

UBC Research Ethics Boards Combined Metrics Report 2019 – 2020

September 2021



THE UNIVERSITY
OF BRITISH COLUMBIA

Vancouver and Okanagan



Committed to Ethical Excellence

The University of British Columbia is committed to promoting research as a fundamental human endeavor deriving from the wish to understand and improve the collective global condition. The University recognizes that the contributions of human participants are essential to progress in many areas of research. All research involving human participants must be conducted in accordance with the highest ethical standards to ensure that the dignity and rights of all participants are protected and respected. The consistent application of these ethical standards is essential to ensuring there is full trust in researchers and the research process.

A fundamental imperative of research involving human participants is respect for human dignity. The University has adopted the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)** to guide the conduct of all research involving human participants, as well as the conduct of its Research Ethics Boards.

UBC's REBs are independent committees established by the University in partnership with its affiliated hospitals and research institutes. On behalf of these institutions, the REBs are mandated to review and oversee the ethical acceptability of all research involving humans conducted under their auspices.

The REBs are accountable to UBC's Vice-President Research & Innovation for their research ethics review processes. However, in conducting their research ethics reviews, the REBs operate impartially, free of inappropriate influence and without interference from UBC and its partner institutions or other external entities.

UBC currently has six affiliated Research Ethics Boards.

Messages from UBC'S Affiliated Research Ethics Boards

The mission of UBC's Affiliated Research Ethics Boards is to create a research ethics culture at the University and its affiliated hospitals, that embodies the core principles of research ethics: justice, beneficence and respect for autonomy.

BC Cancer Research Ethics Board

Chair: Dr. Karen Gelmon (Medical Oncologist)

Vice-Chair: Dr Vivien Bramwell (Medical Oncologist)

Dr. Kristie Westerlaken, **Director, BC Cancer Research Ethics**

BC Cancer Research Ethics had an exciting start to 2020 when our office was re-structured, job roles re-designed, and our mandate expanded considerably. With these changes, our attention is focused on consulting and collaborating with the research community in order to develop initiatives aimed at advancing knowledge and building capacity in ethics and integrity in cancer research. Key deliverables include developing education and training programs for BC Cancer's research community; independent research on current trends/themes in research ethics, integrity, and compliance; as well as the development and implementation of procedures and policies that ensure the safety, respect, welfare, and justice of the participants are prioritized, but are also pragmatic, flexible and progressive so as to support the rapid changes in scientific advances which are making research and research ethics increasingly complex.

Specific to the REB activities, we are continuing efforts to streamline existing processes for the review of research ethics applications, including the Informed Consent Form (ICF). After finalizing our own ICF template in June 2019, we have decided to pivot and overhaul again in order to align with changes from NIH's National Cancer Institute (NCI), and our oncology research collaborators across Canada and the US. In so doing, we have also taken the opportunity to examine and refine guidance around reporting of research results, particularly in relation to genetic, hereditary and material incidental findings.

Of course, due to COVID-19, the past year saw significant impact to many of our research projects, notably in relation to interactions with participants, but also our interactions with research teams. We worked closely with researchers, sponsors and cooperative groups to develop specific COVID-19 related processes that ensured the safety and protection of participants was paramount, but also enabled the scientific integrity of research to be maintained. This included modifications to study enrollment, testing, drug delivery and data monitoring. Although we previously had a practice of hosting drop-in and in-person consultation sessions with researchers and look forward to reinstating this practice, the convenience of Zoom meetings has allowed us to maintain our presence in the BC Cancer research community through the pandemic. We continue to meet "face to face" with many of our research groups to assist in the development of current and new behavioral studies, clinical trials, biobanks, databanks, registries, etc.

We wish to acknowledge and thank our team, the Board members, our administration and leadership, as well as our researchers in working together to ensure oncology research continues to engage patients and the broader community so we can improve cancer care and treatment.

Children & Women’s Research Ethics Board

REB Chair: Dr. Marc Levine (Pharmaceutical Sciences)

Associate Chair: Dr. Caron Strahlendorf (Haematology/Oncology)

Jennie Prasad, **C&W REB Manager**

It is an understatement to say that the last eighteen months have been the most challenging that researchers and REBs have faced in living memory. Despite the personal and professional pressures we have all been under, the Metrics summarized in this report give evidence to the fact that the motivation of researchers and participants to actively pursue new knowledge and better treatments has continued unabated.

Throughout, the C&W REB has been aided by the appointment of a number of new members, and periodic assistance from members of other UBC REBs, as well as the strong support of the UBC Office of Research Ethics. The dedication and collaborative engagement of researchers at Children’s and Women’s have made it possible for the REB to continue to support them and help ensure the overall wellbeing of research participants at this site.

This period has been marked by important developments for our REB. We have been able to hold regular and, when necessary, extraordinary board meetings via Zoom and managed to maintain efficiency in doing so. With support of all the boards we have elevated the practice of electronic consenting to one that sustains research without compromising the principle and practice of informed consent and assent for parents and children. In concert with researchers we have worked out methods for remote monitoring of clinical trials without compromising participants’ privacy and confidentiality. Some of these innovations will likely continue and evolve beyond the demise of the pandemic.

We have also learned some important lessons during this period. We have observed and dealt with cases of fraudulent participation in online survey-based research that provided gifts or remuneration to respondents. Such fraud has the potential to completely undermine the integrity of the research. The advent of research related to vaccination to prevent SARS-CoV-2 infection has resulted in a number of complaints from members of the public. This includes complaints that research appears to advocate for vaccination, or to educate the public about vaccination.

The REB has also recently been addressing concerns about recruitment procedures and privacy in relation to the COVID-19 pandemic and the possible consenting of minors to participate in research without parental involvement. In addressing these issues, we are being assisted by UBC ORE- and PHSA-affiliated lawyers, ethicists, and privacy experts in mapping out our future approaches to the consenting of minors for research in general. Our REB is increasingly facing questions and concerns related to inclusivity of research and the language used in research-related documents and activities with respect to the diversity of family types and gender among potential participants. We are currently working with ethicists, researchers and clinicians to understand and to better advise researchers about evolving best practices.

Finally, none of what has been accomplished during this period would have been possible – and certainly not as effectively – without the excellent and proactive engagement of the C&W REB

staff. They are a cohesive team, and I know that our board members and researchers greatly appreciate their help, advice and ongoing support.

Providence Health Care Research Ethics Board

Chair: Dr. Kuo Hsing Kuo (Pharmacology)

Associate Chairs: Dr. Ingrid Fedoroff (Pain Management); Dr. Stephen Hopton Cann (Epidemiology)

Julie Hadden, **PHC REB Manager, Ethical Reviews**

The PHC REB office reviewed 113 COVID-19 related applications in 2020 and a record number of post-approval activities as many researchers pivoted to transition their studies to on-line methods to sustain their work during the pandemic. The board was nimble in adopting the procedures of UBC REB SOP 501: REB Review During Publicly Declared Emergencies, often going above and beyond the SOP to ensure COVID-19 related projects that could possibly have an immediate impact on the pandemic or patient outcomes were not delayed. This work was supported by one FTE REB Manager and 1.5 FTE staff. The REB Manager was further responsible for governing first the curtailment, and then the re-start of research within Providence Health Care, placing unprecedented responsibility on the REB staff during this reporting period.

The membership of the PHC board is currently comprised of 16 regular members in addition to a number of alternates and ad hoc members. 2019/2020 saw the fruits of a successful member recruitment campaign in 2018 which resulted in the addition of 8 new REB members with expertise in Respiratory Medicine, Genetics, HIV, Biostatistics, Renal Pathology and Laboratory Medicine, Epidemiology, and Health Sciences and Community-Based Research.

The PHC REB continues to support research ethics education within Providence Health Care. The Chair and 2 Associate Chairs of the board are accessible to and there is an open-door policy to attend REB meetings upon request, with the hope of instilling an awareness of research ethics early in the researcher's career. A successful example of this is the REB's routine hosting of Research Fellows from the BC Centre for Substance Use Addiction Research Fellowship program. Fellows attend a minimum of two REB meetings over the course of the year and the positive feedback has led to continued requests by the program for the REB to continue to offer this educational opportunity.

Formal training opportunities for PHC REB members in 2020 were limited due to the pandemic and the resulting impact on REB staff. However, all PHC board members and REB staff will have the opportunity to take "The Fundamentals of OCAP®" eLearning course commencing in 2021.

UBC Behavioural Research Ethics Board

Chair: Dr. Karen Bartlett (School of Population & Public Health)

Co-Chairs: Dr. Anne George (Department of Pediatrics); Dr. William McKellin (Anthropology); Dr. Dana Thordarson (Family Practice; to 2021)

Jean Ruiz, **Senior Behavioural Research Ethics Analyst**

With the University's response to the COVID-19 pandemic, the BREB's priorities shifted from longer term strategic initiatives to immediate support for researchers, which included creating a new website and developing related guidance and resource materials.

The BREB is comprised of 18 regular members and several alternates. We had a successful membership callout in the spring of 2020 which saw the addition of six new members, including one Indigenous faculty member and an Indigenous community member. The membership drive has increased the BREB's expert coverage in the areas of Education, Environment and Sustainability, Pharmaceutical Sciences and Political Science.

Staff were still able complete a few key projects and develop new resources: guidance for "Ensuring Participant Inclusion in Research" (*Ethnicity and race and Gender, sex and sexual orientation*); creating an editable version of the Behavioural ethics applications; and developing support tools for students in the Faculty of Medicine. Working with residents of Vancouver's Downtown Eastside (DTES), staff and BREB members engaged in exploring the community's unique research requirements and supported the development of research ethics training geared to DTES residents who will be involved in research. The resulting course, Community Engaged Research Ethics Training (CERET), is planned for release as an Open Source module.

The BREB continued its support for Critical Indigenous Studies (CIS) to streamline its Ethics Review Committee procedures. A new Archival ethics application was piloted, and the committee's Terms of Reference have been updated (awaiting final signatures).

Staff initiated annual "BREB Landscape" reviews in 2019 to consider how we can better support REB members and researchers, and improve operations; these discussions have generated new initiatives and resource materials that will further enhance the quality of behavioural ethics reviews.

The BREB continues to be involved in the largest number of active harmonized studies in the Province (in 2020, lead board on 212 applications and a partner board on 121 applications).

UBC Clinical Research Ethics Board

Chair: Dr Stephen Hopton Cann (Epidemiology)

Co-chair: Dr. Hugh Freeman (Gastroenterology)

Pia Ganz, **CREB Manager**

This year has been unprecedented in terms of the need for a rapid turnaround of studies related to the COVID-19 pandemic. In order to meet these demands, the CREB developed the document UBC CREB GUIDANCE DURING COVID-19 and arranged special virtual emergency meetings. The guidance is in keeping with the UBC SOP 501: REB Review During Publicly Declared Emergencies to ensure that clinical research that could have an immediate impact on the pandemic or patient outcomes is not delayed. This work was carried out in concert with other UBC affiliated boards and board members who made themselves available on short notice for these urgent meetings.

In addition to these activities, CREB staff have created instructional videos on how to submit an ethics application with topics including: Roadmap to UBC Ethics Review Process, Navigating the RISE ethics application (Part 1), Navigating the RISE Application (Part 2 Clinical), and Submission Tips. Additionally, CREB staff offer custom lectures to individual departments and courses.

Further work has been carried out to create new or updated clinical templates throughout the year including: the new Biobank Protocol Template (January 2020), Minimal Risk Consent Form Template for Clinical Studies (February 2020), BC Common Clinical Informed Consent Form Template – GENETICS (July 2020), and the Optional Biobank/Databank Consent Form Template (August 2020).

Finally, the CREB staff have been busy meeting with research teams to discuss the re-review of old ongoing studies (approved prior to 2008) and facilitating the re-submission and re-review of these older studies to ensure that they meet current standards as per TCPS2 2018 as well as provincial and national data security and confidentiality requirements.

UBC Okanagan Research Ethics Board

Chair: Dr. Carolyn Szostak (IKB Faculty of Arts and Social Sciences)

Associate Chair: Dr. Wendy Klassen (Okanagan School of Education)

Lisa Shearer, **Associate Manager, BREB**

Given the COVID-19 pandemic, coupled with the University's response to conducting research during that time, 2020 was a challenging time for the UBC Okanagan BREB. During the year, four members of the Board resigned and only two replacements were found; additionally, the Associate Chair announced that she would be leaving the Board in 2021. Together, this left the UBCO BREB with fewer members to conduct expedited reviews, during a time when the challenges of COVID were being experienced in many different ways. For the UBCO BREB, similar to the other UBC REB's, this included an increased number of applications and amendments, coupled with an ever-changing research environment. However, despite these challenges, the UBCO BREB has remained committed to ensuring quality service, which is illustrated in turnaround times consistent with previous years.

On the administrative side, UBCO Okanagan BREB began to work consistently with UBC BREB. This has led to collaborations in processes and policies and subsequent increases in efficiencies, which have been invaluable during the past year.

METRICS: Volume

Most REBs saw a decrease in the volume of ethics applications submitted during 2020-21, most likely reflecting the impact of the COVID 19 pandemic on researchers' ability to initiate new research.

UBC's six Affiliated REBS are monitoring an increasingly large number of active human applications. Increases have been experienced annually by almost every UBC affiliated Board.

Over a five-year period from 2015 – 2020 active applications have increased from 8,256 to 10,037.

UBC's six affiliated REBs have also experienced an almost continual rise in new applications being submitted. After five years of continual increases in the number of new applications received, a small decrease was experienced by most boards during 2020.

Both the BREB and C&W REB saw increases in new applications in 2020.

The number of Post-Approval Activities received and processed by UBC's six affiliated REBs has steadily increased over the past five years, from 13,698 in 2015-16 to 17,908 in 2020, an increase of 30%.

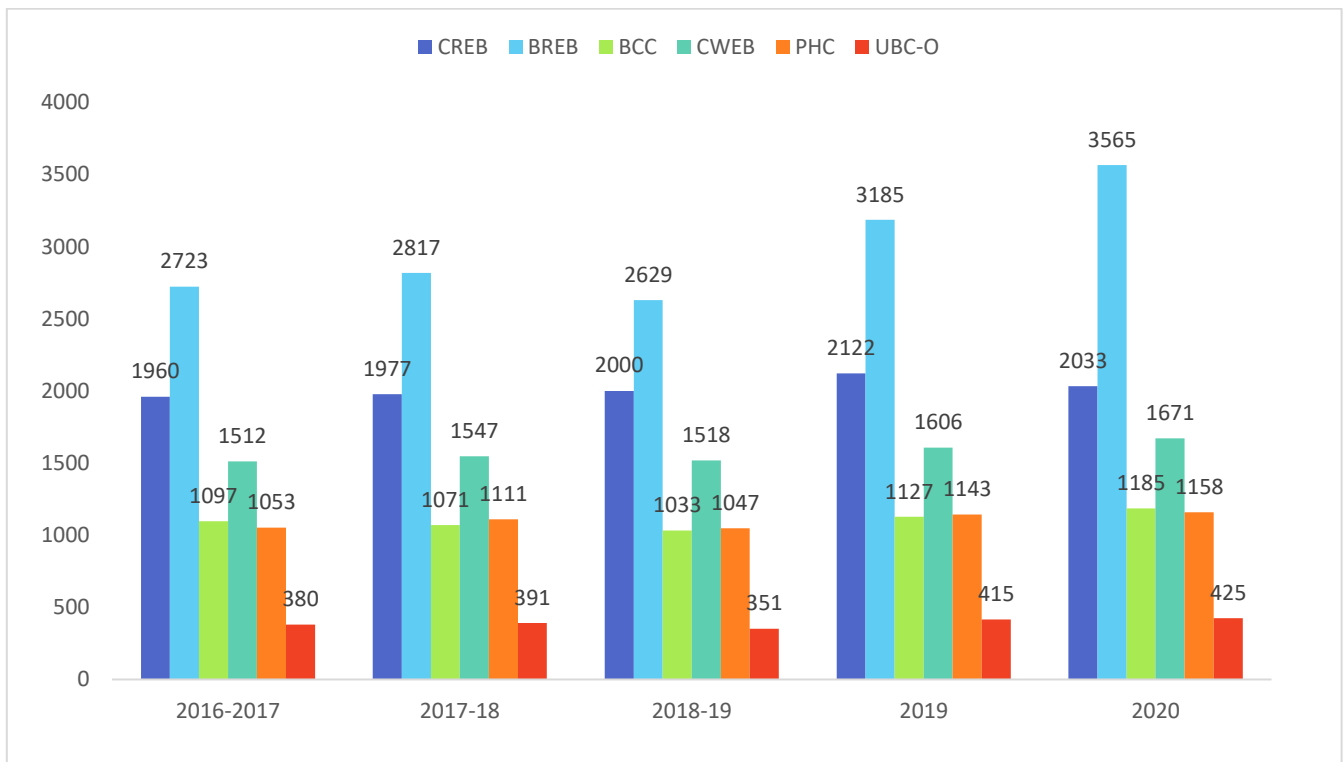
Between 2019 and 2020, all Boards except the CREB experienced a substantial increase in post-approval submissions.

Volume

Active Human Ethics Applications Monitored*

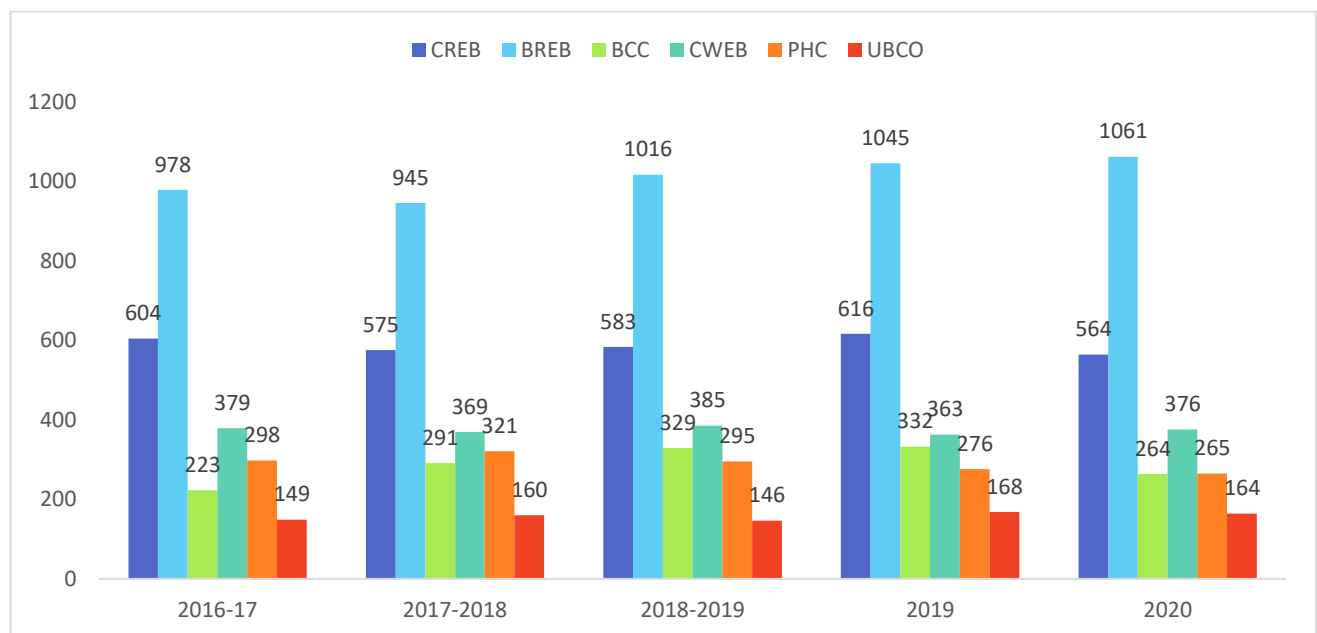
YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO	TOTAL
2014/15	1666	2603	982	1250	898	351	7750
2015/16	1771	2747	1016	1357	986	379	8256
2016-17	1960	2723	1097	1512	1053	380	8725
2017-18	1977	2817	1071	1547	1111	391	8914
2018-19	2000	2629	1033	1518	1047	351	8578
2019	2122	3185	1127	1606	1143	415	9598
2020	2033	3565	1185	1671	1158	425	10,037

*Fiscal until 2019; annual thereafter



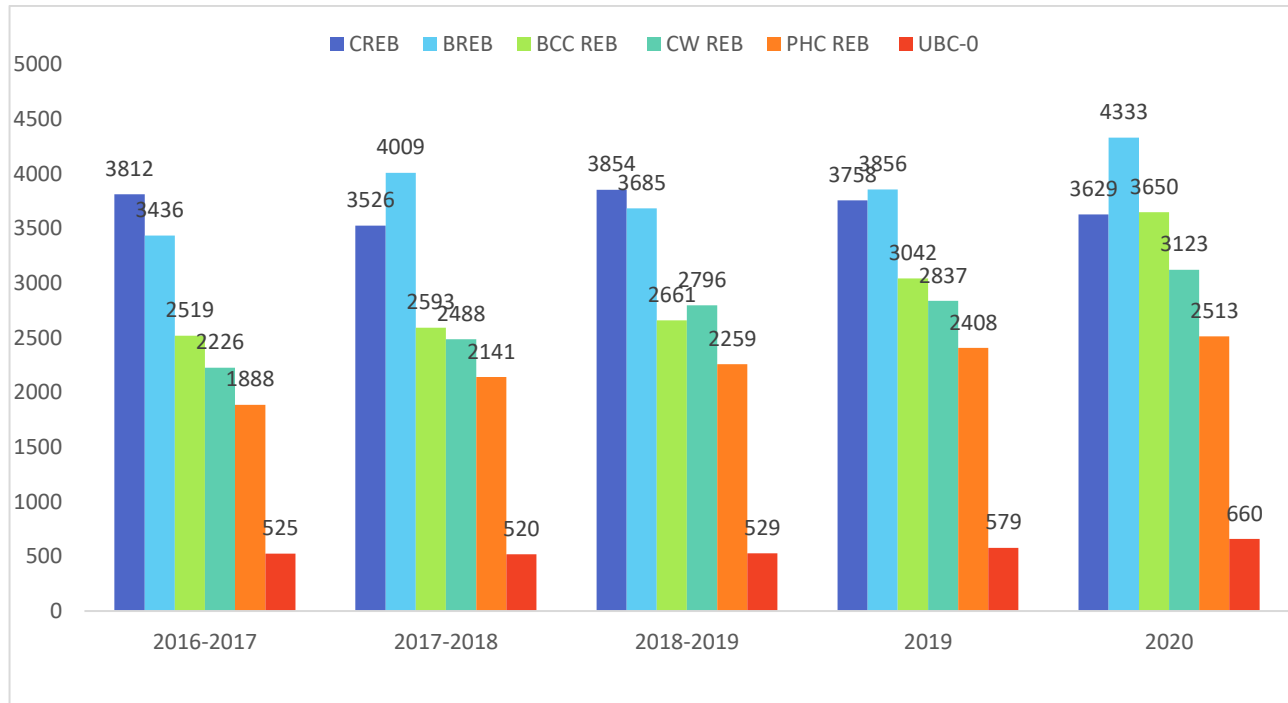
New Human Ethics Applications Received

YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO	TOTAL
2014/15	560	1000	262	334	269	145	2570
2015/16	541	970	226	366	286	149	2538
2016/17	604	978	223	379	298	149	2631
2017-18	575	945	291	369	321	160	2661
2018-19	583	1016	329	385	295	146	2754
2019	616	1045	332	363	276	168	2800
2020	564	1061	267	376	265	164	2697



Post-Approval Activities Received

YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO	TOTAL
2014/15	3225	3355	2370	1898	1461	480	12,789
2015/16	3555	3424	2432	2116	1690	481	13,698
2016/17	3812	3436	2519	2226	1888	525	14,406
2017/18	3526	4009	2593	2488	2141	520	15,277
2018-19	3854	3685	2661	2796	2259	529	15,784
2019	3758	3856	3042	2837	2408	579	16,480
2020	3629	4333	3650	3123	2513	660	17,908



METRICS: Industry Studies

UBC's Affiliated REBS charge private industry a fee for initial review and annual renewals. The clinical REBs currently charge \$3,500 for a new study and \$750 for annual renewals (BCC charges \$4,500 and \$1,000 respectively). The amounts are on par with those charged by most comparative institutions and represent a significant contribution to the boards' budgets, particularly for the four clinical boards.

Industry Sponsored Studies

YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO	TOTAL
2013/14	65	7	43	25	38	0	178
2014/15	87	1	47	20	47	0	202
2015/16	85	4	47	22	42	1	201
2016/17	76	2	38	21	34	1	172
2017/18	58	3	40	30	34	0	165
2018/19	82	7	50	20	34	1	194
2019	75	7	55	21	39	1	198
2020	70	5	46	20	33	1	175

As the table shows, the number of privately funded studies varies considerably by board and by year, making it challenging to estimate in advance the amount of income they are likely to generate. Overall, there was a slight decline between 2019 and 2020, which may have been due to the impact of the COVID-19 pandemic.

METRICS: Deferred Studies

UBC's REBs have the authority to approve studies outright, to approve them with conditions (provisos), to defer them (request that they be substantially revised and re-submitted for review), or to reject them. Rejections are extremely rare, even over a five-year time line.

Deferrals are issued more frequently than rejections and are generally the result of poorly articulated and inadequately considered studies that, in a Board's opinion, could not be approved without substantial changes.

With the exception of C&W, the REBs defer only full board studies. Minimal risk studies that are inadequate are sent back for revision, but not labelled as deferred within the RISE system.

Deferred Studies

YEAR	CREB	BREB	BCC	CWEB*	PHC	UBCO	TOTAL
2015/16	40	11	13	46	14	1	125
2016/17	30	8	13	46	13	2	112
2017/18	15	11	6	62	16	2	112
2018/19	22	19	5	47	4	0	97
2019/20	25	9	9	32	13	1	89
2020/21	12	8	8	30	7	1	66

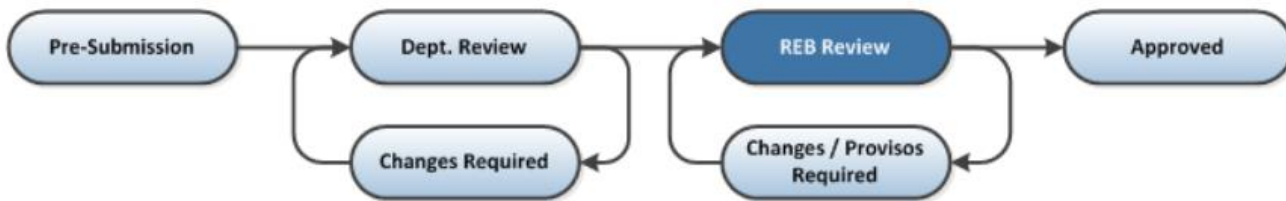
The total number of deferred studies has in general been declining since 2015.

** The C&W REB defers minimal risk as well as full board studies, which accounts for their consistently higher numbers.*

METRICS: TIMELINES

The timeline data in the tables below reflect Information derived from the RISE online database. Data for studies where time to approval took in excess of 200 days have been excluded as being outside the norm and as having the potential to impact results disproportionately. Direct comparison between UBC-affiliated REBs is inexact due to variations in staff resources and scope of work. Some staff are responsible for hospital approvals and other requirements in addition to their support of the REB.

RISe review cycle



Timelines are affected by how frequently the REBs meet. The Clinical REB (CREB) meets twice a month for full board reviews; all other UBC affiliated REBs meet monthly. Deadlines for advance submission of Full Board studies also varies between Boards: UBC-O, CREB, BREB and C&W REBs have lead times of approximately 2 weeks, while PHC and BCC REBs lead times are 3 weeks.

Timelines are affected by the time researchers need to respond to provisos. Although it is a challenge to extract researcher delays from the available data, they do consistently represent a significant portion of the turnaround times.

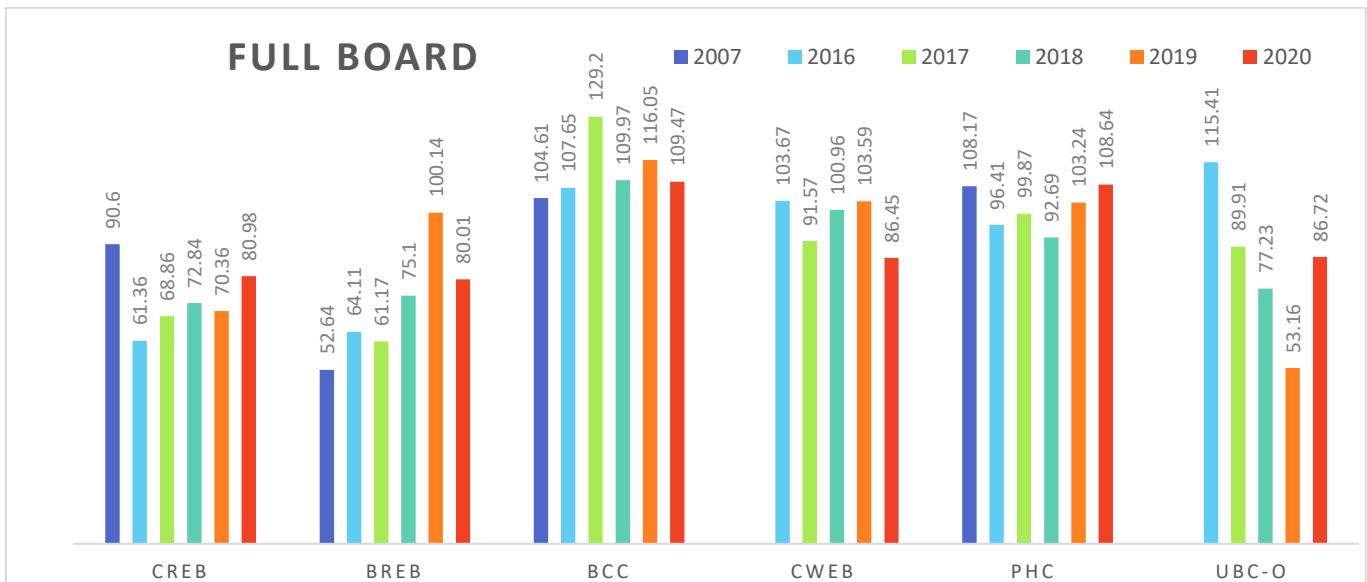
In 2020, the time to get a certificate of approval for studies requiring full board review ranged from 9.5 weeks to 12 weeks, not including lead times.

In 2020 the time to get a certificate of approval for studies that qualified for expedited review ranged from 4.4 weeks to close to 7 weeks.

Timelines

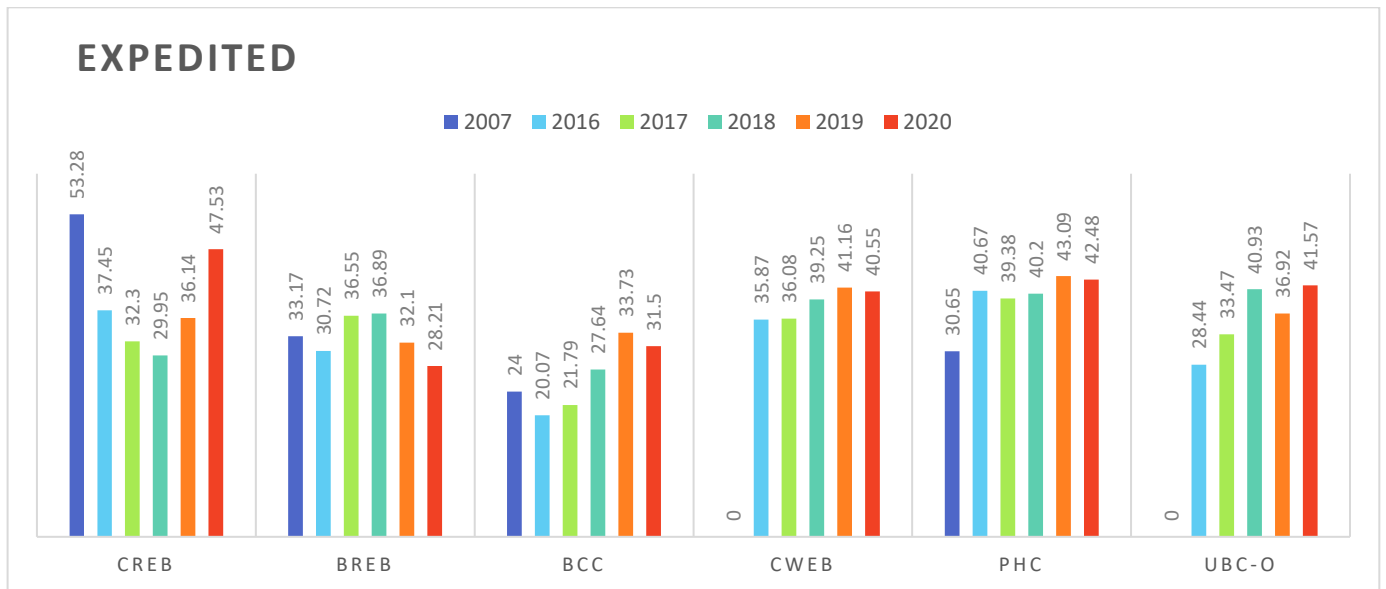
Full Board (Annual) | From Department Approval to Certificate of Approval Issued (avg. days)

YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO
2007 (first year of statistics)	90.60	52.63	104.61	NA	108.17	NA
2016	61.36	64.11	107.65	103.67	96.41	115.41
2017	68.86	61.17	129.20	91.57	99.87	89.91
2018	72.84	75.10	109.97	100.96	92.69	77.23
2019	70.36	100.14	116.05	103.59	103.24	53.16
2020	80.98	80.01	109.47	86.45	108.64	86.72
5 yr. avg less lead time	56.88	62.1	93.5	83.2	79	72.4



Expedited | Department Approval to Certificate of Approval Issued (avg. days)

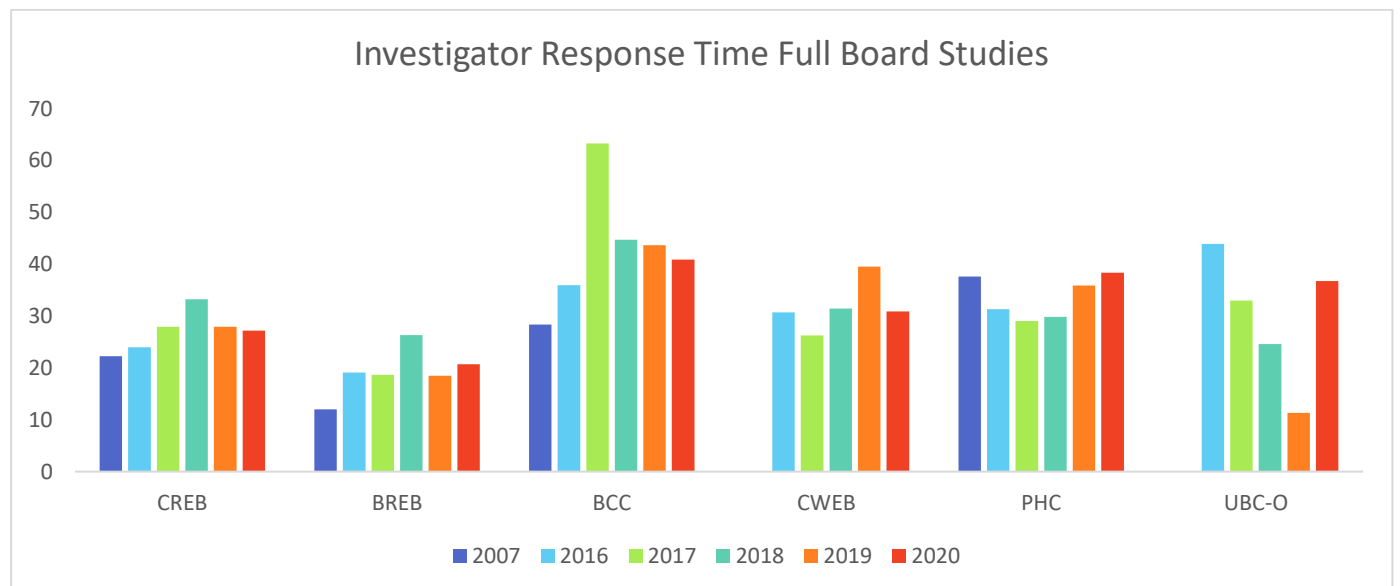
YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO
2007	53.28	33.17	24.00	NA	30.65	NA
2016	37.45	30.72	20.07	35.87	40.67	28.44
2017	32.30	36.55	21.79	36.08	39.38	33.47
2018	29.95	36.89	27.64	39.25	40.20	40.93
2019	36.14	32.10	33.73	41.16	43.09	36.92
2020	47.53	28.21	31.50	40.55	42.48	41.57



Full Board | Investigator Response Time

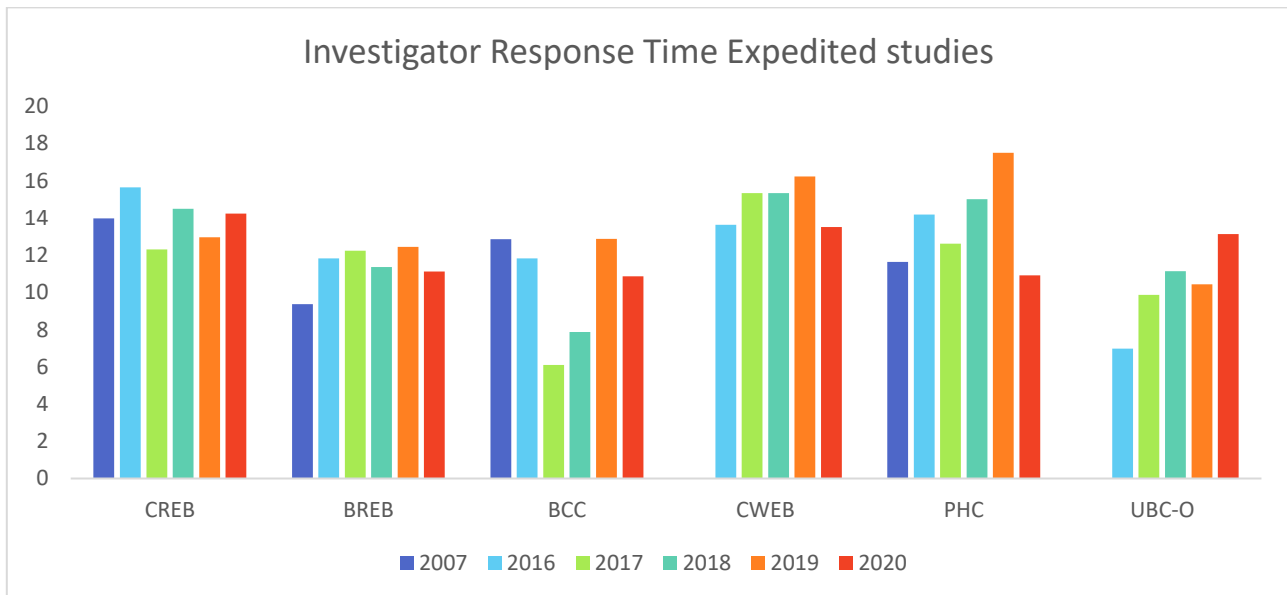
YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO
2007	22.24	12.02	8.39	NA	37.65	NA
2016	24.01	19.12	35.96	30.74	31.32	43.95
2017	27.91	18.69	63.32	26.24	29.03	33.00
2018	33.25	26.31	44.75	31.45	29.86	24.58
2019	27.91	18.51	43.65	39.53	35.91	11.35
2020	27.20	20.74	40.87	30.90	38.35	36.74

These statistics reflect the amount of time (average days) between the entry of the first provisos by the Research Ethics Board and the response to the first provisos by the researcher. There are often more than one set of provisos issued. The numbers reflect the amount of time that the study is with the research team and not in the in-box of the REB.



Expedited | Investigator Response Time

YEAR	CREB	BREB	BCC	CWEB	PHC	UBCO
2007	13.98	9.36	12.85	NA	11.64	NA
2016	15.65	11.83	11.82	13.64	14.18	6.97
2017	12.31	12,24	6.11	15.32	12.62	9.87
2018	14.50	11.36	7.87	15.34	15.00	11.14
2019	12.97	12..44	12.87	16.22	17.50	10.44
2020	14.24	11.12	10.87	13.51	10.91	13.14



The UBC Office of Research Ethics and all affiliated Research Ethics offices would like to extend heart-felt thanks to each REB member and to all staff for the extraordinary amount of work undertaken, especially during the past year of COVID-19 restrictions.

As Dr. Marc Levine (Children’s and Women’s REB Chair) states so well, “It is an understatement to say that the last eighteen months have been the most challenging that researchers and REBs have faced in living memory. Despite the personal and professional pressures we have all been under, the Metrics summarized in this report give evidence to the fact that the motivation of researchers and participants to actively pursue new knowledge and better treatments has continued unabated.”

We could not have achieved the levels of researcher support we were able to sustain without everyone’s commitment and willingness to work under less than optimal circumstances.

For a complete list of members and staff for each REB, go to <https://ethics.research.ubc.ca/about-human-research-ethics/ethics-boards> and select the REB websites.