### 安全管理の取り組み

#### Initiatives in the Area of Safety Management

理研筑波事業所では、事業とその推進を支える研究活動が、各種法令、指針に基づき、安全かつ適切に行なわれるよう努めております。

RIKEN Tsukuba branch ensure that all research activities in RIKEN Tsukuba area are conducted safely and properly in strict compliance with the relevant laws and guidelines.

#### 1. 遺伝子組換え実験安全管理

Safety management for genetic recombination experiments

#### (1) 遺伝子組換え生物等規制法

遺伝子組換え生物の取り扱い等は、法律により、拡散防止措置や廃棄物処理、運搬の手続きが求められています。

#### (2) 遺伝子組換え実験安全委員会

研究計画は、外部の専門家を含めた委員会において、 法令への適合性について審査を受けます。

平成26年度末現在の課題数:22件 (P1·P1A·P1P·P2·P2A)

#### (3) 教育訓練の実施

実験従事者は、法令、 規程、執るべき拡散防 止措置及び安全取扱い 等について教育訓練を 受講します。

(4) 実験施設・設備の点検 安全管理室は、実験室 の拡散防止措置、表示 等の確認及び機器の検 査を定期的に実施して います。



教育訓練の様子 Scene from education and training

 Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.

It specifies necessary measures to prevent the spread of recombinant organisms, etc. that we deal with, and proper procedures for disposal and transportation of waste products.

(2) Genetic Recombination Experiments Committee

Research protocols are reviewed for compliance with the law by safety committee comprising outside experts. As of the end of fiscal 2013: 22 protocols were approved (P1·P1A·P1P·P2·P2A)

#### (3) Education and training

Personnel who perform genetic recombination experiments receive lectures on relevant laws, regulations, measures for preventing the spread of LMOs, and safe handling.

(4) Inspection of experimental facilities and equipment
Tsukuba safety center conduct periodic checks on required
signs and other measures to prevent the spread of LMOs
and inspect equipment in laboratories.

#### 2. 動物実験管理

Proper management for animal experiments

(1) 動物の愛護及び管理に関する法律・研究機関等におけ

#### る動物実験等の実施に関する基本指針

理研筑波地区で実施する動物実験は、動物愛護の観点、科学的な観点から動物実験等を適切に実施するためのガイドライン(基本指針)を遵守し、適切な管理を実施しています。

#### (2) 動物実験審査委員会

研究計画は、外部の専門家を含めた委員会において、 特に3R(苦痛度軽減、代替法、使用動物数の低減)を 重点とし、科学的、倫理的な側面から実験実施が妥当 か否かの審査を受けます。

さらに審査体制、実験動物の管理、飼育施設、教育 訓練状況等に関し、基本指針への適合性について自己 点検・評価を毎年行い、更に外部検証も実施しています。

#### ●平成25年度自己点検・評価結果

実験報告 適正:15件、要改善:0件 飼育管理報告 適正:6件、要改善:0件

#### (3) 教育訓練の実施

動物実験従事者は、 基本指針等及び動物の 取扱い等についての教育 訓練を毎年受講します。

(4) 飼育施設等の点検・確認 飼育・保管・実験に応 じた設備等の適正維持の ため、定期的に点検・確 認を実施しています。



教育訓練の様子 Scene from education

(1) Act on Welfare and Management of Animals and Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions

RIKEN Tsukuba branch conduct animal experiments with consideration of both scientific rationale and animal welfare, complying with the Fundamental Guidelines.

#### (2) Animal Experiments Committee

The Animal Experiments Committee comprising outside experts review research proposals and evaluate them in the viewpoint of science and ethics. More practically, protocols are reviewed for the principles of "3Rs" which stand for Reduction of the number of animals used, Refinement of experiments for less invasive technique, and Replacement with alternative technique.

In addition, the committee conduct voluntary inspection and evaluation every year on our review system, animal management, animal rearing facilities, and the status of education and training, etc. for the conformity with the Fundamental Guidelines. Furthermore the inspection and evaluation are verified by external authorities.

 Results of voluntary inspection/evaluation for fiscal 2013

Experiment reports: Appropriate: 15; improvement required: 0, Rearing management reports: Appropriate: 6; improvement required: 0

# 安全管理の取り組み

#### (3) Education and training

Personnel who conduct animal experiments receive lectures every year on the Fundamental Guidelines and appropriate handling of experimental animals.

#### (4) Inspection/check of animal rearing facilities

We conduct periodic inspections and checks to maintain appropriate facilities for animal rearing, storage, and experimentation.

#### 3. 研究倫理

#### Research ethics

#### (1) 臨床研究指針、ゲノム指針、ES指針ほか

ヒト由来試料の取扱いは、適用を受ける指針に基づき行われます。これら指針の根本にある考え方は、被験者(試料提供者)の尊厳、人権、個人情報を守るための機関の長、研究責任者等の責務、インフォームド・コンセント及び試料の管理等を適正に行うことにあります。

#### (2) 研究倫理委員会

研究計画の倫理的及び科学的妥当性について、医学、 生物学、法律、生命倫理に関する専門家及び一般の立 場の方を含めた委員会で審査を受け研究を実施してい ます。

●平成26年度末現在の課題数:17件

#### (3) 教育訓練の実施

研究者等は、指針及び規程等を踏まえた倫理講習を 受講します。

#### (1) Ethical Guidelines for Clinical Research, Ethical Guidelines for Human Genome and Genetic Sequencing Research, and Ethical Guideline for Human ES cells, etc.

RIKEN researchers deal with biological materials sourced from humans in accordance with the applicable guidelines. The concept underlying the guidelines is that both the Institutional officials and the principle investigator are responsible for protecting human dignity and rights of the subjects who provide biological specimens for research. Based on this concept, they confirm that informed consent is obtained from the subjects and that all materials are managed appropriately to protect personal information of the subjects.

#### (2) Research Ethics Committee

Research Ethics Committee composed of specialists in medicine, biology, law and bioethics and lay persons, review research proposals in light of ethics and scientific rationale, and approve them if appropriate.

As of the end of fiscal 2014: 17 proposals were reviewed

#### (3) Education and training

Researchers and other personnel receive lectures based on the ethical guidelines and regulations.

#### 4. その他安全管理

#### Other issues on safety management

#### (1) 安全管理が必要なもの

前述の1~3の実験には、化学薬品、高圧ガス、放射性物質及び微生物などの取扱いを伴う場合が多く、各法令等に基づく規程等を定め、適正な取扱いを実施しています。また、研究廃棄物、実験排水等についても法令等を遵守し、適正な管理を行っています。

#### (2) 労働安全

労働者の安全確保、設備の健全性の確認等のため、 定期的に研究室の巡視点検を行うとともに、安全のため のマニュアル(冊子)や安全衛生情報紙によりその時々 のトピックス、事例などを踏まえ、労働安全確保のため

の啓発や周知活動を実施

しています。

## (1) Items where safety management is required The above-mentioned

The above-mentioned researches and experiments involve frequent use of



安全のためのマニュアル Safety manuals

chemicals, high-pressure gas, radioactive materials, and microorganisms. Safety center have established in-house code of conducts based on the relevant laws and regulations to ensure that they are handled in an appropriate manner. They also carefully follow the stipulations of applicable laws with regard to management and disposal of waste materials and water.

#### (2) Work environment

RIKEN Tsukuba branch conduct periodical inspection patrol in the laboratories in order to ensure the safety of work environment and check the soundness of equipment. In addition, we provide safety manuals and circulate monthly report with up-to-date topics on safety and health so that all personnel are aware of dangers and hazards associated with their activities.

#### 5. 事業の透明性確保のための活動 Ensuring transparency of our operations

理研BRCの事業活動の意義やこれまでの歴史を知っていただくことを目的に、研究室や高度封じ込め実験施設(現在は使用なし)の見学を受け入れています。また、地域住民の方々には、事業活動と安全管理に関する状況を毎年報告する地元説明会を開催し、活動の透明性を確保すべく努めております。

For providing an opportunity to know the history of RIKEN and the significance of BioResource business, Tsukuba branch welcome common citizens to the tours in our laboratories including an advanced containment facility (not presently in use). They hold an annual explanatory meeting for local residents, at which we thoroughly report on our activities, especially our safety management practices, in order to secure transparency of our activities.





研究室の見学の様子 Scene from laboratory tours