



Health Research Ethics
Board of Alberta
Cancer Committee

Health Research Ethics Board of Alberta
Cancer Committee
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Certification of Ethics Approval - Renewal

This is to acknowledge that the renewal to the research indicated below has been reviewed and on behalf of the Health Research Ethics Board of Alberta (HREBA) – Cancer Committee (CC), I am pleased to advise that approval has been granted.

Ethics ID: HREBA.CC-17-0228_REN5
Principal Investigator: Gina Rayat
Co-Investigator(s): Dan Schiller
Student Co-Investigator(s):
Study Title: Expression of Biomarkers in Gastric Cancer and the Effect of Neoadjuvant Chemotherapy
Sponsor: Bold Therapeutics
Edmonton Civic Employees

Effective: 9-Aug-2022

Expires: 8-Aug-2023

Annual Progress Report reviewed at the HREBA-CC Full Committee Meeting on 09 August 2022.

This Committee is constituted and operates in accordance with the Alberta Health Information Act (HIA), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), Good Clinical Practice (GCP) Guidelines of the International Conference on Harmonization (ICH), Health Canada's *Food and Drug Regulations* (FDR), Part C, Division 5 and is registered with the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), IRB # 00009687.

Members of the HREBA-CC who are named as principal investigators or co-investigators in this research do not participate in discussions related to, nor vote on, such studies when they are presented to the Committee. The membership of this Committee is listed at www.hreba.ca.

This renewal is subject to the following conditions:

1. Approval is granted only for the research described in this application.
2. Any modification to the approved research must be submitted to the Committee for

approval prior to implementation.

3. Reportable events (SAE's, new safety information, protocol deviations, audit findings, privacy breaches, and participant complaints) are to be submitted in accordance with the Committee's reporting requirements.
4. A request to renew this ethics certification must be submitted and reviewed by the Committee in advance of the expiry date indicated above.
5. A closure request must be submitted to the Committee when the research is complete or has been terminated.

Approved on behalf of CC by,

Dale Dewhurst, Chair, HREBA-CC

Date:

9-Aug-2022 1:39 PM

Note: This correspondence includes an electronic signature (validation and approval via an online system).