
FLI Compliance Management System – Annual Report 2019/2020

Abstract

As part of the measures taken to address the FLI problem situations of 2016 (animal welfare crisis) and 2017 (GSP crisis), the FLI Board of Directors established a Compliance Management System (CMS) in October 2018. On the one hand, this continued processes at the FLI that already very efficiently guided rule-compliant work in research. On the other hand, this initiated steps to put existing mechanisms to the test and to enact meaningful optimizations where necessary. The FLI-CMS efforts, which were communicated both internally and externally, repeatedly conveyed to employees the importance of compliant behavior and emphasized the high value placed on this issue by the institute's management.

In order to optimize the FLI's compliance efforts, the exchange of experience with other institutions within and outside the Leibniz Association is to be intensified (e.g. Borstel Research Center, Rheumatism Center Berlin, Leibniz Institute for Natural Product Research and Infection Biology, MPI for Biogeochemistry, MPI for Chemical Ecology, Helmholtz Center Munich). In the further expansion of the CMS, common areas of interest among cooperation partners in the Jena research environment (FSU, UKJ, Jena Leibniz Institutes, etc.) are to be identified in order to exploit the potential for regionally coordinated solutions (e.g. activities of ethics committees and ombudsperson 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 Board of Directors. It meets every two months for a jour fixe. Selected compliance experts are invited to report on relevant issues in their compliance areas; the FLI Board of Directors also participates. In an emergency situation, 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 subsequently 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.

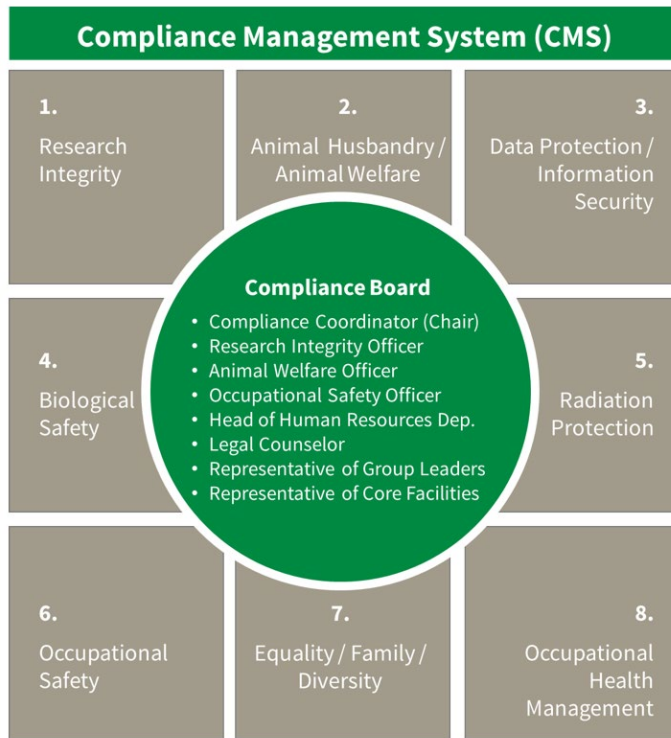


Fig. 1 FLI Compliance Management System (CMS)

Reports of the compliance areas

Area 1 – Research Integrity

To ensure the standards of “Good Scientific Practice” (GSP), the following structural changes were implemented at FLI as of October 2017:

Clarification of the explanations of the GSP standards: This included clarification of the measures for compliance with these standards as well as the contractual obligation for all employees to fully observe and ensure them. The updated version of the GSP Guidelines approved by the Leibniz Association on 11/29/2018 was fully incorporated into the FLI GSP Rules and became effective 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. In addition, the code of conduct of the German Research Foundation (DFG) was published, which must be implemented in the institute-specific rules in order for DFG funding to be received. The DFG has set an implementation date of July 31, 2022. Currently, the ombudspersons are in an exchange of information with Leibniz institutions to clarify questions regarding the implementation of the code.

Work-in-progress seminars: These enable experienced scientists to critically appraise the collection/analysis of results produced by junior scientists. During the Corona emergency (1st half of 2020; see below), these had to be suspended; since October 2020, they have been held digitally.

Advanced training courses: All FLI group leaders, PhD students of the Leibniz Graduate School on Aging (LGSA), and FLI postdocs are required to attend an advanced training course on maintaining GSP standards. Thesis Advisory Committees (TACs) as well as PhD supervisors are required to ensure full GSP compliance on the part of graduate students.

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 (HSM) 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): After an intensive training period, the ELN was implemented as mandatory for all staff on 07.01.2019. The ELN-based optimization of primary research data storage developed at the FLI has made the ELN an important tool for maintaining research integrity.

Assessment Before Submission (ABS): The review of all scientific manuscripts and dissertations based on experimental data, to ensure scientific integrity and statistical plausibility, was introduced at the FLI in March 2018. It has been enforced by Resis S.r.l. since 04.01.2018 and is mandatory. The overall results of the ABS investigations show that the frequency of complaints decreased steadily in the period 2018–2020. However, the fact that correctable issues continue to be identified indicates that (a) continuation of the reviews is advised, and (b) competence in statistical analysis needs to be improved.

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

Planned further development of GSP measures in the area of research integrity:

- ABS analyses revealed frequent statistical errors in scientific manuscripts, so more training courses on statistical methods will be conducted.
- With the election of a second ombudsperson, the FLI now has additional expertise to help solve potential problems in the GSP area.
- As a recipient of DFG third-party funding, the FLI will implement the code “Guidelines for Ensuring Good Scientific Practice” in a legally binding manner.

Area 2 – Animal husbandry, animal welfare

Animal Welfare Department: In this department, established on 01.01.2018, Animal Welfare Officers (TSchB), who are not bound by directives, monitor the proper, rule-compliant performance of all animal experimentation activities at the FLI. The TSchB advise project leaders on the formulation of animal experiment applications, agree on procedures, and report to the competent authority.

Supervising veterinarians of the animal stock: Two veterinarians (on average 1.5 FTE) monitor the welfare and health of the FLI animal stock.

Responsible persons according to § 11 TierSchG: Permission to breed and keep vertebrate animals is delegated to knowledgeable individuals; during the reporting period, these were the animal house managers.

In-House Veterinary Pharmacy (TÄHA): Established at the FLI since 2017, the pharmacy is managed by a veterinarian (0.5 FTE). She dispenses drugs to the project leaders of animal experiments and monitors their proper application.

Animal Protection Committee (TSchA): In accordance with § 6 TierschVersV on 08.18.2016 at the FLI, the committee consists of 10–12 members under the leadership of the TSchB.

Operating instructions: Internally at the FLI, standardized laboratory animal husbandry is continuously monitored via operating instructions and SOPs. These include: air-conditioning of the

animal rooms; hygienic, species-specific food and water supply; appropriate light regime; proper treatment/accommodation of the laboratory animals; daily eye examination/health check; maximum reduction of stress factors; hygiene monitoring; and restriction of access to the animal houses.

Training/education: All employees working with animal experiments are to participate in certified further training on animal welfare for 8 hours per year. Since 2015, this has been documented in the FactScience documentation system.

Communication with authorities: Such communication takes place exclusively via the Animal Welfare Department, including applications for the implementation of animal experimentation projects (TVA), submissions of change requests, etc.

Animal experiment databases: The FLI uses the databases Pyrat (for mouse husbandry), Tick@Lab (for fish husbandry), and AniShare (for exchange of experimental animals). These are maintained by the animal keepers and participating scientists, checked by the project managers, and can be consulted by the TSchB and the animal house managers at any time.

3R principle: This principle is the basis for the ethical evaluation of new animal experiments by the TSchB of the FLI and stands for Replacement (seeking alternatives to animal experiments), Reduction (reducing the number of animals in an experiment), and Refinement (improving the experiment to reduce pain, suffering, and harm to laboratory animals).

Vocational training as an “animal keeper”: Since 2009, 11 trainees have been supervised at the FLI.

Evaluation of FLI animal houses: Since 2018, the annual visit of the Scientific Advisory Board (SAB) also includes discussions with the animal house managers/TSchB about the situation of animal husbandry at the FLI. On June 18, 2019, the animal houses of the FLI were evaluated by an external, internationally composed expert panel (a further SAB evaluation took place in fall 2021).

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

In 2021, plans were made to adopt an FLI Animal Welfare Guideline that will concretize the legally required guidelines. The onboarding of new employees in the area of animal testing is to be optimized.

Area 3 – Data protection, information security

Data protection measures in 2019

- Since 01.01.2019, proof of continued German social security coverage for official travel to EU/EEA countries must be transmitted electronically (EC Regulation No. 883/2004) – this has been implemented by the Personnel Office/Data Protection Officer (DPO).
- The new equipment of the FLI with multifunctional devices for faxing, scanning, and printing with RFID or password access, including emailing, made it necessary to safeguard data protection aspects with the “Works Agreement on Multifunctional Devices” (07.01.2019).
- During the operation of the ELN as well as the documentation systems in animal husbandry, metadata are generated that could potentially be used to control the behavior of employees. For their protection, the “Company Agreement on Electronic Documentation Systems (EDS) at the FLI” was formulated (07.01.2019).
- As of 11.26.2019, the 2nd DSAnpUG-EU Act became effective. Relevant for the FLI is, for example, the passage “In § 26 paragraph 2 sentence 3, the words ‘must be in writing’ are

replaced by the words ‘must be in writing or electronically.’” This allows for greater flexibility when consent must be obtained in the employment relationship: instead of paper documents, electronic consent (e.g. as an email) can now be stored in the electronic personnel file.

Corona-related data protection measures in 2020 (see below)

- “Home office” had to be reassessed from a data protection perspective. It was ensured that the provisions of the BDSG and the EU-DSGVO were also guaranteed at the off-site workplace.
- Increased use was made of video conferencing tools. After data protection-related improvements, the use of Zoom in licensed operations was assessed as proportionate and was implemented.
- In order to circumvent legal uncertainties due to a still lacking EU-DSGVO certification of cloud offers, an own cloud solution was implemented at the FLI.
- The government Corona alert app was recommended to employees as a contact tracking tool.

Brexit (data protection issues): Due to unclear regulatory requirements in the area of data protection as a result of Britain’s departure from the EU, additional clauses were included in cooperation agreements with institutions in the UK to cover the event of a hard Brexit and to commit to the level of data protection of the EU GDPR.

Information security management system (ISMS): The set-up was begun in 2020.

Phishing mails/spam filter: Due to unauthorized third-party access as a result of a phishing email, external emails are marked with [External] in the subject line; the spam filter was adjusted in parallel. Phishing tests are carried out on a regular basis.

IT and information security seminar: A voluntary seminar program on IT and information security was established.

Verification of data leaks in connection with FLI email addresses: This was carried out by several services. Affected FLI employees were informed that their passwords should be considered insecure. In the future, the FLI will automatically be notified when new records with FLI email addresses become known.

Security check of IT systems that can be accessed externally: This was carried out by the Information Security Officer. In 2020, external access to a media server was blocked at short notice because it was using outdated software. In addition, the security for logging into the laboratory animal husbandry software was increased to prevent a possible brute force attack.

Area 4 – Biological safety

All work areas at the FLI that handle biological agents – including their genetically modified forms – are classified as safety level 1 (S1) or 2 (S2). In each genetic engineering facility, at least one project leader is responsible for the planning and execution of the genetic engineering work, the risk assessment of the GMOs, and the documentation of such work. This is reviewed by the Biosafety Officers (BBS).

Surveillance: The genetic engineering facilities/work areas are inspected by the responsible departments of the Thuringian State Office for Consumer Protection prior to commissioning or regularly during operation.

Infection protection: There was a change in personnel in charge during the reporting period.

Import form for biological agents/GMOs: A form was developed that clearly records all relevant information on biological agents or materials being imported.

Update of the Genetic Engineering Safety Regulation (GenTSV, 03.01.2021): Genetic engineering project leaders and BBS must undergo regular training every 5 years (mandatory in-house training: September 2021).

Area 5 – Radiation protection

Radiation Protection Area 1

The FLI, as the operator of Radiation Protection Area 1, has been registered with the Federal Office for Radiation Protection (BfS) according to § 170 StrSchG. Users of Radiation Protection Area 1 are registered in the Radiation Protection Register.

Access: Access is only for instructed users, via transponder activation. Users (exposed persons category A) must be medically examined before starting work, as well as annually (§ 77 StrSchVO). This does not apply to authorized persons of category B (service personnel, such as colleagues from Building Management).

Instruction: Provided before first use on site; further instruction annually (§ 63 StrSchVO).

Dosimetry: Radiation Protection Area 1 is a controlled area (§ 52 StrSchVO) in which the radiation dose to the body must be determined (§§ 64, 65 StrSchVO). Personal dosimeters are to be worn, replaced monthly, and examined for exposure at the State Office for Personal Dosimetry and Radiation Protection Training (LPS Berlin). No exposures were detected during the reporting period.

Disposal of radioactive residues: This was carried out on 11.24.2020 by the company Eckert & Ziegler Nuclitec GmbH.

Radiation Protection Area 2

According to § 5 (36) StrSchG, this represented a high-level radioactive source (HRQ) until 12.31.2020. The source, which remains radioactive due to its half-life, is still in use; however, due to its diminished radioactivity it is no longer considered an HRQ. Therefore, the so-called “Preparatory measures for emergencies or incidents” **were not** required for continued operation after 12.31.2020. A radiation protection officer must be present at the FLI for the facility to be used.

Access/instructions: See Radiation Protection Area 1.

Inspection of the facility for leak tightness: Once a year (TÜV); maintenance/inspection by Best Theratronics.

Reports to BfS/monitoring authority: Measurement results of manufacturer maintenance were communicated to the monitoring authority – no anomalies.

Compliance measure: One user failed to lock the source room on August 11/12, 2020 and was therefore excluded from using the area for 4 weeks.

Radiation Protection Area 3

Access/instructions: See Radiation Protection Area 1 and instructions for animal house FLI-7.

Securing of computer tomography (CT): X-ray modality of the equipment is secured by a key switch (in the possession of Radiation Protection Officer); Radiation Protection Area 3 can also be used in fluorescence or phosphorescence mode (without activating the X-ray tube).

Inspection of the equipment: At 3-month intervals, checks are made to determine whether X-rays are leaking out. The safety shut-off devices are checked monthly. All inspections indicated tightness of the devices and full functionality; the next 5-year inspection of the two CTs by the inspection authority (TÜV) will be in 2023.

Area 6 – Occupational safety

Updating the risk assessments: During the reporting period, work areas in which hazards had already been identified were analyzed with regard to risk factors.

Instruction of employees: This is carried out before the start of work (initial instruction) and regularly thereafter, at least once a year. The heads of the respective organizational units and/or the project leaders are responsible for this. Due to the restrictions caused by the Corona pandemic (see below), instruction has taken place almost exclusively in the form of video conferences since March 2020. In parallel, content was made available via a digital learning platform using a course management system (Moodle).

In-house representatives:

- In order to **improve first-aid training**, in-house training was to be offered in cooperation with the German Red Cross starting in 2020, but this was not possible due to the restrictions imposed by the Corona pandemic. Follow-up training was postponed until 2021.
- **Safety officers** support the work group/area leaders in the implementation of occupational safety/accident prevention and are the contact persons for the occupational safety specialist.
- **Fire protection/evacuation** assistants are trained during one theoretical and one practical in-house training session.

Occupational safety measures:

- **Hearing protection:** A need for action was identified with regard to increased noise exposure in cage preparation. Custom-made earmolds were purchased, providing a high level of wearing and hearing comfort for the affected employees.
- For cases of **working alone**, the head of the respective organizational unit must determine any associated hazards after an employee applies to work alone and, if necessary, specify suitable measures for accident prevention.
- A **laboratory fire** occurred while an ethanol burner was being used. When a vessel containing a flammable liquid was knocked over, the liquid ignited; the laboratory bench and other equipment caught fire. Only one employee was in the work area at the time. The automatic fire alarm system alerted the fire department, which was able to quickly extinguish the fire. The result was property damage and minor burn injuries to the employee. To minimize the risk of fire, it was recommended that ethanol burners be replaced with gas cartridge safety burners. It was determined that refillable practice fire extinguishers would be purchased and staff would be trained to use them.

- **Disposal of hazardous waste:** Together with the responsible waste disposal company, guidelines for handling hazardous waste at the FLI were drawn up. Two information seminars were held for the technical assistants.

Occupational Health and Safety Committee (ASA): As the meetings of the Covid 19 Planning Staff and the Occupational Health Management (OHM) Working Group overlap in terms of topics/personnel, the quarterly meeting schedule was deviated from during the reporting period.

Area 7 – Equality/Family/Diversity

The FLI has been the holder of the **“TOTAL E-QUALITY Award for Equal Opportunities and Diversity”** for a period of 3 years.

In a **survey on the status of implementation of the Leibniz Equality Standards** in April 2020, the FLI achieved 62 out of 68 possible points and is thus above the median of the 92 Leibniz institutions.

In March 2020, the **target quotas for increasing the proportion of women in scientific staff** were adjusted with regard to the fluctuation/cascade model and Leibniz orientation quotas until 2025. The target quotas were updated for filling W2/W3 positions (from 10 to 25%), pay grades E14 (from 32 to 30%) and E13 (from 42 to 50%), and management level (from 23 to 30%).

In the context of the Institute evaluation in September 2019, the Equality officers presented themselves with their own poster. The main areas of activity in the Equality division are: Gender Equality, Diversity, Work & Family Life, and Family Friendliness.

Equality officers were appointed for the new term (2019–23), as well as **two deputies**, who completed numerous further training courses during the reporting period.

The FLI participated in the **German Diversity Day** in May 2019; the same event was held online in 2020. The 2nd networking meeting “Diversity” of the Leibniz Association and the working group “Equal Opportunities and Diversity” took place on 09.26.2019.

On the initiative of the FLI, a **dual-career short profile for clients** was developed in 2019, which greatly facilitated exchanges in dual-career networks.

The FLI has received a high “TEQ-rating” and the “Jena Family seal,” both of which are quality criteria for **family friendliness**; the FLI is also a member of the “Jena Alliance for the Family.” In addition, cooperation agreements have been concluded with two nearby daycare centers, which currently accommodate 9 children of institute employees. A parent-child workroom is available to all employees. During events, the FLI provides childcare when necessary.

Compatibility of family & work: With the start of the Covid-related emergency operations at the FLI (03.23.2020), home office work was ordered for all employees with the exception of an emergency team. At the same time, all daycare centers and schools in Thuringia closed on 03.17 – a particularly challenging situation for the FLI as a family-friendly employer. Together with the Human Resources Department and the Communications Department, ways were sought to keep employees informed of alternative child-care options.

Area 8 – Occupational health management

Health weeks 2019/20 (10.29.2019–10.31.2020) were organized by the FLI Human Resources Department with the Techniker Krankenkasse (TKK), Prowandel GmbH, and the company physician.

Particular challenges for managers arose due to the **health burdens caused by the Corona pandemic** (see below), for which special trainings were offered: Micro Leadership Training for Division Managers of Administration (June/July 2020); E-Nugget (webinar 1 hour); and Healthy Leadership (June 2021). There was additional stress due to the elimination of working in regular teams and the prohibition on common breaks (especially in animal houses); to ease this, consultations were offered from the company doctor and HR department. Other measures included regular email notices to employees encouraging them to communicate stress, the Haufe learning platform for home office, online language courses, contact tracing and management of travel return.

Occupational health care continued to be offered on a regular basis, partly by telephone, including special notices/precautionary home office for risk groups. The SARS-CoV-2 Occupational Health and Safety Rule (since 8/2020) covers attention to mental stress due to the impact of the Corona pandemic, a review of risk assessments, briefings and active communication, and return-to-work counseling by phone for those who have been ill.

Maternity protection in Corona times: Expectant mothers were made aware of the risk posed by COVID-19 and advised by the company physician to avoid going in to work, in line with § 13 of the Maternity Protection Act.

SARS-CoV-2 PCR tests were provided at the FLI to protect employees on a voluntary basis.

In November 2020, the FLI corporate health management (BGM) working group reviewed a digital procedure (Psy-Quick) for recording and assessing mental hazards.

The BGM working group met in the fall of 2020 to establish a network of confidants. These were given the following tasks: providing support through counseling; accompanying employees to private consultations, mediating in the event of conflict, identifying solutions; calling in specialist expertise; implementing preventive measures; implementing multi-stage complaint procedures; educating and raising awareness among employees and managers.

Corona pandemic of 2020

With the outbreak of the Covid pandemic in January 2020, Compliance Areas 2 (Animal Welfare), 6 (Occupational Safety), and 8 (Occupational Health Management) took on special importance. The FLI responded very early to the pandemic-related threat to the health of employees and their families. In addition, animal welfare had to be kept in mind with regard to all restrictive measures.

As the first signs of a possible coronavirus pandemic became known, the Board informed all FLI employees of this impending threat on Jan. 27, 2020 and recommended cancelling any planned travel to China and other risk areas (as assessed by the Robert Koch Institute). It decreed that all those arriving from these areas after Jan. 15, 2020 would have to undergo isolation at home (quarantine) for 14 days from the date of entry under home office working conditions. Instructions were given for the delivery of medical care in the event of symptoms of infection.

The FLI responded to the escalating pandemic in the following weeks by establishing a Corona Planning Staff, which included all members of the Compliance Staff as well as employees with safety-relevant areas of responsibility, including the company physician.

Phase A of the emergency operation was initiated at 11:00 a.m. on 03.23.2020. This was a complete shutdown of the FLI and the transfer of all employees into home office mode. Experimental animals were cared for by our animal care staff in non-overlapping shifts. On 04.20.20, Phase A transitioned into **Phase B**, in which teams of two (one team per work group, two teams per day in a 7-day work week) were allowed to enter the laboratory premises in non-overlapping shift mode. The non-overlapping shift operation of the animal caretakers was maintained. The remaining employees

remained in home office. On 05.11.2020, Phase B transitioned into **Phase C**, in which teams of three (one team per work group, two teams per day in a 7-day work week) were allowed to enter the laboratory premises in non-overlapping shifts. Again, the non-overlapping shift operation of the animal caretakers was prolonged and the remaining staff stayed in home office. On June 1, 2020, the FLI transitioned to **Phase D** emergency operations: under strict hygiene rules – use of protective face masks, distance regulations – the “normal” employees were able to return to the workplace. This phase was maintained until June 2021.

With the first contact of an FLI employee with a person infected with the Coronavirus on 10.23.2020, the **Action Committee Infection/First Contact** was established. This included the Board of Directors, the Human Resources Manager, the Legal Advisor, an occupational safety specialist, a representative of the Works Council, and the Research Coordinator. Rules were drawn up to ban entry to the FLI, which were implemented by the HR department and those affected. With the first case of infection of an employee on 12.14.2020, rules for lifting the ban on entering the FLI were developed, including consultation with the company physician. Subsequently, the Action Committee Infection/First Contact was convened in each case of first contact or infection of an employee, and necessary measures and specifications for further action were discussed and communicated to the affected persons, who were required to comply.