

77th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–20:40, May 28, 2019 (Tuesday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
 Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako, Nakajima  
 Personal information manager: Kayo Akagi  
 Secretariat: Daisuke Usuki, Sumiko Takaoka

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborat or Present	Division Performing	Result	Remarks
1	2019-04	Evaluation for protein measurement system	New	No	Business Strategy Development	Approved with conditions	Language of application document revised and research plan revised and informed consent document revised.
2	2019-05	Evaluation for gene measurement system	New	No	LS Business	Approved with conditions	Language of informed consent document revised.
3	2019-06	Evaluation for gene measurement system	New	No	LS Business	Approved with conditions	Language of informed consent document revised.
4	2018-56	Evaluation for hematology testing system	New	No	Engineering 1	Approved with conditions	Language of presentation document and informed consent document revised.
5	2018-57	Evaluation for hematology testing system	New	No	Engineering 1	Approved with conditions	Language of informed consent document revised.
6	2019-07	Evaluation for hematology testing system	New	Yes	Engineering 1	Approved with conditions	Language of informed consent document revised.
7	2019-08	Evaluation for immunochemistry system	New	No	Engineering 1	Approved	None

Research Plan Number and Content				Joint Collaborat or Present	Division Performing	Result	Remarks
8	2019-09	Evaluation for hemostasis testing system	New	No	Engineering 1	Approved	None
9	2019-10	Research for cell measurement technology	New	Yes	System Technologies Laboratory	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
10	2019-11	Research for protein measurement technology	New	Yes	System Technologies Laboratory	Approved with conditions	Language of presentation document and research plan revised.
11	2019-12	Research for cell measurement technology	New	Yes	Central Research Laboratories	Approved with conditions	Language of presentation document and research plan revised.
12	2019-13	Evaluation for protein measurement system	New	Yes	Clinical Innovation	Approved with conditions	Language of research plan revised.
13	2019-14	Evaluation for microinvasive blood glucose measurement system	New	Yes	Clinical Innovation	Approved with conditions	Language of presentation document
14	2019-15	Evaluation for microinvasive blood glucose measurement system	New	Yes	Clinical Innovation	Approved with conditions	Language of presentation document and research plan revised.
15	2019-16	Evaluation for microinvasive blood glucose measurement system	New	Yes	Clinical Innovation	Approved with conditions	Language of presentation document and research plan revised.

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78th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:20, July 25, 2019 (Thursday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
 Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako, Nakajima  
 Personal information manager: Kayo Akagi  
 Secretariat: Daisuke Usuki, Sumiko Takaoka  
 (Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2017-15	Evaluation for hematology testing system	Renewal	Yes	Engineering 1	Approved with conditions	Language of research plan revised.
2	2019-23	Research for cell measurement technology	New	No	Central Research Laboratories	Approved with conditions	Language of presentation document and research plan revised informed consent document revised.
3	2019-24	Research for cell measurement technology	New	No	Central Research Laboratories	Approved with conditions	Language of presentation document and research plan revised.
4	2019-25	Development for application of hematology testing system	New	No	Scientific Affairs	Approved with conditions	Language of presentation document and research plan revised informed consent document revised.
5	2019-26	Development for application of hematology testing system	New	No	Scientific Affairs	Approved with conditions	Language of research plan revised.
6	2019-27	Evaluation for hemostasis testing system	New	Yes	Engineering 1	Approved with conditions	Confirmation of research plan.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2019-26	Evaluation for hemostasis testing system	New	No	Scientific Affairs	Approved with conditions	Language of research plan revised.
8	2019-27	Evaluation for immunochemistry system	New	Yes	Engineering 1	Approved with conditions	Confirmation of research plan.
9	2017-01	Evaluation for hematology testing system	Renewal	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.

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79th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–19:30, September 24, 2019 (Tuesday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako Nakajima  
 Personal information manager: Kayo Akagi  
 Secretariat: Daisuke Usuki, Sumiko Takaoka

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator or Present	Division Performing	Result	Remarks
1	2019-41	Research for protein measurement technology	New	Yes	System Technologies Laboratory	Approved with conditions	Language of presentation document and research plan revised.
2	2019-42	Research for protein measurement technology	New	Yes	System Technologies Laboratory	Approved with conditions	Approved in joint collaborators' ethics examination. Language of presentation document and research plan revised.
3	2019-43	Research for protein measurement technology	New	No	System Technologies Laboratory	Approved with conditions	Language of presentation document and research plan revised.
4	2019-44	Development for application of hematology testing system	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2019-45	Evaluation for hemostasis testing system	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination.
6	2019-46	Evaluation for urinalysis system	New	No	Engineering 1	Approved with conditions	Language of informed consent document revised.

Research Plan Number and Content				Joint Collaborat or Present	Division Performing	Result	Remarks
7	2019-47	Research for protein measurement technology	New	No	Central Research Laboratories	Approved with conditions	Language of presentation document and research plan revised and informed consent document revised.
8	2019-15	Evaluation for microinvasive blood glucose measurement system	Renewal	Yes	Clinical Innovation	Approved with conditions	Language of presentation document revised
9	2019-16	Evaluation for microinvasive blood glucose measurement system	Renewal	Yes	Clinical Innovation	Approved	None

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80th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–18:40, November 21, 2019 (Thursday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
 Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako Nakajima  
 Personal information manager: Kayo Akagi  
 Secretariat: Daisuke Usuki, Sumiko Takaoka

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2019-59	Evaluation for immunochemistry system	New	Yes	Engineering 1	Approved	None
2	2019-60	Evaluation for gene measurement system	New	Yes	LS Medical Affairs	Approved with conditions	Approved in joint collaborators' ethics examination. Language of research plan revised.
3	2019-61	Development for application of hemostasis testing system	New	Yes	Scientific Affairs	Approved	Approved in joint collaborators' ethics examination.
4	2019-62	Development for application of hematology testing system	New	Yes	Scientific Affairs	Approved	None
5	2019-63	Research for cell measurement technology	New	Yes	Central Research Laboratories	Approved	Approved in joint collaborators' ethics examination.
6	2019-64	Evaluation for cell measurement system	New	No	Business Strategy Development	Approved	Language of presentation document revised

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81th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00--19:00, January 23, 2020 (Thursday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
 Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako Nakajima  
 Personal information manager: Kayo Akagi  
 Secretariat: Daisuke Usuki, Sumiko Takaoka

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2019-67	Development for application of hematology testing system	New	Yes	Scientific Affairs	Approved with conditions	Approved in joint collaborators' ethics examination.
2	2019-68	Development for application of hemostasis testing system	New	Yes	Scientific Affairs	Approved with conditions	Language of research plan revised.
3	2019-69	Development for application of hematology testing system	New	Yes	Scientific Affairs	Approved with conditions	Language of research plan revised.
4	2019-70	Research for gene measurement technology	New	Yes	Central Research Laboratories	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2019-71	Evaluation for hemostasis testing system	New	Yes	Engineering 1	Approved	None
6	2019-72	Evaluation for urinalysis system	New	No	Engineering 1	Approved	None



Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2019-73	Evaluation for urinalysis system	New	Yes	Engineering 2	Approved with conditions	Approved in joint collaborators' ethics examination.
8	2019-74	Evaluation for protein measurement system	New	Yes	Clinical Innovation	Approved with conditions	Approved in joint collaborators' ethics examination.
9	2019-75	Evaluation for protein measurement system	New	No	Clinical Innovation	Approved with conditions Approved	Language of presentation document and research plan revised.

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82th Deliberation Results, Research Ethics Examination Committee, Sysmex Corporation

1. Session Overview

Time and date: 17:00–20:35, March 23, 2020 (Monday)  
 Location: Conference Room 602, 6F, Sysmex Corporation headquarters  
 Committee members: Kenji Tsujimoto(committee chair), Yasunori Maekawa (committee deputy chair),  
 Muneo Yabuki, Mika Tochihara, Eiji Maruyama, Yoshifumi Matsumoto,  
 Katsuyuki Nakazawa, Takako Nakajima  
 Secretariat: Daisuke Usuki, Sumiko Takaoka

(Honorifics omitted, underlined personnel absent)

2. Deliberation Results

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
1	2019-16	Evaluation for microinvasive blood glucose measurement system	Renewal	Yes	Clinical Innovation	Approved	None
2	2019-82	Evaluation for hematology testing system	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination.
3	2019-83	Evaluation for urinalysis system	New	Yes	Engineering 2	Approved with conditions	Approved in joint collaborators' ethics examination.
4	2019-84	Evaluation for immunochemistry system	New	Yes	Engineering 1	Approved with conditions	Approved in joint collaborators' ethics examination.
5	2019-85	Evaluation for hematology testing system	New	Yes	Engineering 2	Approved with conditions	Approved in joint collaborators' ethics examination.
6	2019-86	Evaluation for hemostasis testing system	New	Yes	Sysmex International Reagents Corporation	Approved with conditions	Language of informed consent document revised.

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
7	2019-87	Evaluation for cell measurement system	New	No	Clinical Innovation	Approved	None
8	2019-88	Evaluation for hematology and immunochemistry system	New	No	JEA Region	Approved	None
9	2019-89	Evaluation for cell measurement system	New	No	Business Strategy Development	Approved	None
10	2019-90	Evaluation for gene measurement system	New	No	LS Business	Approved	None
11	2019-91	Evaluation for standard analyzers	New	No	Scientific Affairs	Approved	None
12	2019-92	Evaluation for standard analyzers	New	No	Scientific Affairs	Approved with conditions	Language of informed consent document revised.
13	2019-93	Evaluation for standard analyzers	New	No	Scientific Affairs	Approved	None
14	2019-94	Evaluation for hematology testing system	New	No	Engineering 2	Approved with conditions	Language of presentation document and research plan revised.
15	2019-95	Evaluation for hematology testing system	New	No	Engineering 2	Approved with conditions	Language of presentation document and research plan revised.
16	2019-97	Evaluation for immunochemistry system	New	No	Engineering 1	Approved with conditions	Language of presentation document and research plan revised.
17	2019-98	Evaluation for immunochemistry system	New	No	Engineering 1	Approved	None
18	2019-99	Evaluation for immunochemistry system	New	No	Engineering 1	Approved with conditions	Language of informed consent document revised

Research Plan Number and Content				Joint Collaborator Present	Division Performing	Result	Remarks
19	2019-100	Evaluation for immunochemistry system	New	No	Engineering 1	Approved	None
20	2019-101	Evaluation for hematology testing system	New	No	Engineering 1	Approved	None
21	2019-102	Evaluation for hematology testing system	New	No	Engineering 1	Approved with conditions	Language of presentation document and research plan revised.
22	2019-103	Evaluation for hematology testing system	New	No	Engineering 1	Approved	None
23	2019-104	Evaluation for hemostasis testing system	New	No	Engineering 1	Approved	None
24	2019-105	Evaluation for hemostasis testing system	New	No	Engineering 1	Approved	None

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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	2018-78	Evaluation for hematology testing system	New	Yes	Engineering 1	2019/2/15~ 4/4	Approved	None
2	2019-01	Development for application of immunochemistry system	New	Yes	Scientific Affairs	2019/4/4~ 4/8	Approved	None
3	2019-02	Development for application of hematology testing system	New	Yes	Scientific Affairs	2019/4/9~ 4/15	Approved	None
4	2018-75	Evaluation for gene measurement system	New	Yes	LS Medical Affairs	2019/4/16~ 4/24	Approved	None
5	2018-76	Evaluation for gene measurement system	New	Yes	LS Medical Affairs	2019/4/16~ 4/24	Approved	None
6	2019-03	Evaluation for immunochemistry system	New	Yes	Engineering 1	2019/4/24~ 5/7	Approved	None
7	2019-17	Evaluation for hemostasis testing system	New	Yes	Engineering 2	2018/3/16~ 3/20	Approved	None
8	2019-18	Research for gene measurement technology	New	Yes	Central Research Laboratories	2019/5/9~ 5/10	Approved	None
9	2019-19	Research for cell measurement technology	New	Yes	System Technologies Laboratory	2019/5/27~ 5/31	Approved	None
10	2019-20	Evaluation for immunochemistry system	New	Yes	Engineering 1	2019/6/13~ 6/17	Approved	None
11	2019-22	Evaluation for hematology testing system	New	Yes	Engineering 1	2019/6/21~ 6/21	Approved	None
12	2019-21	Evaluation for cell measurement system	New	Yes	Clinical Innovation	2019/6/13~ 6/26	Approved	None
13	2019-29	Research for gene measurement technology	New	Yes	Central Research Laboratories	2019/7/4~ 7/5	Approved	None
14	2019-31	Evaluation for hematology testing system	New	Yes	Engineering 1	2019/7/4~ 7/5	Approved	None
15	2019-30	Evaluation for hemostasis testing system	New	Yes	Engineering 2	2019/7/2~ 7/12	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
16	2019-32	Research for cell measurement technology	New	Yes	System Technologies Laboratory	2019/7/5~7/12	Approved	None
17	2019-34	Evaluation for gene measurement system	New	Yes	LS Medical Affairs	2019/7/17~7/22	Approved	None
18	2019-36	Evaluation for cell measurement system	New	Yes	Clinical Innovation	2019/7/30~2019/8/1	Approved	None
19	2019-33	Evaluation for urinalysis system	New	Yes	Engineering 2	2019/7/9~8/5	Approved	None
20	2019-37	Development for application of urinalysis system	New	Yes	Scientific Affairs	2019/7/30~8/5	Approved	None
21	2019-38	Development for application of urinalysis system	New	Yes	Scientific Affairs	2019/7/30~8/5	Approved	None
22	2019-39	Research for protein measurement technology	New	Yes	Central Research Laboratories	2019/8/5~8/5	Approved	None
23	2019-50	Evaluation for gene measurement system	New	Yes	LS Medical Affairs	2019/8/29~8/30	Approved	None
24	2019-40	Evaluation for hematology testing system	New	Yes	Engineering 1	2019/8/7~9/2	Approved	None
25	2019-30	Evaluation for immunochemistry system	New	Yes	Engineering 2	2019/7/2~7/12	Approved	None
26	2019-49	Research for cell measurement technology	New	Yes	System Technologies Laboratory	2019/9/4~9/6	Approved	None
27	2019-50	Development for application of immunochemistry system	New	Yes	Scientific Affairs	2019/9/4~9/6	Approved	None
28	2019-51	Application development for clinical data analysis	New	Yes	Scientific Affairs	2019/9/13~9/17	Approved	None
29	2019-53	Development for application of hematology testing system	New	Yes	Central Research Laboratories	2019/9/19~9/20	Approved	None
30	2019-54	Research for protein measurement technology	New	Yes	Scientific Affairs	2019/9/20~9/24	Approved	None
31	2019-52	Evaluation for cell measurement system	New	Yes	Central Research Laboratories	2019/9/19~9/26	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
32	2019-55	Development for application of immunochemistry system	New	Yes	Clinical Innovation	2019/9/27~10/4	Approved	None
33	2019-56	Evaluation for gene measurement system	New	Yes	Scientific Affairs	2019/10/4~10/15	Approved	None
34	2019-48	Development for application of immunochemistry system	New	Yes	LS Medical Affairs	2019/9/20~10/23	Approved	None
35	2019-57	Evaluation for hemostasis testing system	New	Yes	Scientific Affairs	2019/10/24~10/28	Approved	None
36	2019-58	Evaluation for hematology testing system	New	Yes	Engineering 2	2019/10/25~11/5	Approved	None
37	2018-32	Research for cell measurement technology	New	Yes	Engineering 2	2019/9/27~9/30	Approved	None
38	2018-56	Evaluation for hematology testing system	New	Yes	Engineering 1	2019/9/27~10/3	Approved	None
39	2019-65	Evaluation for immunochemistry system	New	Yes	Engineering 1	2019/11/7~11/8	Approved	None
40	2019-71	Research for cell measurement technology	Renewal	Yes	Central Research Laboratories	2019/10/30~11/8	Approved	None
41	2019-70	Evaluation for gene measurement system	Renewal	Yes	LS Business	2019/11/15~11/20	Approved	None
42	2019-66	Development for application of immunochemistry system	New	Yes	Scientific Affairs	2019/11/26~12/11	Approved	None
43	2019-60	Evaluation for gene measurement system	Renewal	Yes	LS Medical Affairs	2019/12/20~12/25	Approved	None
44	2019-77	Evaluation for hemostasis testing system	New	Yes	Engineering 2	2019/12/24~12/26	Approved	None
45	2019-76	Development for application of hemostasis testing system	New	Yes	Scientific Affairs	2019/12/24~12/27	Approved	None
46	2018-67	Evaluation for protein measurement system	Renewal	Yes	Clinical Innovation	2019/12/26~2020/1/10	Approved	None
47	2019-78	Evaluation for gene measurement system	New	Yes	LS Business	2020/1/16~1/21	Approved	None

Research Plan Number and Content				Joint Collaborator Present	Joint Collaborator Present	Examination period	Result	Remarks
48	2016-18	Development for application of hematology testing system	Renewal	Yes	Scientific Affairs	2020/1/7~ 1/21	Approved	None
49	2018-26	Evaluation for hematology testing system	Renewal	Yes	Engineering 1	2020/1/7~ 1/21	Approved	None
50	2018-69	Evaluation for gene measurement system	Renewal	Yes	LS Business	2020/1/27~ 2/3	Approved	None
51	2019-79	Research for cell measurement technology	New	Yes	System Technologies Laboratory	2020/2/4~ 2/12	Approved	None
52	2019-80	Evaluation for gene measurement system	New	Yes	LS Business	2020/2/7~ 2/18	Approved	None
53	2019-81	Evaluation for protein measurement system	New	Yes	Clinical Innovation	2020/2/14~ 2/18	Approved	None
54	2019-106	Evaluation for gene measurement system	New	Yes	LS Business	2020/2/17~ 2/21	Approved	None
55	2016-49	Research for cell measurement technology	Renewal	Yes	Central Research Laboratories	2020/1/31~ 2/21	Approved	None
56	2019-107	Evaluation for immunochemistry system	New	Yes	Engineering 1	2020/2/27~ 3/2	Approved	None