

65th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:30, May 25, 2017 (Thursday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto(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	2017-01	Research related to evaluation of hematology analyzer	New	Yes	HU Business Development	Approved	Language of informed consent document revised.
2	2017-02	Research related to breast cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Confirm how to create provision record
3	2017-03	Evaluation of Immunological test	New	Yes	Central Research Laboratories	Approved	None
4	2017-04	Application development of flow cytometer	New	Yes	Scientific Affairs	Approved	None
5	2017-05	Application development of flow cytometer	New	No	Scientific Affairs	Approved	None
6	2017-06	Evaluation of hematology analyzer	New	No	Engineering 2	Approved	None
7	2017-07	Evaluation of hematology analyzer	New	No	Engineering 2	Approved	None
8	2017-08	Evaluation of coagulation analyzer	New	No	Engineering 2	Approved	None
9	2017-09	Evaluation of coagulation analyzer and reagent	New	No	Engineering 2	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
10	2017-10	Evaluation of cytoscreening technology	New	No	Central Research Laboratorise	Approved	None
11	2015-29	Research related to cancer diagnosis method	Renewal	Yes	Central Research Laboratorise	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.

EOD

66th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:50, July 18, 2017 (Tuesday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto (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	2017-16	Research related to stomach cancer diagnosis method	New	Yes	Central Research Laboratorise	Approved with conditions	Approved in joint collaborators' and rerated institution ethics examination.
2	2017-17	Development of new blood test diagnostic method	New	Yes	HU Business Development	Approved with conditions	Language of research plan revised. Language of informed consent document revised.
3	2017-18	Research related to coagulation test	New	Yes	ICH Business Development	Approved with conditions	Language of research plan revised.
4	2017-19	Development of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
5	2017-20	Development of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Language of informed consent document revised.
6	2017-21	Development of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Language of informed consent document revised.
7	2017-22	Research of microinvasive blood glucose measurement	New	No	Clinical Innovation	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2017-23	Evaluation of coagulation analyzer	New	No	Engineering 2	Approved with conditions	Language of research plan revised.

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67th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–20:10, September 14, 2017 (Thursday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto (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	2016-33	Research related to cancer diagnosis method	Renewal	Yes	Central Research Laboratorise	Approved	None
2	2014-40	Evaluation of hematology analyzer	Renewal	Yes	Engineering 1	Approved	None
3	2017-28	Research related to breast cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
4	2017-29	Research related to breast cancer diagnosis method	New	Yes	LS Business	Approved	None
5	2017-30	Research of microinvasive blood glucose measurement	New	Yes	Clinical Innovation	Approved with conditions	Confirmation of research plan.
6	2017-32	Evaluation of coagulation analyzer	New	Yes	ICH Business Development	Approved with conditions	Language of presentation document revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2017-33	Evaluation of coagulation analyzer	New	Yes	ICH Business Development	Approved with conditions	Language of presentation document and application document revised.
8	2017-34	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised. Confirmation of informed consent document.
9	2017-35	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Confirmation of informed consent document.
10	2017-36	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Language of presentation document and research plan revised.
11	2017-37	Evaluation of coagulation analyzer	New	Yes	Engineering 2	Approved	Approved in joint collaborators' ethics examination.
12	2017-38	Research related to testing for diabetes mellitus	New	Yes	Scientific Affairs	Approved with conditions	Language of presentation document and research plan revised. Approved in joint collaborators' ethics examination.
13	2017-39	Research related to testing for diabetes mellitus	New	Yes	Scientific Affairs	Approved with conditions	Language of research plan and informed consent document revised. Approved in joint collaborators' ethics examination.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
14	2017-40	Research of hematology analyzer	New	No	Scientific Affairs	Approved with conditions	Confirmation of research plan. Language of research plan and informed consent document revised.
15	2017-41	Research related to cancer monitoring method	New	No	Central Research Laboratorise	Approved	None

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68th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:10, November 21, 2017 (Thursday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto (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	2017-43	Research related to cancer monitoring method	New	Yes	Central Research Laboratorise	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
2	2017-44	Research related to cancer monitoring method	New	Yes	Central Research Laboratorise	Approved	None
3	2017-45	Research related to cytoscreening	New	Yes	Technology Development	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised. Language of informed consent document revised.
4	2017-46	Evaluation of hematology analyzer	New	No	Engineering 1	Approved with conditions	Language of presentation document and research plan revised.

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69th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:00, January 25, 2018 (Thursday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto (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	2017-53	Research related to drug eruption diagnosis method	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination.
2	2017-54	Evaluation of breast cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised. Language of informed consent document revised
3	2017-55	Research related to lung cancer diagnosis method	New	Yes	Central Research Laboratorise	Approved with conditions	Approved in joint collaborators' ethics examination. Language of application document revised
4	2017-56	Research related to genome diagnosis	New	Yes	Central Research Laboratorise	Approved with conditions	Language of presentation document and research plan revised. Language of informed consent document revised
5	2017-57	Research related to breast cancer and Prostate cancer diagnosis method	New	Yes	Central Research Laboratorise	Approved with conditions	Approved in joint collaborators' ethics examination.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
6	2017-58	Development of cytoscreening technology	New	Yes	Technology Development	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
7	2017-59	Evaluation of immunochemistry analyzer	New	No	Technology Development	Approved with conditions	Language of informed consent document revised
8	2017-61	Evaluation of coagulation reagent	New	No	Engineering 1	Approved	None

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70th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:40, March 20, 2018 (Tuesday)
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters
 Committee members: Kenji Tsujimoto (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	2017-72	Evaluation of hematology analyzer	New	Yes	Engineering 1	Approved	Approved in joint collaborators' ethics examination.
2	2017-73	Evaluation of urinalysis analyzer and reagent	New	Yes	Engineering 2	Approved	Approved in joint collaborators' ethics examination.
3	2017-74	Evaluation of immunochemistry analyzer and reagent	New	Yes	Engineering 1	Approved	Approved in joint collaborators' ethics examination.
4	2017-64	Research of microinvasive blood glucose measurement	New	Yes	Technology Development	Approved with conditions	Language of presentation document and research plan revised.
5	2017-65	Evaluation of cervical cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised
6	2017-66	Evaluation of endometrial cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised.
7	2017-67	Evaluation of cervical cancer and endometrial cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2017-71	Research related to evaluation of hematology analyzer	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination.
9	2017-69	Research related to biliary tract cancer diagnosis method	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised. Language of research plan and other documents revised.
10	2017-70	Evaluation of coagulation analyzer	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised.
11	2017-76	Evaluation of hematology analyzer	New	No	Engineering 1	Approved with conditions	Confirmation of research plan.
12	2017-77	Evaluation of hematology analyzer	New	No	Engineering 1	Approved with conditions	Language of research plan revised. Confirmation of research plan.
13	2017-78	Evaluation of Immunochemistry reagent	New	No	Engineering 1	Approved with conditions	Confirmation of research plan.
14	2017-79	Evaluation of immunochemistry reagent	New	No	Engineering 1	Approved with conditions	Confirmation of research plan.
15	2017-80	Evaluation of immunochemistry reagent	New	No	Engineering 1	Approved with conditions	Confirmation of research plan.
16	2017-80	Evaluation of coagulation reagent	New	No	Engineering 1	Approved with conditions	Confirmation of research plan.
17	2017-75	Development of dementia diagnosis method technology	New	No	Central Research Laboratorise	Approved with conditions	Language of informed consent document revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
18	2017-82	Ensuring and verification of standard analyzers traceability	New	No	Scientific Affairs	Approved	None
19	2017-83	Evaluation of the next reference counter	New	NO	Scientific Affairs	Approved	None
20	2017-84	Verification of standard analyzers traceability	New	No	Scientific Affairs	Approved	None
21	2017-85	Obtain evidence data of post-marketing products	New	No	Scientific Affairs	Approved	None
22	2017-86	Evaluation of coagulation reagent	New	No	Sysmex International Reagents Corporation	Approved	None
23	2017-87	Evaluation of coagulation reagent	New	No	Sysmex International Reagents Corporation	Approved	None

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Rapid Screening Results, Research Ethics Examination Committee, Sysmex Corporation

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Examination period	Result	Remarks
1	2017-11	Evaluation of hematology analyzer	New	Yes	Engineering 1	2017/5/8-5/11	Approved	None
2	2017-12	Development of infection diagnostic method	New	Yes	HU Business Development	2017/5/18-5/31	Approved	None
3	2017-13	Evaluation of immunochemistry analyzer and reagent	New	Yes	Engineering 1	2017/6/6-6/8	Approved	None
4	2017-14	Research related to Coagulation test	New	Yes	ICH Business Development	2016/6/9-6/20	Approved	None
5	2017-15	Application development of flow cytometer	New	Yes	HU Business Development	2017/6/14-6/20	Approved	None
6	2017-24	Evaluation of coagulation reagent	New	Yes	Engineering 1	2017/7/3-7/7	Approved	None
7	2017-25	Evaluation of coagulation reagent	New	Yes	Engineering 1	2017/7/3-7/7	Approved	None
8	2017-26	Evaluation of coagulation analyzer	New	Yes	Engineering 1	2017/7/3-7/7	Approved	None
9	2017-27	Evaluation of coagulation analyzer	New	Yes	Engineering 2	2017/8/21-8/25	Approved	None
10	2017-42	Evaluation of colon cancer diagnosis method	New	Yes	LS Business	2017/9/1-9/5	Approved	None
11	2017-47	Evaluation of immunochemistry analyzer and reagent	New	Yes	Engineering 1	2017/11/10-11/21	Approved	None
12	2017-48	Development of cytoscreening technology	New	Yes	Technology Development	2017/11/16-11/21	Approved	None
13	2017-49	Research related to cancer diagnosis method	New	Yes	Bio-Diagnostic Reagent Technology Center	2017/11/17-11/29	Approved	None
14	2017-50	Evaluation of coagulation analyzer	New	Yes	Engineering 1	2017/12/6-12/15	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Examination period	Result	Remarks
15	2017-51	Research related to cancer diagnosis method	New	Yes	Central Research Laboratorise	2017/12/19-12/28	Approved	None
16	2017-60	Research related to Immunological test	New	Yes	Engineering 1	2018/2/28-3/1	Approved	None
17	2017-68	Research related to diabetes mellitus diagnosis method	New	Yes	Clinical Innovation	2018/3/7	Approved	None
18	2017-88	Research related to immunochemistry reagent	New	Yes	Technology Strategy	2018/3/1-3/7	Approved	None
19	2017-90	Evaluation of immunochemistry analyzer	New	Yes	Scientific Affairs	2018/3/12-3/19	Approved	None
20	2017-89	Evaluation of cervical cancer diagnosis method	New	Yes	Clinical Innovation	2018/3/8-3/14	Approved	None
21	2017-91	Research of new biomarker	New	Yes	Technology Strategy	2018/3/15-3/20	Approved	None
22	2017-92	Research related to Heart disease diagnosis method	New	Yes	Central Research Laboratorise	2018/3/16-3/20	Approved	None

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