

TENTATIVE TRANSLATION

Enforcement Rules for Kyoto University Regulations Regarding Safety Control of Recombinant DNA Experiments, etc.

March 29, 2021

Enacted by Decision of the Executive Director for Research

Article 1 Purpose

These enforcement rules provide matters necessary for the enforcement of Kyoto University Regulations Regarding Safety Control of Recombinant DNA Experiments, etc. (Notification No. 16 of March 29, 2021; hereinafter referred to as the “Regulations”) based on the provisions of Article 31 of the Regulations.

Article 2 Application for Recombinant DNA Experiments

1. The format for the application mentioned in Paragraph 1, Article 11 of the Regulations shall be as shown on Form 1.
2. The formats for application and attached report mentioned in Paragraph 1, Article 12 of the Regulations (including the cases where Paragraphs 1 and 2 of Article 13 are applied), shall be as shown in Forms 2-1 and 2-2.
3. The application and plan specified in the preceding paragraph shall be generated and submitted online using Kyoto University Application System for Experiments Using Living Modified Organism (hereinafter referred to as “KUELMO”). When a cell fusion experiment is to be performed, a paper-based application and plan shall be submitted.

Article 3 Report for Recombinant DNA Experiments

1. The format of the report mentioned in Article 20 of the Regulations shall be as shown on Form 3 and Form 4.
2. The report specified in the preceding paragraph shall be generated and submitted online using KUELMO.

Article 4 Application and Information Provision Sheet concerning Transfer, etc. of Genetically Modified Living Organisms, etc.

The formats for application and attached plan mentioned in Paragraph 1, Article 23 of the Regulations, as well as the format for information provision sheet mentioned in Article 24 of the Regulations shall be as shown in Forms 5-1, 5-2, and 5-3.

Article 5 Application for Import

The format of the application mentioned in Paragraph 1 of Article 25 of the Regulations shall be as shown on Form 6.

Article 6 Number of Copies to Be Submitted, etc.

The forms specified starting from Article 2 to the preceding article, other documents to be submitted, the number of copies to be submitted, and submission due dates are specified in the attached table.

Supplementary Provisions

1. These enforcement rules shall come into effect on April 1, 2021.
2. As for recombinant DNA experiments that have been completed before the use of KUELMO, paper-based reports shall be submitted regardless of the provisions in Paragraph 2 of Article 3.

Attached Table

Subject matter	Documents and number of copies to be submitted	Submission due date
Minister-approved experiments	Application for the Regulations Concerning Type 1 Use (Form 1): 1 copy Approval Application for the Regulations Concerning Type 1 Use: 1 copy Assessment on Biodiversity Impact: 1 copy	As needed
Institution-approved experiments	Application for Recombinant DNA Experiment (Form 2-1): 1 copy Recombinant DNA Experiment Plan (Form 2-2): 1 copy For conducting experiments funded by the Grants-in-Aid for Scientific Research (KAKENHI), a copy of the research proposal document shall be attached for each project.	Application for experiments for which submission of a research proposal document for KAKENHI is required: End of November of each year Application for conducting other experiments: As needed
Minister-verified experiments	Application for Recombinant DNA Experiment (Form 2-1): 1 copy Recombinant DNA Experiment Plan (Form 2-2): 1 copy Application to confirm containment measures to be taken in Type 2 Use: 1 copy For conducting experiments funded by the Grants-in-Aid for Scientific Research (KAKENHI), a copy of the research proposal document shall be attached for each project.	
Report of completion and suspension	Result (Completion/Suspension) Report of Recombinant DNA Experiments (Form 3): 1 copy Result Report of Recombinant DNA Experiments (Form 4): 1 copy	Immediately after completion or suspension of the experiment. When the person responsible for the experiments is to be transferred to another institution or retires from the University, in principle, the report must be completed before the person responsible for the experiments leaves the University.
Transfer and receipt of genetically modified living organisms, etc.	Application for Transfer/Receipt of Genetically Modified Living Organisms (Form 5-1): 1 copy Plan for Transfer/Receipt of Genetically Modified Living Organisms (Form 5-2): 1 copy Provision of Information for Transfer/Provision/Commission of Genetically Modified Living Organisms (Form 5-3): 1 copy Form 5-3 is not needed at the time of application for receipt.	As needed
Application and report for import to the competent minister	Import Application (Form 6): 1 copy Import Report: 1 copy	As needed

(Form 1)

Application for the Regulations Concerning Type 1 Use

MM/DD/YYYY

To the President of Kyoto University

Person responsible
for the experiment

Organization name/

Department name _____

Job title _____

Name _____

I hereby apply for approval by the competent minister of the Regulations Concerning Type 1 Use below. The necessary documents are attached.

Title of the research concerned with the Regulations Concerning Type 1 Use

(Form 2-1)

Application for Recombinant DNA Experiments

MM/DD/YYYY

To the President of Kyoto University

Person responsible for the experiment	Organization name/ Department name	
	Job title	
	Name	

I hereby apply to conduct the following recombinant DNA experiment as stated in the attached experiment plan.

Subject name of recombinant DNA experiment

Recombinant DNA Experiment Plan

MM/DD/YYYY

Type of application (Note 1)	Classification of experiment (Note 2)	Containment measures (physical containment) (Note 2)	Public grant (Note 3)
<input type="checkbox"/> New <input type="checkbox"/> Continuing (Y: M: No.) <input type="checkbox"/> Change (Y: M: No.)	<ul style="list-style-type: none"> - Experiments using microorganisms/cultured cells as hosts <ul style="list-style-type: none"> <input type="checkbox"/> Unidentified DNA experiment <input type="checkbox"/> Identified DNA experiment <input type="checkbox"/> Mass culture experiment - Experiment using animals <ul style="list-style-type: none"> <input type="checkbox"/> Creation <input type="checkbox"/> Use <input type="checkbox"/> Inoculation - Experiment using plants <ul style="list-style-type: none"> <input type="checkbox"/> Creation <input type="checkbox"/> Use <input type="checkbox"/> Inoculation 	<input type="checkbox"/> P1 <input type="checkbox"/> LSC <input type="checkbox"/> P2 <input type="checkbox"/> LS1 <input type="checkbox"/> P3 <input type="checkbox"/> LS2 <input type="checkbox"/> P1A <input type="checkbox"/> P1P <input type="checkbox"/> P2A <input type="checkbox"/> P2P <input type="checkbox"/> P3A <input type="checkbox"/> P3P <input type="checkbox"/> Special breeding section <input type="checkbox"/> Special netted-house	<input type="checkbox"/> Yes <input type="checkbox"/> MEXT <input type="checkbox"/> Grants-in-Aid for Scientific Research (KAKENHI) <input type="checkbox"/> Others () <input type="checkbox"/> No

Subject name				
Implementation period of the experiment (Note 4)		From (Month/Year) to (Month/Year)		
Person responsible for the experiment	Address of department			
	Organization name/ Department name/ Job title			
	Name	TEL:		
		FAX:		
		E-mail:		
Lab location	Address			
	Name of laboratory			
Experimenter	Name	Organization name/ Job title	Name of host and related years of experience (Note 5)	Years of experience in recombinant DNA experiment (Note 6)

Special notes for the implementation of this experiment plan (Note 7) (for use of the Committee only)		
	Chairperson's Department/Job title/Name	
Purpose of the experiment		
Overview of the experiment		
Need to conduct this recombinant DNA experiment (Note 8)		
Justification for approval by the Minister (Note 9)		

Combinations of DNA donor, vector and host (Note 10)							
DNA/nucleic acid donor (Note 11)	Type of DNA/nucleic acid (Note 12)	DNA/nucleic acid to be isolated for unidentified DNA experiment (Note 13)	Donor DNA/nucleic acid for identified DNA experiment (Note 14)	Vector (Note 15)	Host (Note 16)	Containment measures (containment level) (Note 17)	Remarks

Characteristics and biological risks of the DNA/nucleic acid donor (Note 18)	
Characteristics and properties of the DNA/nucleic acid to be isolated or the donor DNA/nucleic acid and its product (Note 19)	
Characteristics, transmissibility, and host dependency of the vector (Note 20)	

Characteristics of the host, mechanisms of genetic exchange (Note 21)	
Characteristics of the host-vector system, degree of containment measures (biological containment) and deactivation method (Note 22)	
Process and method of DNA/nucleic acid introduction to creating recombinant animals and plants (Note 23)	
Characteristics and risks of genetically modified living organism (recombinants) or animals and plants to be inoculated with genetically modified living organisms (recombinants) (Note 24)	
Containment measures for mass culture experiment of recombinant microorganisms or recombinant animals and plants, animals and plants to be inoculated with genetically modified living organism (recombinants) in (Note 25)	
Treatment of genetically modified living organism (recombinants) after the experiment	

Facility and equipment containment measures (physical containment)	Location (Note 26)	
	Structure (Note 27)	
	Facility (Note 28)	

Instructions to complete this Plan Document

Complete each item in this form. Indicate the document number in the appropriate space when attaching the supplementary document(s).

- Note 1: Check the box beside the appropriate type of application.
- Note 2: Check all boxes that apply.
- Note 3: Check the appropriate box. If a public grant is applicable, include the type of public grant.
- Note 4: Write the planned implementation period. There is a 5 year maximum.
- Note 5: Write the years of experience of the experimenter in handling the organism to be used as hosts. If microorganisms, animals, and plants all serve as hosts, write the years of experience (if any) for each host.
- Note 6: Write the years of experience (if any) in conducting recombinant DNA experiments.
- Note 7: Indicate specific points that the Kyoto University Recombinant DNA Experiment Safety Committee noted regarding this experiment (e.g., the validity of the experiment plan, place, and experimenters).
- Note 8: Briefly explain the need to conduct your experiment if it involves a mass culture, inoculation of genetically modified living organisms (recombinants) to animals or plants, or proteinaceous toxin-producing genetic material in vertebrates.
- Note 9: Write which Type 2 Ministerial Ordinance Annex I items apply to your experiment.
- Note 10: Illustrate the relationship between the DNA/nucleic acid donor, vector, and host. Number, underline, and connect each combination.
- Note 11: Write the species name or strain name of the organisms to serve as the DNA/nucleic acid donor.
- Note 12: Write the types of donor DNA/nucleic acid (e.g., genomic DNA, complementary DNA, and synthetic DNA).
- Note 13: This is for an unidentified DNA/nucleic acid experiment. Write the name of DNA/nucleic acid to be isolated from the nucleic acid mixture.
- Note 14: This is for an identified DNA/nucleic acid experiment. Write the name (and literature, if any) of the donor DNA/nucleic acid to be used.
- Note 15: Write the name of the vector.
- Note 16: Write the name of the host species, strain of host, or cultured cells. If your experiment involves inoculation of genetically modified living organisms (recombinants) to animals and plants, indicate "inoculation experiment" in the remarks column.
- Note 17: Write the containment measure level for each combination.
- Note 18: For a DNA/nucleic acid donor, write the containment measure level and its characteristics as necessary, the distribution in the natural environment, and risks to experimenters such as pathogenicity, parasiticity, and saprophyticity. If it produces a proteinaceous toxin, write the LD 50 and the structure of the toxin gene.
- Note 19: Write a brief description of the DNA/nucleic acid to be isolated and its products. In the case of identified DNA/nucleic acid, attach material describing its base sequence or the identification process and note the material number.
- Note 20: Write the origin, drug resistance and specific character, transmissibility, and host dependency of the vector. Attach a supporting result report or literature as necessary. If it is a virus vector, write the containment measure level.
- Note 21: When a microorganism serves as a host, write its characteristics (e.g., auxotrophicity, drug resistance, and optimum growing conditions). When using cultured cells as a host for a virus, describe the possibility of genetic information exchange with the nucleic acid of the host or the nucleic acid derived from the coexisting virus in the host. If the host is pathogenic, carcinogenic, or toxicogenic, provide details.
- Note 22: When using a host-vector system with a microorganism as its host, write the viability, transmissibility, inactivation method, and its expected efficiency, except in the case of a certified host-vector system. When using a virus, write the containment measure level against its transmissibility.
- Note 23: Complete this column when creating a genetically modified animal or plant. Write the differentiation process and the introduction method when introducing nucleic acid into cells such as an egg, embryo, seed, and biological body.
- Note 24: Write the expected characteristics to be acquired due to recombination of an organism or inoculation of a genetically modified living organism (recombinant). Clearly indicate the expected changes in the characteristics of infectiveness, pathogenicity, parasiticity, saprophyticity, and toxicogenicity.
- Note 25: This covers mass culture experiments and experiments using animals and plants. Describe the control procedures to prevent leakage, escape, and litter during culturing, breeding, and cultivating, as well as containment measures such as inactivation of seeds, water, and excreta.
- Note 26: Illustrate the location of the laboratory and experiment section as well as the arrangement of experimental equipment/devices and upload it as an "attached document."
- Note 27: Illustrate the facility structure rated as P3 or higher.
- Note 28: Add the names of the equipment and devices in a facility rated as P2 or higher.

("Note xx" in the form can be deleted.)

(Form 3)

Result (Completion/Suspension) Report of Recombinant DNA Experiments

MM/DD/YYYY

To the President of Kyoto University

Person responsible for the experiment	Organization name/ Department name	
	Job title	
	Name	

I hereby submit the result (completion/suspension) report for the following recombinant DNA experiment.

Subject name of recombinant DNA experiment	Approval number

(Form 4)

Result Report of Recombinant DNA Experiments

MM/DD/YYYY

Approval number (Note 1)	Classification of experiment (Note 2)	Containment measures (physical containment) (Note 2)	Public grant (Note 3)
(Year/Month) No.	- Experiments using microorganisms/cultured cells as hosts <input type="checkbox"/> Unidentified DNA experiment <input type="checkbox"/> Identified DNA experiment <input type="checkbox"/> Mass culture experiment - Experiment using animals <input type="checkbox"/> Creation <input type="checkbox"/> Use <input type="checkbox"/> Inoculation - Experiment using plants <input type="checkbox"/> Creation <input type="checkbox"/> Use <input type="checkbox"/> Inoculation	<input type="checkbox"/> P1 <input type="checkbox"/> LSC <input type="checkbox"/> P2 <input type="checkbox"/> LS1 <input type="checkbox"/> P3 <input type="checkbox"/> LS2 <input type="checkbox"/> P1A <input type="checkbox"/> P1P <input type="checkbox"/> P2A <input type="checkbox"/> P2P <input type="checkbox"/> P3A <input type="checkbox"/> P3P <input type="checkbox"/> Special breeding section <input type="checkbox"/> Special netted-house	<input type="checkbox"/> Yes <input type="checkbox"/> MEXT <input type="checkbox"/> Grants-in-Aid for Scientific Research (KAKENHI) <input type="checkbox"/> Others () <input type="checkbox"/> No

Subject name				
Implementation period of the experiment (Note 4)		From (Month/Year) to (Month/Year)		
Person responsible for the experiment	Address of department			
	Organization name/ Department name/ Job title			
	Name	TEL: FAX: E-mail:		
Lab location	Address			
	Name of laboratory			
Experimenter	Name	Organization name/ Job title	Name of host and related years of experience (Note 5)	Years of experience in recombinant DNA experiment (Note 6)
Committee for Safety	Address of Kyoto University		Yoshida-honmachi, Sakyo-ku, Kyoto-shi, 606-8501	
	Chairperson	Organization name/ Department name/ Job title		
		Name		

Purpose of the experiment	
Overview of the experiment	

Combinations of DNA donor, vector and host (Note 7)							
DNA/nucleic acid donor (Note 8)	Type of DNA/nucleic acid (Note 9)	DNA/nucleic acid to be isolated for unidentified DNA experiment (Note 10)	Donor DNA/nucleic acid for identified DNA experiment (Note 11)	Vector (Note 12)	Host (Note 13)	Containment measures (containment level) (Note 14)	Remarks

Describe the preservation and disposal method of any genetically modified living organisms (recombinants).	
Items written in confirmation notification by the minister (Note 15)	
Results of experiment (Note 15)	
Opinions on the safety evaluation of this experiment (Note 16)	

Instructions for Completing this Report

Complete each item in this form. Indicate the document number in the appropriate space when attaching the supplementary document(s).

Note 1: Write both the approval date by the institution and the approval number.

Note 2: Check all boxes that apply.

Note 3: Check the appropriate box. If a public grant is applicable, include the type of public grant.

Note 4: Write the implementation period of the experiment.

Note 5: Write the years of experience of the experimenter in handling the organism to be used as hosts. If microorganisms, animals, and plants all serve as hosts, write the years of experience (if any) for each host.

Note 6: Write the years of experience (if any) in recombinant DNA experiments.

Note 7: Clarify the relationship between the DNA/nucleic acid donor, vector, and host by numbering, underlining, and connecting with lines for each combination.

Note 8: Write the species name or strain name of the organisms to serve as the DNA/nucleic acid donor.

Note 9: Write the types of donor DNA/nucleic acid (e.g., genomic DNA, complementary DNA, and synthetic DNA).

Note 10: This is for an unidentified DNA experiment. Write the name of the DNA/nucleic acid to be isolated from the nucleic acid mixture.

Note 11: This is for an identified DNA experiment. Write the name of the DNA/nucleic acid used.

Note 12: Write the name of the vector.

Note 13: Write the species name or strain name of the host.

Note 14: Write the containment measure level for each combination.

Note 15: Write the items which the minister verification notice determined must be reported and their results.

Note 16: Write necessary items to evaluate the safety of the experiment (i.e., unexpected phenomena and health risk to experimenters due to recombinant DNA experiments).

("Note xx" in the form can be deleted.)

(Form 5-1)

Application for Transfer/Receipt of Genetically Modified Living Organisms

MM/DD/YYYY

To the President of Kyoto University

Person responsible for the experiment	(Organization name and department name)	
	(Job title)	
	(Name)	

I hereby apply for approval to transfer or receive the following genetically modified living organisms (recombinants) as described in the attached plan.

Strain name of the genetically modified living organisms, etc. (recombinants) to be transferred or received.

(Form 5-2)

Plan for Transfer/Receipt of Genetically Modified Living Organisms

Applicant (Organization name/ department name/job title)

(Name)

Transferor/provider of genetically modified living organisms	Location of the organization/department of the transferor/provider		
	Organization name/Department name/Job title		
	Name		
	Genetically modified living organisms (recombinants) to be transferred and provided	Strain name	
		Characteristics of genetically modified living organisms (recombinants)	
	Developed experiment	Subject name	
		Date	
Approver			
Person who receives or acquires the genetically modified living organisms	Location of the organization/department of the person		
	Organization name/Department name/Job title		
	Name		
	Description of research in the organization		
	Purpose of use		

Provision of Information for Transfer/Provision/Commission of Genetically Modified Living Organisms

Person in charge of acceptance (recipient)

To *****

Person responsible for the experiment
(Organization name, department name, job title)
Address:
Name:
Contact: Tel:
Fax:
E-mail:

In accordance with Paragraph 1, Article 26 of the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, I hereby provide information for the transfer, etc. of the following genetically modified living organisms, etc. that are subject to Type 2 use, etc. at Kyoto University.

Strain name						
Characteristics of genetically modified living organisms	Names of organism species that provided nucleic acid					
	Names of donor nucleic acids					
	Whether or not a vector is used	Yes/No (indicate if Yes)				
	Host					
Kyoto University Organizational Approval No. Approval date (yyyy/mm/dd)		MM/DD/YYYY				
Containment measures required by Kyoto University		P1 P1A P1P	P2 P2A P2P	P3 P3A P3P	Special breeding section Special netted-house () () Indicate the level if apply.	Others
Containment measures required by law		P1 P1A P1P	P2 P2A P2P	P3 P3A P3P	Special breeding section/Minister-verified/Others Special netted-house () () Indicate the level if apply.	
Number of LMOs						
Transfer date (yyyy/mm/dd)		MM/DD/YYYY				
Purpose of transfer		Joint research/Transfer to another research institution, etc. Cryopreservation/Cleaning/Microorganism test/Others				
Detailed information (Note)		Yes () No				
Additional information (e.g., whether it is subject to Regulations related to the Enforcement of the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Genetically Modified Living Organisms, Article 16, (i), (ii) or (iv)).						

Note: In the cases where high-level containment measures or verification by the minister, etc. are required, or where the counterpart organization requests, detailed information (e.g., copy of experiment application of the University) shall be attached.

(Form 6)

Import Application

MM/DD/YYYY

To the President of Kyoto University

Person responsible
for the experiment

Organization name/

Department name _____

Job title _____

Name _____

I hereby apply with the necessary documents for approval by the competent minister concerning the import described below.

Type of organisms to be imported	
Usage of organisms to be imported	
Exporting country/region of the organisms to be imported.	