

The 184th joint meeting of Human Investigation Committee and Ethics Committee for Genome Research

Date: September 30, 2011 (Friday), 9:00 - 11:15

Place Auditorium (Hiroshima), 3rd fl. meeting room (Nagasaki) (teleconference)

< Genome research review >

	Department	Research project title	Review results	Summary
1	Clinical Studies	Study on Genetic Background of Short QT	Approved	<p>◆ With regard to the explanation given in the Appendix 3, “Request for Cooperation,” descriptions regarding those with short QT syndrome should be restricted to the minimum necessary in order to minimize a sense of anxiety to be experienced by such individuals. The description, “...there may be disadvantages for you in employment, marriage, and insurance purchase...” should be watered down.</p> <p>◆ With a view to decreasing burden of donors, the two appended documents, “Agreement” and “Written Consent for the Genetic Analysis” should be combined due to overlapping between these two forms. An additional box for “use of epidemiological information stored at RERF” should be included under the sentence, “Please check the appropriate boxes below.” in the “Written Consent for the Genetic Analysis.”</p>
2	Clinical Studies	Study for the Epidemiological and Genetic Basis of Progressive Cardiac Conduction Defect	Approved	<p>◆ With regard to the explanation given in the Appendix 3, “Request for Cooperation,” descriptions regarding those with short QT syndrome should be restricted to the minimum necessary in order to minimize a sense of anxiety to be experienced by such individuals. The description, “...there may be disadvantages for you in employment, marriage, and insurance purchase...” should be watered down.</p> <p>◆ With a view to decreasing burden of donors, the two appended documents, “Agreement” and “Written Consent for the Genetic Analysis” should be combined due to overlapping between these two forms. An additional box for “use of epidemiological information stored at RERF” should be included under the sentence, “Please check the appropriate boxes below.” in the “Written Consent for the Genetic Analysis.”</p>
3	Clinical Studies	Revision to the consent form for AHS participants	Approved	<p>◆ The following items under 5-(1) should be included as common items for confirmation.: “Terms of future research,” “future research protocol will be available by request,” “publication of research results,” and “advantages and disadvantages from collaborating in research.”</p> <p>◆ The items 4. and 5. of the consent form include the expressions “samples (serum, plasma, blood cell, and urine)” and “samples,” which should be made consistent with the expressions used in the explanatory notes.</p>

*The above Research Protocol was approved after confirmation that the relevant modifications were made properly.