

## The 203rd meeting of Human Investigation Committee

Date: October 1, 2014 (Wednesday), 13:30 - 15:30

Place E-201(Hiroshima), 3rd fl. meeting room (Nagasaki) (teleconference)

### <Epidemiological research review >

	Department	Research project title	Review results	Summary
1	Clinical Studies	The association between subclinical hypothyroidism and cardiovascular risk factors according to age: an individual participant pooled analysis of large international cohort studies (Addendum to RP A10-08 “The association between subclinical thyroid dysfunction and cardiovascular disease and mortality: An individual participant pooled analysis of large international cohort studies”)	Approved	<ul style="list-style-type: none"> <li>◆ Concerning disposal of provided materials, it is necessary to confirm arrangements with collaborating research organizations.</li> <li>◆ It is necessary to explain the following items in the RP and make revisions of related checklists in a manner to reflect the actual status.               <ol style="list-style-type: none"> <li>1) Projected benefits/risks for study subjects</li> <li>2) Conflicts of interest</li> <li>3) Methods/period of storage of materials and methods of discarding materials (including the period following the study completion)</li> </ol> </li> </ul>
2	Clinical Studies	The relation between low thyroid function and anemia, and the impact of both conditions on adverse outcomes: Addendum to RP A10-08	Approved	<ul style="list-style-type: none"> <li>◆ With regard to “ Policy for selecting study subjects” of the application for ethical review, further detailed information, including the number of new subjects, should be provided.</li> <li>◆ It is necessary to explain the following items in the RP and make revisions of related checklists in a manner to reflect the actual status.               <ol style="list-style-type: none"> <li>1) Anonymization of materials (in the case of provision to outside)</li> <li>2) Conflicts of interest</li> <li>3) Necessity of storage of materials, storage period, and methods of discarding materials (including the period following the study completion)</li> </ol> </li> </ul>

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