

53th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:10, May 20, 2015 (Thursday)  
 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: Daisuke Usuki

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-01	Research related to testing for diabetes mellitus	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised. Confirmation of method of obtaining informed consent.
2	2015-02	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved	None
3	2015-03	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2015-04	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
5	2015-05	Development of measurement method using flow cytometer	New	Yes	Research & Industry Business	Approved	None
6	2015-06	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
7	2015-07	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
8	2015-08	Evaluation of hemostasis analyzer and reagent	New	No	Hemostasis Product Engineering	Approved	None
9	2015-09	Evaluation of hemostasis analyzer and reagent	New	No	Scientific Affairs	Approved	None
10	2015-10	Research related to hematology analyzer measurement method	New	No	Central Research Laboratories	Approved	None
11	2015-11	Evaluation of hematology analyzer measurement method	New	Yes	Regulatory Affairs and Quality Assurance	Approved with conditions	Approved in joint collaborators' ethics examination.

54th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:20, July 23, 2015 (Thursday)  
 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: Daisuke Usuki

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-12	Research related to pancreatic cancer diagnosis method	New	Yes	Central Research Laboratories	Approved	None
2	2015-13	Research related to kidney disease diagnosis method	New	Yes	Technology Development Div.	Approved	None
3	2015-14	Evaluation of urinalysis analyzer	New	Yes	UB Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2015-15	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
5	2015-16	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
6	2015-17	Consideration of issues related to hematology analyzer	New	Yes	Scientific Affairs	Approved with conditions	Language of research plan revised.
7	2015-18	Research related to digestive organ cancer	New	Yes	Research & Industry Business	Approved with conditions	Approved in joint collaborators' ethics examination.
8	2015-19	Research related to skin cancer	New	Yes	Research & Industry Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation material revised.
9	2015-20	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
10	2015-21	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
11	2015-22	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
12	2015-23	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
13	2015-24	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
14	2015-25	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
15	2015-26	Evaluation of hemostasis analyzer and reagent	New	No	Hemostasis Product Engineering	Approved with conditions	Language of informed consent document revised.
16	2014-46	Research related to breast cancer diagnosis method	Renewal	Yes	Life Science Product Engineering	Approved	None

55th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:15, September 14, 2015 (Monday)  
 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: Daisuke Usuki

(Honorifics omitted)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-27	Research related to glaucoma diagnosis method	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
2	2015-28	Research related to rheumatoid arthritis diagnosis method	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
3	2015-29	Research related to breast cancer diagnosis method	New	Yes	Central Research Laboratories	Approved with conditions	Language of information disclosure document revised.
4	2015-30	Evaluation of urinalysis analyzer	New	Yes	UB Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
5	2015-31	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved	None
6	2015-32	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
7	2015-33	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Submitted informed consent document.
8	2015-34	Evaluation of hemostasis analyzer and reagent	New	Yes	Scientific Affairs	Re-examine	Examine at next and subsequent screenings.
9	2015-35	Evaluation of hemostasis analyzer	New	Yes	Scientific Affairs	-	Application withdrawn.
10	2015-36	Evaluation of hemostasis analyzer	New	Yes	Scientific Affairs	Approved	None
11	2015-37	Research related to hematopoietic cancer	New	Yes	Research & Industry Business	Approved with conditions	Approved in joint collaborators' ethics examination.
12	2015-38	Application development of flow cytometer	New	No	Research & Industry Business	Approved	None
13	2015-39	Research related to blood glucose diagnosis method	New	No	Central Research Laboratories	Approved	None
14	2015-40	Research related to gene testing technologies	New	No	Technology Development Div.	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
15	2015-41	Evaluation of cervical cancer diagnosis method	New	No	UB Product Engineering	Approved	None



56th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:30, November 17, 2015 (Tuesday)  
 Location: Conference Room 602, 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: Daisuke Usuki

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-43	Research related to osteosarcoma diagnosis Method	New	Yes	Central Research Laboratories	Approved	None
2	2015-44	Research related to iPS cells	New	Yes	Central Research Laboratories	Approved	None
3	2015-46	Research related to organ perfusion culture system	New	Yes	Central Research Laboratories	Approved	None
4	2015-47	Research related to organ perfusion culture system	New	No	Central Research Laboratories	Approved	None
5	2015-42	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Collaborators added to be examined with rapid screening as soon as the documents are set.
6	2015-51	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2015-50	Evaluation of hemostasis analyzer and reagent	New	Yes	Scientific Affairs	Approved	None
8	2015-48	Evaluation of immunochemistry reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
9	2015-49	Evaluation of immunochemistry reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None

57th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:00, January 21, 2016 (Thursday)  
 Location: Conference Room 602 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: Daisuke Usuki

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-53	Research related to lung cancer diagnosis method	New	Yes	Central Research Laboratories	Approved	Collaborators added to be examined with rapid screening as soon as the documents are set.
2	2015-54	Research related to liver cancer diagnosis Method	New	Yes	Central Research Laboratories	Approved	None
3	2015-55	Research related to genome diagnostics	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2015-65	Research related to iPS cells	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2015-56	Research related to cervical cancer diagnosis method	New	Yes	UB Product Engineering	Approved with conditions	Submission of joint collaborators' education records.
6	2015-57	Research related to testing method for immunochemistry	New	Yes	Immunology & Chemistry Product Engineering	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2015-59	Research related to breast cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
8	2015-58	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Language of research plan revised.
9	2015-63	Research related to testing for diabetes	New	Yes	Hematology Product Engineering	Approved with conditions	Submission of joint collaborators' examination proxy statement.
10	2015-60	Research related to respiratory disease diagnosis method	New	No	Central Research Laboratories	Approved	None
11	2015-61	Research related to testing for diabetes	New	No	Technology Development Div.	Approved	None
12	2015-62	Evaluation of hemostasis analyzer and reagent	New	No	Hemostasis Product Engineering	Approved	None

58th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: : 17:00–19:50, March 24, 2016 (Thursday)  
 Location: Conference Room 602, 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: Daisuke Usuki

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2015-66	Research related to genetic testing method	New	Yes	Technology Development Div.	Approved	Approved in joint collaborators' ethics examination.
2	2015-68	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
3	2015-69	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2015-70	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2015-71	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination. Collaborators added to be examined with rapid screening as soon as the documents are set.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
6	2015-90	Research related to colorectal cancer diagnosis method	New	Yes	Life Science Product Engineering	Approved with conditions	Approved in joint collaborators' ethics examination.
7	2015-72	Research related to testing method for leukemia	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination.
8	2015-73	Evaluation of hematology analyzer	New	Yes	Hematology Product Engineering	Approved	None
9	2015-74	Evaluation of urinalysis analyzer	New	Yes	UB Product Engineering	Approved	None
10	2015-75	Evaluation of immunochemistry analyzer and reagent	New	Yes	Immunology & Chemistry Product Engineering	Approved	None
11	2015-76	Evaluation of hematology analyzer	New	No	Hematology Product Engineering	Approved	None
12	2015-77	Evaluation of hematology analyzer	New	No	Hematology Product Engineering	Approved	None
13	2015-78	Evaluation of hemostasis analyzer and reagent	New	No	Hemostasis Product Engineering	Approved	None
14	2015-79	Evaluation of urinalysis analyzer	New	No	UB Product Engineering	Approved	None
15	2015-89	Evaluation of immunochemistry test parameters and reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
16	2015-85	Research related to new immunochemistry reagent test parameters	New	No	Immunology & Chemistry Product Engineering	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
17	2015-87	Evaluation of immunochemistry analyzer and reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
18	2015-86	Evaluation of immunochemistry analyzer and reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
19	2015-88	Evaluation of immunochemistry analyzer and reagent	New	No	Immunology & Chemistry Product Engineering	Approved	None
20	2015-80	Evaluation of the next reference counter	New	No	Scientific Affairs	Approved	None
21	2015-81	Ensuring and verification of standard analyzers traceability	New	No	Scientific Affairs	Approved	None
22	2015-82	Development of the measurement method with using flow cytometer	New	No	Research & Industry Business	Approved	None
23	2015-83	Quality evaluation of hemostasis reagent	New	No	Sysmex International Reagents Corporation	Approved	None
24	2015-84	Quality evaluation of hemostasis reagent	New	No	Sysmex International Reagents Co., Ltd	Approved	None

Rapid Screening Results, Research Ethics Examination Committee, Sysmex Corporation

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Examination Period	Result	Remarks
1	2015-52	Research related to testing method for immunochemistry	New	Yes	Immunology & Chemistry Product Engineering	2015/11/13 -11/20	Approved	None
2	2015-64	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	2015/12/18 -2016/1/5	Approved	None
3	2015-67	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	2016/3/16 -3/25	Approved	None
4	2015-91	Evaluation of hemostasis analyzer and reagent	New	Yes	Hemostasis Product Engineering	2016/3/17 -3/25	Approved	None