

PE/SOP2
Administrative Rules and Regulations of Database for Drug Use-Result Surveys

Approval signature

Date of Approval

Yasushi Nakano
 Chairperson of Group B

(month/day/year)

Issue	Date of delivery (month/day/year)	Date of enforcement (month/day/year)	Main points of revision
First issue	09/20/2005 September 20, 2005	09/20/2005 September 20, 2005	—
Second issue	07/18/2008 July 18, 2008	07/01/2008 July 1, 2008	User fee, data storage, data view
Third issue	08/27/2009 August 27, 2009	08/27/2009 August 27, 2009	Expansion of ranges of users Clarification of processes Inclusion of additional formats Inclusion of exclusion of liability
Fourth issue			

This Agreement in Japanese shall be an original document and if there is any difference in nuance or inconsistency between the Agreement in Japanese and the English translation or other English documents to be prepared in connection with this Agreement, the Agreement in Japanese will prevail in any respect.

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RAD-AR Council, Japan

Administrative Rules and Regulations for the Database for Drug Use-Results Surveys

1. Usage of the Database

1) Eligible Users

Using database service shall be principally provided to practitioners and researchers of the member companies of RAD-AR Council, Japan (hereinafter referred as RCJ) only. However, researchers from educational institutions and public research institutions (equivalent to independent administrative institutions, national and public hospitals, etc.), and non-member companies that provided their data shall be equally able to use the database as well as member companies.

2) Review of Applications for Approval of Using the Database

1. A person who is interested in using the database (hereinafter referred as applicant) shall file the Application Form for Using the Database for Drug Use-Results Surveys (Format 1) in the name of the chief researcher to Director-General of RCJ along with the study protocol. In addition, RCJ may require applicants who are from non-member companies to submit their personal identification documents along with the application form.

2. The following items shall be written in the study protocol at minimum:

Name and professional affiliation of the chief researcher and practitioner involved in the research, purpose of the research, duration of the research, articles to be analyzed, contents to be analyzed, evaluation methods of the analysis results, and intention to publish the study result.

3. Experts from the Ikuyaku-Academy Protocol Review Committee of RCJ shall review the application and the study protocol, and determine promptly whether the applicant may use the database or not. In addition, amendment of the study protocol may be required following review of submitted application.

4. RCJ shall inform promptly whether the applicant may use the database or not. Approval of usage shall be notified in writing with the Permission for Using the Database (Format 2).

3) Submission of the Study Report

Applicants shall submit the Study Report (Format 3) to RCJ immediately after completion of the study, regardless of intention to publish the result.

4) Publication of the Study Result

Publication of the study results shall be performed under the approval of RCJ, with review of the submitted pre-publication draft in advance. In addition, this stipulation shall remain in force after submission of the study report.

5) Usage fees for the Database

Using the database service shall be free of charge in principle. However, if any expenses associated with the usage occur, the actual expenses shall be collected.

6) Provision and Restitution of Data

Appropriate data for the contents of the study protocol shall be provided with a CD-ROM. The CD-ROM shall be returned immediately after completion of the study. Any data which is saved in

a personal computer should be deleted completely.

2. Storage of the Database

The original database shall be saved on a CD-ROM, and stored in a secure, locked location.

3. Reference of the Database

Employees of the member companies shall be able to access the database with a dedicated purpose computer at the RCJ office by submitting the Application form for Reference of the Database for Drug Use-Results Surveys (Format 4) to the Director-General of RCJ in advance. However, publication of contents of references or any removal of data is prohibited.

4. Confidentiality

RCJ and experts of Ikuyaku-Academy Protocol Review Committee shall keep in strict confidence any and all information which has been provided from applicants or which may have come to their knowledge in the process of review, and shall not disclose it to a third party.

5. Responsibility

1) Usage of the Database

RCJ shall not be responsible for any legal actions, complaints, obligations, expenses, costs, losses or damages which may directly or indirectly occur to the applicants by using the CD-ROM (including usage or reference). However, this shall not apply if the direct losses or damages arise due to intention or negligence of RCJ. This stipulation will survive to be valid after returning the CD-ROM and referring of the database.

6. Revision of Administrative Rules and Regulations

Revision of the administrative rules and regulations shall require the approval of the steering committee of RCJ. However, applicants should follow the revised contents when a revision of the rules and regulations come into force during their study periods.

7. Others

1) RCJ shall discuss disclosure of information which may have come to their attention by using the Database for Drug Use-Results Surveys or which has been provided from applicants to a third party in advance, and disclose it after receiving approval from the applicants.

2) Other events which are not mentioned in particular in the administrative roles and regulations, shall be discussed when each event occurs.

End of file

Establishment date September 20, 2005

4th Revision date June 28, 2011

Format 1

Date

RAD-AR Council, Japan
Application Form for Using the Database for Drug Use-Results Surveys

Mr. Tohru Ebihara, Director-General
RAD-AR Council, Japan

Applicant
Signature

Name

Professional affiliation

I hereby pledge as follows:

1. To use the particular information of the database as required, based on the study protocol.
2. Not to review each agent individually.
3. That RAD-AR Council, Japan and the applicants shall maintain all information confidential relevant to using database.
4. To comply with the Personal Information Protection Law.
5. To comply with the Administrative Rules and Regulations of Database for Drug Use-Result Surveys.

1. Database to be used (Please make a check in the appropriate box.)

- Database for Drug Use-Results Surveys of Antihypertensives
- Database for Drug Use-Results Surveys of Antibacterial agents
- Database for Drug Use-Results Surveys of Antihyperlipidemic agents

2. Duration of Research

From Month, 20yy to Month, 20yy

3. Articles to be analyzed (describe specifically as much as possible)

4. Study protocol (refer to attached document in detail)

5. Scheduled submitting period of the study report

Month, 20yy

Format 2

Date

For the Applicant

Tohru Ebihara, Director-General
RAD-AR Council, Japan

RAD-AR Council, Japan
Permission for Using the Database for Drug Use-Results Surveys

The filed study protocol has been examined and its contents approved. We hereby permit you to use the Database for Drug Use-Result Surveys as follows:

Date of application: Month Day, 20yy

Database to be used: Database for Drug Use-Results Surveys
(Antihypertensives / Antibacterial agents)

Duration of Research: From Month Day, 20yy to Month Day, 20yy

*Consult RCJ in advance if you need to extend the duration according to progress of the research.

Format 3

Date

RAD-AR Council, Japan
Study Report of Using the Database for Drug Use-Results Surveys

Mr. Tohru Ebihara, Director-General
RAD-AR Council, Japan

Reporter

Signature

Name

Professional affiliation

Since the study has finished as follows, I return the database herewith, in keeping with article 1. 6) of Administrative Rules and Regulations for the Database for Drug Use-Results Surveys. I hereby pledge to comply with the Administrative Rules and Regulations for the Database after returning the database.

1. Database which has been used (Please make a check in the appropriate box.)
 - Database for Drug Use-Results Surveys of Antihypertensives
 - Database for Drug Use-Results Surveys of Antibacterial agents
 - Database for Drug Use-Results Surveys of Antihyperlipidemic agents
2. Duration of Research
From Month, 20yy to Month, 20yy
3. Contents of the study (refer to the attached sheet in detail)
4. Scheduled for publication of the study
 - Intend to publish (schedule: Month, 20yy)
 - Do not intend to publish
 - Undecided

Format 4

Date

RAD-AR Council, Japan
Application form for Reference of the Database for Drug Use-Results Surveys

Mr. Tohru Ebihara, Director-General
RAD-AR Council, Japan

Applicant
Signature

Name

Professional affiliation

1. Database for reference (Please make a check in the appropriate box.)
 - Database for Drug Use-Results Surveys of Antihypertensives
 - Database for Drug Use-Results Surveys of Antibacterial agents
 - Database for Drug Use-Results Surveys of Antihyperlipidemic agents
2. Preferred date for reference
Day of the week, Month Day, Year, from 00:00 to 00:00
3. Name of person who references the database
(If another person refer to the database in place of the applicant or the applicant is accompanied by another person)

Format (internal regulations)

Date

Mr./Ms. XX
XX Co.,Ltd.
XX Division XX Group

Tohru Ebihara, Director-General
RAD-AR Council, Japan

Pharmacoepidemiology Committee of RAD-AR Council, Japan
Delegation of a Member of Ikuyaku-Academy Protocol Review Committee (Request)

We would hereby like you to cooperate with us as follows, regarding the matter above mentioned. We look forward to receiving your agreement.

Job title: Member of Ikuyaku-Academy Protocol Review Committee
Pharmacoepidemiology Committee of RAD-AR Council, Japan

Job contents: Review of validity of protocols for using the Database for Drug
Use-Results Surveys

Place to work: RAD-AR Council, Japan
(Address) Nihonbashi N Bldg.
1-4-2 Nihonbashi Horidomecho, Chuo-ku, Tokyo

Duration: From Month Day, 20yy to Month Day, 20yy

*The duration may be extended depending on progress of review.