



Executive Summary

Please find below the annual metrics for the applications submitted to the Health Research Ethics Authority's (HREA) Health Research Ethics Board (HREB) during the 2024-25, and 2025-26 fiscal years. The applications are divided into the following categories:

1. Clinical Trials Applications
2. Non-Clinical Trials Applications
3. Genetics/Genomics Applications

These metrics provide information regarding the following sub-headings:

New Study Applications

This describes the **number of new study applications** submitted to the HREB in each quarter. These are divided into "complete" and "incomplete".

Complete applications are received with all required information and documentation. They are reviewed by the Ethics Officer and sent on to the relevant decision-making committee.

Incomplete applications are deemed to be missing critical information and/or required documentation. They are returned to the applicant with detailed instructions as to what is required to complete the application.

Reviews and First Decision

This section describes the new applications that received an **initial review** by the HREB in the quarter, irrespective of the date of submission. This metric allows the HREA to confirm compliance with the legislatively mandated thirty (30) day timeline for rendering a decision on a new research application.

This timeline breaks down the average, median and range of days from the receipt of a complete application to the time it receives the first decision from the HREB.

Final Decision

This section describes all applications that received a **final decision** from the HREB in the quarter, irrespective of the date of submission. This metric is of limited use in adjudicating the efficiency of the HREB review process, as the HREB cannot control the amount of time an application remains with a researcher following first review when changes are required in order to render a final decision.

Time to Final Decision – This timeline breaks down the average, median and range of days from the receipt of a complete submission to the final decision of the HREB. The 75th and 90th percentile is also included in this section.

Total Active Studies

This section provides the total number of HREB active studies from Oct 2011 (start of Research Portal) to end of each quarter.

Events

This section describes the number of events received by the HREB in each quarter. These events are in addition to new and resubmitted applications and reflect the review workload of the HREB and the Research Ethics Office.

NON-CLINICAL TRIALS

	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
NEW STUDY APPLICATIONS								
Total received	32	47	35	36	53	34	42	49
Complete	27	41	34	33	48	30	39	43
Incomplete	5	6	1	3	5	4	3	6
REVIEWS AND FIRST DECISION								
Total number new studies reviewed by HREB	34	41	33	40	38	36	36	36
Average days to FIRST decision	13.2	13.1	13.71	13.43	10.82	12.97	12.2	13.2
Median days to FIRST decision	14	13	15	13	12	11.5	11.5	13
Range of days to FIRST decision	1-22	0-26	1-28	1-29	1-25	1-29	3-29	5-29
FINAL DECISION								
Total number studies receiving final decision	22	30	58	31	31	58	32	44
Average days to FINAL decision	40.1	33	60.42	48.52	48.55	57.8	62.7	61.02
Median days to FINAL decision	22	24	49.5	48	35	46	57	47
75 th percentile	41	57.8	88.75	65.5	63.5	65	92.5	78
90 th percentile	98	71.4	108.4	77	100	112.7	132.8	122.7
Range of days to FINAL decision	7-147	3-98	20-147	7-133	1-174	8-261	7-165	7-201

GENETIC/GENOMIC STUDIES

SUBMISSIONS	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
Total	3	1	5	3	1	2	2	0
Complete	3	1	2	2	0	2	2	0
Incomplete	0	0	3	1	1	0	0	0
REVIEWS AND FIRST DECISION								
Total number new studies reviewed by HREB	3	1	2	4	1	2	1	0
Average days to FIRST decision	17	20	16.5	16.2 5	8	20	10	0
Median days to FIRST decision	15	20	16.5	16.5	8	20	23	0
Range of days to FIRST decision	15-21	20	14-19	14- 18	8	16-24	7	0
FINAL DECISION								
Total number studies receiving final decision	2	3	1	4	0	2	0	3
Average days to FINAL decision	32.5	44	28	46	0	53.5	0	122
Median days to FINAL decision	32.5	46	28	40	0	53.5	0	83
75th percentile	33.75	51	28	25	0	54.3	0	143
90th percentile	34.5	54	28	56.6	0	52.2	0	179
Range of days to FINAL decision	30-35	30-56	28	25- 79	0	52-55	0	83-203

CLINICAL TRIALS

SUBMISSIONS	Q1 2024-25	Q2	Q3	Q4	Q1 2025- 26	Q2	Q3	Q4
Total	10	14	14	13	15	13	9	10
Complete	9	8	12	12	15	13	9	9
Incomplete	1	6	2	1	0	0	0	1
REVIEWS AND FIRST DECISION								
Total number new studies reviewed by HREB	8	10	16	14	16	13	9	9
Average days to FIRST decision	13	14.3	16.56	20.36	15.2	17.3	16.5	14.8
Median days to FIRST decision	15	14	16	16	15	15	16	15.5
Range of days to FIRST decision	7-17	9-29	2-25	7-29	5-20	8-29	10-21	5-21
FINAL DECISION								
Total number studies receiving final decision	8	11	10	14	13	17	11	9
Average days to FINAL decision	87.5	70.6	64.3	69	59.7	100.9	60.3	103.3
Median days to FINAL decision	75.5	48	52	63.5	58	65	40	94
75th percentile	43	58.8	64.25	95.8	86	114	75	141
90th percentile	140.7	183	94.6	104.4	98	242.6	93	178.6
Range of days to FINAL decision	39-210	10-233	15-190	28-128	2-58	37-280	22-182	37-213

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HREB Total Active Studies (NCT/GG/CT)

Active Studies	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
Total	614	608	540	579	593	609	591	581
HREB – CT	186	183	179	175	185	193	188	175
HREB – NCT	383	379	358	356	359	355	352	357
HREB – GG	45	46	48	48	49	51	51	49

EVENTS

HREB-CT	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
TOTAL # OF EVENTS	224	206	243	304	192	203	237	233
Adverse Events	11	11	12	14	6	16	5	4
Protocol/Application Amendments	83	52	51	82	50	74	69	71
Annual Renewal, Study Close-out	50	45	52	60	51	38	41	60
Safety Reports	25	22	26	30	13	15	16	16
Investigator Brochure/Product Monograph	7	17	19	14	17	17	17	29
Protocol Deviations	15	7	5	31	6	8	33	19
Staff Changes	30	32	59	67	35	27	47	28
Other	3	20	19	6	14	8	9	6

HREB-NCT	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
TOTAL # OF EVENTS	190	180	177	190	114	127	132	138
Adverse Events	0	0	0	2	0	0	0	0
Protocol/Application Amendments	58	52	36	54	26	34	31	34
Annual Renewal, Study Close-out	91	68	81	81	59	65	75	60
Safety Reports	0	0	0	0	0	0	0	0
Investigator Brochure/Product Monograph	0	0	0	0	0	0	0	0
Protocol Deviations	3	4	3	4	5	1	4	1
Staff Changes	31	54	57	49	24	27	19	43
Other	7	2	0	0	0	0	3	0

HREB-GG	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
TOTAL # OF EVENTS	30	24	24	18	29	25	26	46
Adverse Events	0	0	0	0	1	0	0	0
Protocol/Application Amendments	4	4	5	3	7	5	8	14
Annual Renewal, Study Close-out	18	14	10	8	17	14	9	12
Safety Reports	0	0	0	0	0	0	0	0
Investigator Brochure/Product Monograph	0	0	0	0	0	0	0	0
Protocol Deviations	0	0	0	0	0	0	0	1
Staff Changes	8	6	8	6	4	6	7	19

Other	0	0	1	1	0	0	2	0
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Multijurisdictional Research

Please find below the annual metrics for health research that has been submitted to the HREA, which has already been reviewed by a competent Canadian research ethics body or a qualifying research ethics body and which holds current research ethics approval from that body.

The submissions are divided into the following categories:

1. Notification and Acknowledgement
2. Summary Review

Notification and Acknowledgement

These metrics provide information regarding the following sub-headings:

New Submissions

This describes the **number of notifications submitted** to the HREA in each quarter. These are divided into “complete” and “incomplete”.

Complete submissions are received with all required information and documentation. They are reviewed by the Research Ethics Office for determination of Acknowledgement or referral for HREB review.

Incomplete applications are deemed to be missing critical information and/or required documentation. They are returned to the applicant with detailed instructions as to what is required to complete the application.

Reviews and Decisions

This describes the **number of notifications that were reviewed** by the HREA in each quarter. These are divided into “acknowledged by the HREA” and “referred for HREB review.”

Summary Review

New Submissions

This describes the **number of summary review applications submitted** to the HREA in each quarter. These are divided into “complete” and “incomplete”.

Complete submissions are received with all required information and documentation. They are reviewed by the Ethics Officer and sent to the relevant decision-making committee.

Incomplete applications are deemed to be missing critical information and/or required documentation. They are returned to the applicant with detailed instructions as to what is required to complete the application.

Reviews and Decisions

This describes the **number of summary review applications that were reviewed** by the HREB in each quarter. These are divided into “receiving summary review” and “referred for full HREB review.”

Multi-Jurisdictional Research

Notification and Acknowledgement

	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
NOTIFICATIONS								
Total Received	n/a	n/a	n/a	n/a	n/a	1	1	1
Complete	n/a	n/a	n/a	n/a	n/a	1	1	1
Incomplete	n/a	n/a	n/a	n/a	n/a	0	0	0
REVIEWS AND DECISIONS								
Total number new studies reviewed by HREA	n/a	n/a	n/a	n/a	n/a	1	1	0
Total number studies Acknowledged by HREA	n/a	n/a	n/a	n/a	n/a	1	1	0
Total number studies ineligible for Notification and Acknowledgement	n/a	n/a	n/a	n/a	n/a	0	0	0

Multi-Jurisdictional Research Summary Review and Approval

	Q1 2024-25	Q2	Q3	Q4	Q1 2025-26	Q2	Q3	Q4
NOTIFICATIONS								
Total Received	n/a	n/a	n/a	n/a	n/a	0	0	0
Complete	n/a	n/a	n/a	n/a	n/a	0	0	0
Incomplete	n/a	n/a	n/a	n/a	n/a	0	0	0
REVIEWS AND DECISIONS								
Total number new studies reviewed by HREB	n/a	n/a	n/a	n/a	n/a	0	0	0
Total number studies receiving Summary Review Approval	n/a	n/a	n/a	n/a	n/a	0	0	0
Total number studies ineligible for Summary Review	n/a	n/a	n/a	n/a	n/a	0	0	0