

47th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–20:15, May 20, 2014 (Tuesday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-01	Research related to prognosis prediction method for colorectal cancer	New	Yes	Central Research Laboratories	Approved with conditions	Language of research plan revised
2	2014-02	Research related to detection of leukemia cells	New	Yes	Technology Development Div.	Approved with conditions	Approved in joint collaborator's ethics examination
3	2014-03	Research related to detection of leukemia cells	New	No	Technology Development Div.	Approved	None
4	2014-04	Research related to gene testing for chronic myelogenous leukemia	New	Yes	Technology Development Div.	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised Language of consent and explanation form revised
5	-	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Re-examine	Examine at next screening
6	2014-05	Evaluation of immunochemistry reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved	None
7	2014-06	Evaluation of immunochemistry reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved	None
8	2014-07	Evaluation of immunochemistry reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
9	2014-08	Research related to chronic hepatic disease	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
10	2014-09	Evaluation of hemostasis analyzer	New	Yes	Hemostasis Product Engineering	Approved	None
11	2014-10	Evaluation of hemostasis analyzer	New	Yes	Hemostasis Product Engineering	Approved	None
12	2014-11	Evaluation of hemostasis reagent	New	No	Hemostasis Product Engineering	Approved	None
13	2014-12	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved	None
14	-	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Re-examine	Examine at next screening
15	-	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Re-examine	Examine at next screening
16	-	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Re-examine	Examine at next screening
17	-	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Re-examine	Examine at next screening
18	2013-24	Evaluation of hemostasis analyzer and reagent	Renewal	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
19	2014-13	Research related to breast cancer prognosis prediction	New	Yes	Life Science Product Engineering	Approved with conditions	Language of research plan revised
20	2014-14	Research related to peripheral white blood cell morphology	New	Yes	Scientific Affairs	Approved with conditions	Language of consent and explanation form revised
21	2014-15	Research related to triglyceride deposit cardiomyovasculopathy	New	Yes	Scientific Affairs	Approved	None
22	2014-16	Evaluation of non-invasive hemoglobin analyzer	New	Yes	New Business Development	Approved with conditions	Language of consent and explanation form revised

48th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:30, July 18, 2014 (Friday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-19	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Re-examine	Re-examine with rapid screening
2	2014-20	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
3	2014-17	Research related to cervical cancer diagnosis method	New	Yes	Central Research Laboratories	Approved	None
4	2014-18	Research related to anemia differentiation	New	Yes	Technology Development Div.	Approved	None
5	2014-21	Evaluation of immunochemistry reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised
6	2014-22	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
7	2014-23	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2014-24	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	-	Application withdrawn
9	2014-25	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
10	2014-26	Research related to lung cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Language of consent and explanation form revised
11	2013-05	Evaluation of cancer reagent effectiveness	Renewal	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination

49th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:10, September 9, 2014 (Tuesday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted; underlined personnel absent)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-27	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Re-examination	Re-examine with rapid screening
2	2014-28	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised
3	2014-29	Research related to effectiveness of hemostasis reagent monitoring	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
4	2014-30	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
5	2014-31	Research related to detection of leukemia cells	New	Yes	Technology Development Div.	Approved	None
6	2014-32	Research related to new testing method for hematopoietic stem cell transplants	New	Yes	Technology Development Div.	Approved with conditions	Approved in joint collaborator's ethics examination
7	2014-33	Research related to genetic testing for chronic myelogenous leukemia	New	Yes	Technology Development Div.	Approved with conditions	Approved in joint collaborator's ethics examination

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2014-34	Research related to lung cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
9	2014-35	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved	None
10	2014-36	Research related to cervical cancer screening system	New	No	UB Product Engineering	Approved	None
11	2014-37	Research related to new immunochemistry reagent test parameters	New	No	Immunology & Chemistry Product Engineering	Approved with conditions	Language of research plan revised
12	2014-38	Evaluation of hemostasis reagent performance	New	No	Sysmex International Reagents Corporation	Approved	None

50th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:40, November 11, 2014 (Tuesday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-39	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved	None
2	2014-40	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
3	2014-41	Evaluation of urinalysis analyzer	New	Yes	UB Product Engineering	Approved with conditions	Language of research plan revised Language of consent and explanation form revised
4	2014-42	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
5	2014-43	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved	None
6	2014-44	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Language of research plan revised
7	2014-45	Research related to immunochemistry reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2014-46	Research related to breast cancer prognosis prediction	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
9	2014-47	Research related to the relationship between uncultured bacteria and urinary tract infections	New	Yes	Scientific Affairs	Approved	None
10	2014-48	Research related to new immunochemistry measurement technologies	New	No	Technology Development Div.	Approved	None

51st Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:40, January 21, 2015 (Wednesday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted; underlined personnel absent)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-49	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised
2	2014-50	Research related to activated neutrophils	New	Yes	Scientific Affairs	Approved	None
3	2014-51	Research related to immature red blood cells	New	No	Scientific Affairs	Approved	None
4	2014-52	Evaluation of urinalysis analyzer performance	New	Yes	UB Product Engineering	Approved with conditions	Language of research plan revised
5	2014-53	Cervical cancer screening system research	New	No	UB Product Engineering	Approved	None
6	2014-54	Evaluation of immunochemistry measurement reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
7	2014-55	Research related to lung cancer testing reagent	New	Yes	Life Science Product Engineering	Approved with conditions	Language of research plan revised Language of consent and explanation form revised
8	2014-34	Research related to lung cancer diagnosis method	Ren.	Yes	Life Science Product Engineering	-	Application withdrawn

52nd Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:30, March 17, 2015 (Wednesday)
 Location: Conference Room C, 6F, Sysmex Corporation headquarters
 Committee members: Fumio Kubota (committee chair), Yasuhiro Oyama (committee deputy chair), Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto, Katsuyuki Nakazawa, Takako Nakajima
 Personal information manager: Kayo Akagi
 Secretariat: Teruya Matsumoto

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2014-56	Research related to skin cancer immune reaction	New	Yes	FCM Business Planning	Approved with conditions	Approved in joint collaborator's ethics examination
2	2014-57	Research related to diagnosis method for asthma airway hyper-responsiveness	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborator's ethics examination
3	2014-58	Research related to the effectiveness of hemostasis reagent monitoring	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised
4	2014-59	Evaluation of urinalysis analyzer effectiveness	New	Yes	UB Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Language of research plan revised
5	2014-60	Research related to urinary cholesterol measurement	New	Yes	UB Product Engineering	Re-examine	Re-examine after language of research plan revised
6	2014-61	Research related to saliva cholesterol measurement	New	Yes	UB Product Engineering	Re-examine	Re-examine after language of research plan revised

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2014-62	Research related to breast cancer prognosis prediction	New	Yes	Life Science Product Engineering	Approved	None
8	2014-63	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination Annual progress report
9	2014-64	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
10	2014-65	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
11	2014-66	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved	None
12	2014-67	Evaluation of hemostasis reagent	New	Yes	Hemostasis Product Engineering	Approved	None
13	2014-68	Research related to breast cancer prognosis prediction	New	Yes	Technology Development Div.	Approved with conditions	Approved in joint collaborator's ethics examination
14	2014-34	Research related to lung cancer diagnosis method	Renewal	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
15	2014-55	Research related to lung cancer diagnosis method	Renewal	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
16	2014-69	Research related to minimally invasive blood glucose measurement method	New	No	Central Research Laboratories	Approved	None
17	2014-70	Research related to new cell measurement method	New	No	Central Research Laboratories	Approved	None
18	2014-71	Evaluation of hematology analyzer	New	No	Hematology Product	Approved	None

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
					Engineering		
19	2014-72	Evaluation of hematology analyzer	New	No	Hematology Product Engineering	Approved	None
20	2014-74	Evaluation of immunochemistry reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
21	2014-73	Evaluation of clinical chemistry reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
22	2014-75	Evaluation of immunochemistry reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
23	2014-76	Research related to standard instrument traceability	New	No	Scientific Affairs	Approved	None
24	2014-77	Quality evaluation of hemostasis reagent	New	No	Symex International Reagents Corporation	Approved	None
25	2014-78	Quality evaluation of hemostasis reagent	New	No	Symex International Reagents Corporation	Approved	None
26	2014-83	Immunochemistry reagent performance and quality evaluation	New	No	Immunology & Chemistry Product Engineering	Approved	None
27	2014-79	Research related to hematology reagent and instrument measurement accuracy and reproducibility enhancement	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination

Research Plan Number and Research Content				Joint Collaborator Present	Division Performing	Result	Remarks
28	2014-80	Research related to urinalysis reagent and instrument measurement accuracy and reproducibility enhancement	New	Yes	UB Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
29	2014-81	Research related to Immunology and clinical chemistry reagent and instrument measurement accuracy and reproducibility enhancement	New	Yes	Immunology & Chemistry Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination
30	2014-82	Research related to hemostasis reagent and instrument measurement accuracy and reproducibility enhancement	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborator's ethics examination