

71th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:30, May 29, 2018 (Tuesday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasuhiro Oyama (committee deputy chair),  
 Muneo Yabuki, Mika Tochiwara, 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 or Present	Division Performing	Result	Remarks
1	2018-06	Research related to coagulation test	New	Yes	ICH Business Development	Approved with conditions	Confirmation of research plan and informed consent document. Language of presentation document revised.
2	2018-07	Research related to coagulation test	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised. Confirmation of research plan.
3	2018-08	Evaluation of lung cancer diagnosis method	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2018-09	Research related to cytoscreening	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2018-10	Evaluation of cancer diagnosis method	New	No	Central Research Laboratories	Approved	None
6	2018-11	Construction of traceability system	New	No	Engineering 1	Approved	None

Research Plan Number and Content				Joint Collaborat or Present	Division Performing	Result	Remarks
7	2018-12	Application development of flow cytometer	New	No	Business Strategy Development	Approved with conditions	Language of presentation document and research plan revised.

EOD

72th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:30, July 13, 2018 (Friday)  
 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, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2018-17	Evaluation of hematology analyzer	New	Yes	Scientific Affairs	Approved with conditions	Language of research plan and other documents revised.
2	2018-18	Evaluation of coagulation analyzer	New	No	Engineering 2	Approved	None
3	2018-19	Research related to atopic dermatitis diagnosis method	New	Yes	Technology Development	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2018-20	Research related to coagulation test	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2018-21	Research related to coagulation test	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination.
6	2017-30	Research related to testing for diabetes mellitus	Renewal	Yes	Clinical Innovation	Approved with conditions	Approved in joint collaborators' ethics examination.

EOD

73th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:40, September 18, 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, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2018-26	Evaluation of hematology analyzer	New	Yes	Engineering 1	Approved with conditions	Language of presentation document revised.
2	2018-27	Evaluation of hematology analyzer	New	Yes	Engineering 1	Approved with conditions	Language of presentation document and research plan revised.
3	2018-28	Research related to urinalysis analyzer	New	Yes	Scientific Affairs	Re-examine	Language of research plan revised.
4	2018-29	Research related to coagulation test	New	Yes	ICH Business Development	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
5	2018-30	Software development of hematology analyzer	New	No	HU Business Development	Approved	Language of presentation document and research plan revised.
6	2018-31	Performance evaluation of hematology analyzer	New	No	Manufacturing Management	Approved with conditions	Language of presentation document and research plan revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2018-32	Evaluation of cancer diagnosis method	New	No	Central Research Laboratories	Approved with conditions	Language of presentation document and research plan revised.
8	2017-82	Ensuring and verification of standard analyzers traceability	New	No	Scientific Affairs	Re-examine	Language of research plan revised.

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74th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:30, November 21, 2018 (Wednesday)  
 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, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2018-37	Research of hematology analyzer	New	Yes	Business Strategy Development	Approved	Language of presentation document and research plan revised. Approved in joint collaborators' ethics examination.
2	2018-38	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of informed consent document revised.
3	2018-39	Evaluation of coagulation reagent	New	No	Engineering 1	Approved	Language of informed consent document revised.
4	2018-40	Application development of flow cytometer	New	No	Scientific Affairs	Approved	Language of presentation document and research plan revised.

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75th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:30, January 23, 2019 (Wednesday)  
 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, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2017-28	Research related to breast cancer diagnosis method	New	Yes	LS Business	Approved	None
2	2018-47	Evaluation of cancer diagnosis method	New	Yes	Central Research Laboratories	Approved	Approved in joint collaborators'ethics examination.
3	2018-48	Research related to urinalysis analyzer	New	Yes	Scientific Affairs	Approved	Language of research plan and informed consent document revised.
4	2018-49	Evaluation of new primary care products	New	Yes	Business Strategy Development	Approved	Approved in joint collaborators'ethics examination. Language of presentation document and research plan revised.

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76th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–20:45, March 1, 2018 (Friday)  
 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, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2018-52	Evaluation of hematology analyzers and reagents	New	Yes	Engineering 1	Approved	Approved in joint collaborators' ethics examination.
2	2018-53	Evaluation of urinalysis analyzer and reagent	New	Yes	Engineering 2	Approved	Approved in joint collaborators' ethics examination.
3	2018-54	Evaluation of immunochemistry analyzer and reagent	New	Yes	Engineering 1	Approved	Approved in joint collaborators' ethics examination.
4	2018-55	Evaluation of coagulation analyzer	New	Yes	Engineering 2	Approved	Approved in joint collaborators' ethics examination.
5	2018-56	Evaluation of hematology analyzer	New	No	Engineering 1	Re-examine	Language of research plan revised.
6	2018-57	Evaluation of hematology analyzer	New	No	Engineering 1	Re-examine	Language of research plan revised.
7	2018-58	Evaluation of immunochemistry reagent	New	No	Engineering 1	Approved	Language of research plan revised.



Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
8	2018-59	Evaluation of immunochemistry reagent	New	No	Engineering 1	Approved	None
9	2018-60	Evaluation of immunochemistry reagent	New	No	Engineering 1	Approved	Language of informed consent document revised.
10	2018-61	Ensuring and verification of standard analyzers traceability	New	No	Scientific Affairs	Approved	None
11	2018-62	Evaluation of the next reference counter	New	No	Scientific Affairs	Approved	Language of informed consent document revised.
12	2018-63	Verification of standard analyzers traceability	New	No	Scientific Affairs	Approved	Language of informed consent document revised.
13	2018-64	Evaluation of coagulation reagent	New	No	Sysmex International Reagents Corporation	Approved	Language of informed consent document revised.
14	2018-65	Evaluation of coagulation reagent	New	No	Sysmex International Reagents Corporation	Approved	Language of research plan and informed consent document revised.
15	2018-66	Verification of standard analyzers traceability	New	No	Clinical Innovation	Approved	Language of presentation document and research plan and informed consent document revised.
16	2018-67	Evaluation of cancer diagnosis method	New	No	Clinical Innovation	Approved	Language of informed consent document revised.
17	2018-68	Evaluation of gene testing technologies	New	No	LS Business	Approved	Language of presentation document and research plan revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
18	2018-69	Research related to stomach cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
19	2018-70	Research related to colon cancer diagnosis method	New	Yes	LS Business	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
20	2018-71	Research related to Hematopoietic stem cell transplantation diagnosis method	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
21	2018-72	Research related to atopic dermatitis diagnosis method	New	Yes	Technology Development	Approved	None
22	2018-73	Research related to Improve the performance of medical antibodies	New	Yes	Technology Strategy	Approved with conditions	Approved in joint collaborators' ethics examination.
23	2018-74	Research related to cancer diagnosis method	New	Yes	Technology Strategy	Approved with conditions	Approved in joint collaborators' ethics examination.

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Rapid Screening Results, Research Ethics Examination Committee, Sysmex Corporation

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
1	2018-01	Evaluation of coagulation analyzer	New	Yes	Engineering 2	2018/4/5 ~4/10	Approved	None
2	2018-02	Evaluation of gene testing technologies	New	Yes	LS Business	2018/4/6 ~4/12	Approved	None
3	2018-03	Evaluation of gene testing technologies	New	Yes	LS Business	2018/4/6 ~4/12	Approved	None
4	2018-04	Evaluation of coagulation analyzer	New	Yes	Engineering 2	2018/4/2 5~5/11	Approved	None
5	2018-05	Research related to urinalysis analyzer	New	Yes	Engineering 2	2018/4/2 6~ 2018/5/1 1	Approved	None
6	2018-13	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	2018/5/7 ~5/11	Approved	None
7	2018-15	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	2018/5/3 1~6/15	Approved	None
8	2018-16	Evaluation of cervical cancer screening system	New	Yes	Clinical Innovation	2018/6/1 ~6/15	Approved	None
9	2018-14	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	2018/5/3 1~6/22	Approved	None
10	2018-22	Evaluation of coagulation analyzer	New	Yes	Engineering 2	2018/7/4 ~7/10	Approved	None
11	2018-23	Application development of flow cytometer	New	Yes	Engineering 1	2018/7/1 9~ 2020/9/2 4	Approved	None
12	2018-24	Evaluation of hematology analyzer	New	Yes	Scientific Affairs	2018/7/2 3~8/22	Approved	None
13	2018-25	Research related to coagulation test	New	Yes	Engineering 1	2018/8/2 ~8/22	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
14	2018-33	Research related to coagulation test	New	Yes	Engineering 1	2018/8/23~9/7	Approved	None
15	2018-34	Evaluation of immunochemistry reagent	New	Yes	Engineering 1	2018/9/7~10/2	Approved	None
16	2018-35	Research related to lung cancer diagnosis method	New	Yes	Central Research Laboratories	2018/9/28~10/10	Approved	None
17	2018-36	Research related to coagulation test	New	Yes	Engineering 1	2018/10/22~10/29	Approved	None
18	2018-41	Research related to coagulation test	New	Yes	Engineering 1	2018/10/26~10/29	Approved	None
19	2018-42	Evaluation of lung cancer diagnosis method	New	Yes	Clinical Innovation	2018/11/12~11/19	Approved	None
20	2018-43	Evaluation of lung cancer diagnosis method	New	Yes	LS Business	2018/11/16~11/27	Approved	None
21	2018-44	Research related to kidney disease diagnosis method	New	Yes	Technology Strategy	2018/11/28~12/5	Approved	None
22	2018-45	Research related to coagulation test	New	Yes	Engineering 1	2018/12/7~12/13	Approved	None
23	2018-46	Evaluation of coagulation reagent	New	Yes	Engineering 1	2018/12/10~12/13	Approved	None
24	2018-43	Evaluation of lung cancer diagnosis method	New	Yes	LS Business	2018/12/18~12/26	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
25	2018-50	Evaluation of gene testing technologies	New	Yes	LS Business	2018/12/25~ 2019/1/9	Approved	None
26	2018-51	Evaluation of coagulation reagent	New	Yes	Engineering 1	2019/1/7~ 1/11	Approved	None
27	2018-43	Evaluation of lung cancer diagnosis method	New	Yes	LS Business	2019/1/24~ 1/30	Approved	None
28	2018-77	Research related to urinalysis analyzer	New	Yes	HU Business Development	2019/2/6~ 2/13	Approved	None
29	2018-75	Research related to colon cancer diagnosis method	New	Yes	LS Business	2019/2/6~ 2/18	Approved	None
30	2018-76	Research related to colon cancer diagnosis method	New	Yes	LS Business	2019/2/6~ 2/18	Approved	None
31	2018-79	Research related to utilization of clinical test data	New	Yes	Business Strategy Development	2019/2/26~ 3/1	Approved	None
32	2018-50	Evaluation of gene testing technologies	New	Yes	LS Business	2019/3/5~ 3/13	Approved	None
33	2018-80	Evaluation of hematology analyzer	New	Yes	Engineering 1	2019/3/20~ 3/28	Approved	None
34	2018-81	Research related to coagulation test	New	Yes	Engineering 1	2019/3/20~ 3/28	Approved	None

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