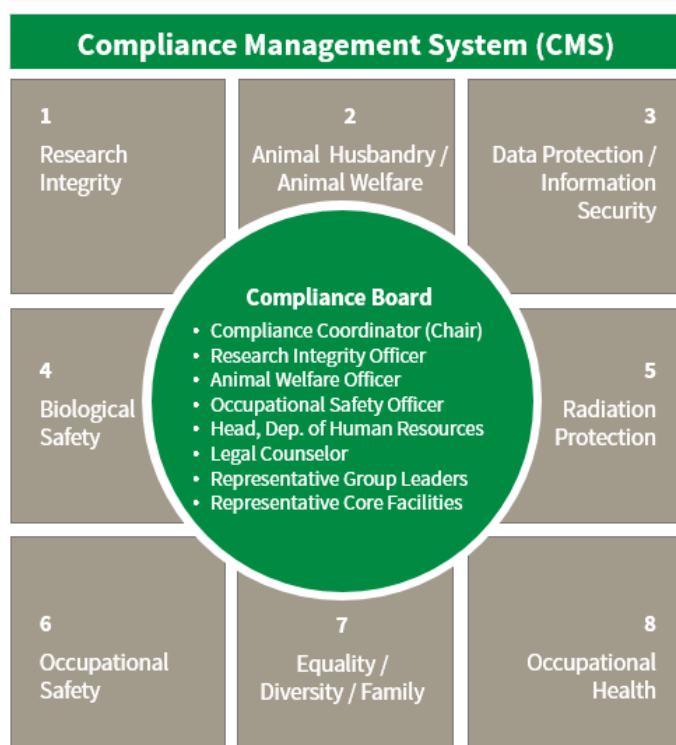


Fig. 1 **The Compliance Management System (CMS) of the FLI**

Reports of the Compliance Areas

Area 1 – Research Integrity

In the reporting period 2021, two ombudspersons were appointed at the FLI. To ensure the standards of Good Scientific Practice (GSP), the following structural changes were implemented at the FLI as of October 2017:

Clarification of the explanations of the GSP standards: This included a clarification of the measures for compliance with these standards as well as the contractual obligation of all employees to fully observe and guarantee them. The updated version of the GSP guidelines adopted by the Leibniz Association on November 29, 2018 was fully incorporated into the GSP rules of the FLI and came into force in May 2019 (<https://www.leibniz-fli.de/research/good-scientific-practice>). On November 28, 2019, the GSP guidelines of the Leibniz Association were updated again. This was accompanied by the publication of a DFG code, which must be incorporated into the institute-specific rules by July 31, 2023 if DFG funding is to be received. An updated version of the FLI Guidelines for Good Scientific Practice was prepared in 2022, taking into account all the stipulations of the DFG.

Work-in-Progress Seminars enable experienced scientists to critically appraise the collection/analysis of results produced by junior scientists. As part of the Corona emergency operation measures, the event has been held digitally since October 2020 and enjoys a high level of acceptance.

Research Data Management (RDM): Since January 2021, the RDM has been supported by a PhD scientist (Data Steward) from the FLI. Since the end of 2020, a central data archive has been under construction; this is largely financed by third-party funds. In addition to the spatially redundant backup of primary data, it allows a systematic linking of data sets and types.

Electronic Laboratory Notebook (ELN): The FLI has introduced the use of an electronic laboratory notebook (ELN) for the complete recording of all research procedures and the archiving of all primary research data.

Assessment Before Submission (ABS): In March 2018 the FLI instituted the mandatory review of all scientific manuscripts and dissertations based on experimental data, for both scientific integrity and statistical plausibility. Since April 1, 2018 this review has been carried out by the company Resis S.r.l. Over the last few years the number of manuscripts and dissertations passing without objections has steadily increased (period 2018 to 2021). Through its Core Facilities the FLI has significantly supported working groups in experimental planning and with workshops on data analytics and statistics. These activities have clearly contributed to this positive development and have promoted increased attention to detail as well as statistical expertise.

Publication activity (FLI rules): The measures introduced to safeguard GSP standards have proven to be highly effective and have met with high acceptance and participation on the part of FLI staff. Some measures represent pilot activities (ABS, ELN) and have achieved considerable attention in the scientific community.

Area 2 – Laboratory Animal Care, Animal Welfare

Animal Welfare Department: This was established on 01.01.2018, with animal welfare officers (AWO), who are free from directives, monitoring the proper, rule-compliant performance of all animal experimentation activities at the FLI. The AWOs advise project leaders on the formulation of animal experiment applications, approve procedures, and report to the competent authority.

Supervisory veterinarians: Three veterinarians supervise the welfare and health of the FLI's animal population.

Persons responsible according to § 11 TierSchG: The license to breed and keep vertebrate animals is delegated to knowledgeable individuals; during the reporting period, these were the managers of the animal facilities.

Veterinary Pharmacy (VP): This has been established at the FLI since 2017 and is supervised by a veterinarian (0.5 FTE). She dispenses drugs to the project managers of animal experiments and supervises the proper administration of the drugs.

Animal Welfare Committee (AWC): This was established at the FLI on August 13, 2016 in accordance with § 6 TierschVersV and consists of 10–13 members led by the AWO.

Operational instructions: Within the FLI, standardized laboratory animal husbandry is continuously monitored through service instructions and SOPs.

Training/Further Education: All employees working with animal experiments are to participate in certified further training on animal welfare for 8 hours per year. A continuous offer of animal welfare-related training and further education will be made available on the revised intranet site of the animal welfare department.

Communication with authorities: This takes place exclusively via the Animal Welfare Department, incl. applications for the implementation of animal experimentation projects, submissions of change requests, etc.

Animal experiment databases: At the FLI, these include *Pyrat* for mouse husbandry, *Tick@Lab* for fish husbandry, and *AniShare* for the exchange of experimental animals. The databases are maintained by the animal keepers and participating scientists, checked by the project managers, and can be accessed at any time by the AWO and the animal facility managers.

3R Principle: The 3R principles – *Replace* (look for alternatives to animal experimentation) / *Reduce* (reduce the number of animals in the experiment) / *Refine* (improve the experiment to reduce pain, suffering, and harm to laboratory animals) – are the basis for the ethical evaluation by the AWO of new experiments.

Vocational training “Animal Keeper”: Since 2009, 11 candidates have completed this training at the FLI.

Inspections by the competent veterinary office: The Special-purpose Association Veterinary and Food Control Office Jena-Saale-Holzland (ZVL) carries out announced and unannounced inspections of the FLI animal houses.

Area 3 – Data Protection, Information Security

Since December 1, 2002, the FLI has had one Data Protection Officer. In March 2020, in addition, one Information Security Officer was appointed.

Data protection and information security measures in 2021:

- Data-protection-compliant design of the **Company agreement “Mobile Working.”**
- Data-protection-compliant implementation of the **eBITE applicant management system.**
- Re-organization of **server certification procedures.**
- Data privacy impact assessments for **Microsoft Office365 (O365).**
- Data-protection-compliant establishment of an **email archive system** at the FLI.
- Adjustment of settings of the **SAP team calendar.**
- Data-protection-compliant use of **video-conferencing systems.**
- Negative position on the use of **Slack** at the FLI.
- Change of the data storage regime for **monitoring the GC40 and isotope laboratory.**
- Control of the legal bases for the process of **end-use statements.**
- Conformity assessment of the use of **DocuSign.**
- Position on, and control of the processes regarding, the use of data from **UK Biobank.**
- **Training:** Data privacy training for new staff continued in 2021 using an online training tool. New employees are requested to complete this training and subsequently prove this by presenting the certificate of completion.
An exchange of experience took place between the Finance and Purchasing department of the FLI and the information security officer of the UKJ. Among other things, a targeted attack on the UKJ was presented. Furthermore, a phishing simulation was carried out in which 150 recipients at the FLI were exposed to a realistic phishing attack. The results will be used for technical improvements and further training and awareness measures.
- Review of **attack vectors and information leaks.**
- IT-security-compliant **installation of new systems.**
- Publication of the **Information Security Guideline** by the Information Security Officer.

Area 4 – Biological Safety

All work areas at the FLI where biological agents – including their genetically modified forms – are handled are genetic engineering facilities of safety level 1 (S1) or 2 (S2). In each genetic engineering

facility, at least one project manager is responsible for the planning and execution of the genetic engineering work, the risk assessment of the GMOs, and maintaining the appropriate records. This is checked by the Biological Safety Officers (BSO).

Monitoring: The genetic engineering facilities / work areas are monitored before commissioning and regularly during operation by the competent departments of the Thuringian State Office for Consumer Protection.

Update of the German Ordinance on Genetic Engineering Safety (GenTSV, March 1, 2021): Genetic engineering project managers and BSOs must undergo regular training every 5 years (mandatory in-house training: October 2021).

Area 5 – Radiation Protection

Pandemic-related operational restrictions in 2021. The use of (access to) the radiation protection areas was restricted in accordance with the respective current “FLI rules in COVID-19 contingency operations 2021” and the infection protection concept of the FLI. This concerned in particular the external users of the gamma source GC40, who at times were not granted access.

Radiation Protection Area 1

As the operator of radiation protection area 1, the FLI was registered according to §170 StrSchG with the Federal Office for Radiation Protection (BfS). Users of radiation protection area 1 are registered in the radiation protection register.

Access: Only instructed users are granted access by transponder activation. Users (exposed persons category A) must be examined by a physician before starting work, as well as annually (§77 StrlSchV). This is not required for authorized persons of category B (service personnel).

Instruction: This takes place before the first use and through further annual briefings (§63 StrlSchV).

Dosimetry: Radiation protection area 1 is a *controlled area* (§52 StrlSchV), in which the body dose must be measured (§§64, 65 StrlSchV). Personal dosimeters must be worn, exchanged monthly, and examined for exposure at the State Institute for Personal Dosimetry and Radiation Protection Training (LPS Berlin). No user exposures were detected during the reporting period.

Disposal of radioactive residues: No radioactive residues required disposal in 2021.

Radiation Protection Area 2

According to §5 (36) StrSchG this represents a High Activity Radioactive Source (HRS). “Preparatory measures for emergencies or incidents” were not necessary for further operation after December 31, 2020 due to the still existing residual activity of the source. For the facility to be used, a radiation protection officer must be present at the FLI.

Access/Instruction: see radiation protection area 1

Inspection of the facility for leaks: once annually (TÜV); regular maintenance/inspection by Best Theratronics.

Reports to BfS/ supervising authority: The measurement results from the manufacturer maintenance were communicated to the supervisory authority – there were no abnormalities.

Compliance measures: In 2021, there were a few insignificant “non-compliance cases” because users did not register sufficiently or not at all in the user manual. They were notified of this by email.

Radiation Protection Area 3

Access/Instruction: see radiation protection area 1; This also mandates the necessary briefings for entering the animal house in FLI 7, where the two CTs are located.

Securing the computer tomography (CT): The X-ray modality of the units is secured by a key switch (kept by the radiation protection officer); radiation protection area 3 can also be operated in fluorescence or phosphorescence mode (without activation of the X-ray tube).

Inspection of the devices: At 3-month intervals, checks are carried out to determine whether X-rays are leaking to the outside. The safety shutdown devices are checked monthly. All inspections indicated that the devices are leak-tight and fully functional; the next 5-year inspection of the two CTs by TÜV is set for 2023.

Area 6 – Occupational Safety

In-house officers:

- In order to improve **First Aid Training**, two training courses were offered as in-house training in cooperation with the German Red Cross in 2021.
- **Safety officers** support the working group/area managers in the implementation of occupational health and safety/accident prevention and are the contact persons for the occupational safety specialist.
- **Fire protection / evacuation assistants** are trained in one theoretical and one practical in-house training session.

Updating the risk assessments (RA): During the reporting period, the RAs were updated in four working groups. Two documents were submitted to the competent authority (TLV, Department of Occupational Safety and Health) as part of the notification procedures for laboratory relocations to other FLI buildings.

Instruction of employees: This is carried out before the start of the activity (initial training) and regularly thereafter, at least once a year. The heads of the respective organizational units and/or the project managers are responsible for this.

Occupational health and safety measures:

- **Point suction unit at perfusion workstation:** There were reports of irritation of the respiratory tract and the eyes as well as unpleasant odors emanating from the perfusion workstation. As a technical protective measure, a source extraction system was installed at the perfusion workstation and connected to the exhaust air system. This measure has proven to be very effective.

Occupational Safety Committee (OSC): As the regular meetings of the COVID-19 Planning Unit and the Occupational Health Management (OHM) overlap with both the topics and the participants of the OSC, the quarterly meeting schedule was waived during the reporting period.

Area 7 – Equal Opportunity/Family/Diversity

The FLI has been awarded the **“TOTAL E-QUALITY certificate for equal opportunities and diversity”** for a period of 3 years.

At the **Gender Equality Plan** workshop in November 2021, the minimum requirements of the European Work Program 2021–2022 were discussed. The FLI **Gender Equality Plan** will be adapted accordingly in 2022.

In March 2021, the **target quotas for increasing the proportion of women in scientific staff** were reviewed with regard to the fluctuation/cascade model and the Leibniz orientation quotas until 2025. The existing target quotas for filling W2/W3 positions (25%), pay grades E14 (30%), E13 (50%), and management level (30%) were retained.

An **equal opportunity officer (EOO)** and 2 deputies were appointed for the new election period (2019–23), and completed numerous further training courses during the reporting period.

Diversity Day in 2021 once again took place online. The FLI participated in a poster campaign for “Diversity Day” in May 2021. The **21st Equal Opportunities Conference of the Leibniz Alliance** took place in March 2021.

The FLI is an active member of the **Dual-Career Network Thuringia** and was able to successfully find a job for a colleague within the network partners in 2021.

The FLI has been awarded the TEQ Certificate and the Jena Family Seal, quality criteria for **family friendliness**, and is also a member of the Jena Alliance for Families. In addition, cooperation agreements have been concluded with two nearby day care centers, which also accommodate children of institute employees. A parent-child workroom is available to all employees. During events, the FLI offers emergency child care.

Compatibility of Family & Career: Due to the Corona situation, a new form of work – “mobile work” – was established at the FLI. In order to regulate this form of work, a new **Mobile Work Agreement** was concluded in July 2021. The EOO is one of the newly established trustworthy representatives.

Area 8 – Occupational Health Management

The FLI working group on occupational health management (OHM) took on the task of developing a concept for **integrating mental stress into the risk assessment (RA)**. Concept development workshops should take place in 2022.

The establishment of **trustworthy representatives** as “first aid” contact persons for employees with perceived stress or for advice and support in cases of conflict was agreed at the end of 2020 in the CA Equal Opportunity. In 2021 a concept for the implementation of this was developed, a page was designed for the intranet, and the trustworthy representatives were professionally trained.

Occupational health care continued to be offered regularly, in part by telephone: special instructions/precautionary home office for at-risk groups; occupational health and safety rules for SARS-CoV-2 (since 8/2020); attention to mental stress due to the effects of the Corona pandemic; reviews of risk assessments, briefings, and active communication; return-to-work advice for those recovered from COVID.

In 2021, more use was made of preventive medical checkups and talks with the company physician on reintegration into the workplace. The number of days lost due to sick leave decreased.

Digital Healthweek 2021 (April 26–30, 2021) was organized by the FLI HR department together with the Techniker Krankenkasse.

As an additional measure to keep employees healthy the FLI provides supplementary work equipment for individual optimization of **ergonomic workplace conditions** after individual requirements have been determined by the company physician. These include: VDU workstation

glasses, individual otoplastics, height-adjustable desks and desk attachments, particularly back-friendly chairs, and footrests. This gives employees who have back problems related to sitting, for example, the opportunity to alternate between sitting and standing at their computer workstations.

Maternity leave in times of Corona: Expectant mothers in particular were informed about the risk of SARS CoV-2 and advised by the company physician. The option of a temporary leave of absence in accordance with §13 Maternity Protection Act was exercised.

SARS-CoV-2 PCR tests at the FLI for the protection of employees were very well received (over 350 employees registered). It was possible to detect infections in employees and interrupt chains of infection.

Corona Pandemic in 2021

During the pandemic situation in 2021, a key pillar of the in-house infection control concept was the **Corona Planning Unit**, which was established at the beginning of the pandemic (January 2020) and included all members of the Compliance Board as well as additional employees with safety-relevant areas of responsibility.

The Corona Planning Unit regularly analyzed the infection situation and, taking into account the continuously changing federal and state regulations, defined measures to minimize the health risk to employees and to protect the critical infrastructure at the Institute. In each case, employees were informed by the Executive Board of the established measures and rules in the form of **“FLI guidelines in COVID-19 operation” of phases D to G including adapted implementation regulations**.

The most important compliance-relevant measures implemented include the following:

- The establishment of an **in-house PCR method** for the analysis of SARS-CoV-2 in gargle samples.
- In order to reduce contacts at the FLI the option of **home office** continued to be offered to employees in 2021 when objectively suitable.
- From the beginning 2021 all persons were required to wear a certified **face mask**, such as Type II or II R surgical masks with CE marking and FFP2 masks without exhalation valves. Both types were made available to employees. With the amendment of the SARS-CoV-2 occupational health and safety regulation on November 22, 2021, the provision of such masks by the FLI became mandatory.
- With the updated Infection Protection Act, which came into force on November 24, 2021, extended workplace regulations were specified throughout Germany. Access to the workplace was then only permitted to employees with **3G status** (vaccinated, recovered, or tested negative). Accordingly, the FLI was obliged to check the relevant documents. Employees without vaccination or convalescent status were only granted access to the FLI upon presentation of a negative test result.
- **Returning from abroad:** According to the coronavirus entry regulations valid at the respective time, employees of the FLI who had been in an area classified as a virus variant area before returning to Germany had to observe special registration, verification, and, if necessary, quarantine obligations before re-entering the country. Employees were regularly informed of this by the Human Resources department.

Conclusion

The establishment of a Compliance Management System (CMS) in October 2018 on the one hand incorporated existing processes at the FLI, which already very efficiently guided rule-compliant work within the framework of the research-related activities of the FLI. On the other hand, the introduction of the CMS initiated a process that put existing mechanisms to the test and implemented meaningful optimizations where necessary. This optimization process is an ongoing process that should also enable further improvements and adaptations to new circumstances and current challenges in the future.

With the introduction of the **Compliance Board**, a committee was created whose members analyze the respective compliance topics and, if necessary, current situations with a high level of commitment and enter into direct, regular exchange with the FLI Board of Directors. The work of the Compliance Board, or rather the activities of the **Corona Planning Unit** derived from the Compliance Board, have thus far enabled the FLI to successfully protect the institute against the threats of the Corona pandemic.

Ensuring compliant behavior requires comprehensive, continuous efforts. With the FLI Compliance Management System, an institutional structure has been established that supports this effort to the maximum.