

Stakeholder Committee on Usage of RERF's Stored Biosamples Committee's Advice

【Table of Contents】

1.	Introduction	1
2.	Details of meetings	2
3.	Outline of meetings	2
4.	Issues and advice from the committee	2

1. Introduction

The Atomic Bomb Casualty Commission (ABCC), the predecessor to the Radiation Effects Research Foundation (RERF), was established in 1947, and reorganized into RERF in 1975. RERF is the U.S.-Japan binational funding organization. Health effects from radiation among A-bomb survivors and their children in Hiroshima and Nagasaki have been studied over 70 years. This has been possible thanks only to collaboration from the survivors and their children. Study results based on such collaboration have greatly contributed to radiology, and the studies in Hiroshima and Nagasaki can be called globally unique research on medical effects of radiation.

On the other hand, in terms of research during the ABCC days, there have been criticism and opposition from the A-bomb survivors, such as “only research and no treatment” and “no disclosure of research results to the study participants.” RERF since the reorganization has prioritized the study participants’ human rights and personal information protection giving serious consideration to the way of providing information and the use of biological samples, but even 73 years after its establishment, distrust of ABCC-RERF seems to linger. One reason for this may be that RERF has not given full attention to public relations activities intended for the A-bomb survivors and the general public; to continue its research, RERF will have to obtain their understanding more than before.

Now, the extraordinary progress of life sciences in recent years has made it possible to elucidate life phenomena and disease states at the molecular/gene level. RERF has been provided valuable biological samples, such as blood, from the A-bomb survivors for many years. Molecular research involving such samples is believed to bring important progress not only in the field of radiology, but also in cancer research and medicine as a whole, contributing significantly to the health and well-being of humanity. RERF is carefully preparing for conducting such studies, but there are many challenges to solve.

One of the challenges is handling of personal information; in particular, the genomic information is the ultimate personal information inherited by the offspring and requires strict information management. Furthermore, in conducting research, it is necessary to fully explain research to the donors and obtain their consent for research cooperation, and relevant procedures also should be controlled strictly. In collaboration with researchers in Japan and abroad, it is essential to limit the use of biological specimens to research for peaceful purpose giving thought to the survivor's desire for peacefulness; preparation of a mechanism ensuring this is crucial for obtaining the A-bomb survivors’ understanding for research collaboration. To return the research result to the sample donors is yet another challenge.

In this context, the Stakeholder Committee on Usage of RERF's Stored Biosamples was established each in Hiroshima and Nagasaki to obtain objective opinions in terms of usage of

the biosamples stored by RERF. The committee's task is to provide advice on use of RERF's stored biosamples in genomic research and on the biosamples' cooperative use with domestic and international research organizations, and finally to gain understanding of the foundation's research activities from the general public as well as the A-bomb survivors. In accordance with the guidelines for establishing this committee, the RERF Chairman first nominated and appointed the chairs to the Hiroshima and Nagasaki Stakeholder Committees. The committee chairs nominated members from among local academic and legal experts, AHS participants, non-participant A-bomb survivors, and other persons deemed necessary, who were then appointed by the RERF Chairman. Establishing such a committee was the first of its kind in the history of RERF.

We as consulted members considered the point of consultation from RERF seriously and, as a result of discussions spanning about two years, compiled details of our advice and review in this report, as below.

2. Details of meetings

In Hiroshima, the first meeting was held on May 11, 2018, the second on September 6, 2018, the third on June 5, 2019, and the fourth on September 19, 2019. In Nagasaki, the first meeting was held on August 31, 2018, the second on December 18, 2018, and the third on October, 10, 2019.

On March 19, 2019, the joint meeting of Hiroshima and Nagasaki chairs and vice-chairs was held in Hiroshima. The second joint meeting was held via videoconference between Hiroshima and Nagasaki on May 1, 2020.

3. Outline of meetings

At the meetings, RERF explained the outline of its research, its stored biosamples, and the importance of and the need for future research using the stored biosamples. Subsequently, the committee members were requested to provide their comments. The issues discussed by the committee and advice on them covered a lot of ground; we divided them into seven categories attaching our advice to each issue as below.

4. Issues and advice from the committee

1) Establishment of relationship of trust with A-bomb survivors (AHS participants), improved provision of information, and returning research results

Advice 1:

One of the effective approaches to build trusting relationship with the AHS participants is to improve the method of information provision and the content of information to be provided. In the future, RERF should make effort to provide the participants with information useful for their health management. It is necessary for RERF to draft improvement plans for information provision and establish a framework to strengthen a relationship of trust with the study participants.

2) Enhancing the provision of information to A-bomb survivors (in general) and the general public

Advice 2:

RERF should make more efforts to provide information to A-bomb survivors and the general public to deepen their understanding of RERF research by introducing more effective approaches to enhance its PR activities.

3) Ways to exclude military research when conducting collaborative research with foreign countries

Advice 3:

RERF needs to develop the measures to eliminate military research to ensure that RERF can only conduct collaborative research with overseas institutes for peaceful purposes.

4) How to address ethical issues: Part 1 (Laws and regulations • guidelines)

Advice 4:

RERF should implement safety control by complying with the national ethical guidelines to conduct its research with considerable care. In addition, RERF should consider the uniqueness involved in the handling of A-bomb survivors' biosamples, and develop its own guidelines or charter in writing as a mechanism for the provision of biological samples for research.

5) How to address ethical issues: Part 2 (Consent to research)

Advice 5:

When obtaining consent for research using the stored biosamples, RERF should strive to provide the donors with detailed explanations to obtain their understanding. When obtaining consent from elderly A-bomb survivors, RERF must consider reducing their burden. When obtaining consent for individual studies after comprehensive consent had been obtained, RERF should review whether there are ways to simplify the procedures. RERF also needs to review possible solutions to the issue of the use of biological samples of the deceased survivors. Considering the uniqueness of RERF's study participants, RERF should consider the composition of the IRB and how to ensure the reliability of the IRB.

6) Various issues relating to genome analyses

Advice 6:

When conducting genome analysis, RERF needs to carefully identify the ways to explain the study participants about the research procedures and the extent and method of returning of genome analysis results. RERF should establish a system of genetic counseling and follow-up before initiating the study.

7) Other issues

Advice 7:

RERF should conduct research to produce results in accordance with the objectives stipulated in the RERF Articles of Incorporation while considering the sensitivities of A-bomb survivors, who have long aspired for peace.