

## DEPARTMENT OF MEDICAL GENETICS - CLINICAL RESEARCH COMMITTEE

### GENERAL INFORMATION – To help you through the process

This information package has been compiled to simplify as much as possible the application process for obtaining the required approvals to conduct research.

1. Generally most projects, including chart review, require application to:
  - Department's Clinical Research Committee (CRC) **AND**
  - UBC/C&W Research Ethics Board (UBC/C&W REB) **OR** other UBC associated REBs
2. The Head of the Department is Chair of the Department of Medical Genetics Clinical Research Committee. Forms are included at the end of this document, or obtained from:

Deb Furlong  
Administrative Assistant to Department Head      Phone: 604-875-3489  
Head, Department of Medical Genetics              Email: [dfurlong@cw.bc.ca](mailto:dfurlong@cw.bc.ca)  
Children's & Women's Health Centre of B.C.  
4500 Oak Street, Room C201, Vancouver BC, V6H 3N1

3. Additional forms and information:

Clinical Research Committee (CRC)  
Marion Thomas, PhD  
Research Program Manager                              Phone: 604 875-2000 ext. 4927  
Dept. Medical Genetics, C352                              Email: [mthomas@cw.bc.ca](mailto:mthomas@cw.bc.ca)

Forms also available on the Teamsite: <http://teamsites/sites/MedGenetics/re/default.aspx> and the UBC Department of Medical Genetics Website: <http://www.medgen.ubc.ca/hr/forms.htm>

UBC/C&W REB    [http://www.cfri.ca/research\\_support/forms/overview.asp](http://www.cfri.ca/research_support/forms/overview.asp)  
Maryam Ghafouri, Admin. Coordinator              Phone: 604 875-3103  
A2-136, 950 West 28 Ave.                              Fax: 604-875-2496  
Vancouver, BC V5Z 4H4                              Email: [mghafouri@cw.bc.ca](mailto:mghafouri@cw.bc.ca)

Marion Thomas, PhD  
Research Program Manager                              Phone: 604 875-2000 ext. 4927  
Dept. Medical Genetics, C352                              Email: [mthomas@cw.bc.ca](mailto:mthomas@cw.bc.ca)

*For further information or updates on UBC/C&W REB processes, forms, contact:*

UBC/C&W REB  
Room A2-136, 950 West 28<sup>th</sup> Avenue              Phone: 604-875-3103 Fax: 604-875-2496  
Vancouver, B.C. V5Z 4H4                              Email: [cwreb@cw.bc.ca](mailto:cwreb@cw.bc.ca); RISE: <https://rise.ubc.ca>

4. It is the responsibility of the primary investigator to schedule a meeting with the Medical Director and Program Manager of the Provincial Medical Genetics Program (PMGP) prior to implementation of the project, to discuss the impact of the research project on the workload of the clinic staff and to ensure that systems are in place.

Dr. Barbara McGillivray, Medical Director, Provincial Medical Genetics Program (PMGP)  
Phone: 604-875-2819      Email: [bmccgillivray@cw.bc.ca](mailto:bmccgillivray@cw.bc.ca)

Michelle Ostan, Acting Program Manager, Provincial Medical Genetics Program (PMGP)  
Phone: 604-875-3598      Email: [mostan@cw.bc.ca](mailto:mostan@cw.bc.ca)

## RESEARCH INFORMATION PACKAGE

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  - B. Clinical Research Committee Application for Research Projects  
(description of **Form 2**)
  - C. Clinical Research Committee Application for Directed Study Projects by Genetic Counselling Students (MEDG 548)  
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- III. **UBC/C&W Research Ethics Board – Ethical & Scientific Review**
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## I. Provincial Medical Genetics Program (Clinical Research Procedure)

The following are excerpts from the Provincial Medical Genetics Program Clinical Research Procedure regarding the review of charts for research or service purposes.

### Confidentiality:

- i. All publications resulting from research investigations on the clinical records must be seen by the Head of the Department for consideration and approval prior to the publication. Such publications will acknowledge the source of data and the fact of adherence to strict rules of confidentiality.
- ii. No person assigned to processing clinical record data will create or release any listing or tabulations without prior agreement of the University, Hospital and Department Head via the Clinical Research Committee. No computer output from the clinical record data will be released without prior agreement for the above.

### Security:

- iii. Charts must NOT be removed from the Department to be worked on, or for research purposes.

### Access for Research Purposes:

- iv. A. All individuals, including Residents, Fellows, Genetic Counselling students or others, wishing access to charts to do a research study of any kind, must apply in writing to the University, Hospital and the Department Head via the Clinical Research Committee (CRC Form 2 or 3 ). After consultation, as necessary, with the Committee approval may be granted if the project is well designed and relevant. Until approval is obtained from the Department Head, printouts from the database or listings of any kind for the project cannot be obtained.
- iv. B. All individuals, including Residents, Fellows, Genetic Counselling students or others, wishing access to charts to do a project related to service must apply in writing to the PMGP - Medical Director (Dr. Barbara McGillivray) for approval (CRC Form 1).
- iv. C. If the PMGP - Medical Director views the project as research related (and NOT service), an application must be submitted to the Clinical Research Committee (CRC Form 2 or 3) and UBC/C&W REB.

## II. Department Forms

### A. Application for Access to Charts for Service Projects

#### i. Purpose of Application Form:

This application form (**CRC Form 1** – attached) is completed when the request to review patient database queries or charts is related to patient care activities and where **no patient contact is involved**. The following are examples of patient care activities:

- Quality Assurance Activities (waiting list review, chart audit, review of number and type of referrals for workload evaluation, etc.)
- Finding a family with a specific diagnosis who would be interested in talking with another family recently diagnosed
- Diagnosis searches for funding of new programs

If the quality assurance activity or other activities listed above provide information that may be published, approval should be obtained from the Clinical Research Committee (use CRC Form 2 - attached). Similarly, if during the course of a service project the decision is made to submit the study for publication, approval must be obtained from the Clinical Research Committee.

#### ii. Process of Obtaining Approval:

- a) Obtain application form from Department Head's Administrative Assistant
- b) Complete form and submit **electronically** to the Medical Director for approval
- c) Once the Medical Director makes a decision, the original application is returned to the applicant, and a copy is returned to the Records Clerk

## II. Department Forms

### B. Clinical Research Committee Application for Research

#### i. Purpose of Application Form:

This application form (**CRC Form 2** - attached) is completed for all projects that require the **use of patient records** (except service projects) **or contact with patients**. Requests for queries of the patient database or access to patient records, will not be provided until approval is obtained.

#### ii. Process of Obtaining Approval:

- a) Obtain application form from the Department Head's Administrative Assistant.
- b) Complete form and submit **electronically** to the Department Head's Administrative Assistant (Deb Furlong) for review, it will then be given to the Department Head to take forward to Clinical Research Committee for approval.
- c) Submit an application for approval from the UBC/C&W Research Ethics Board (see Section IV).
- e) The Principal Investigator(s) and Records Clerk receive notification of the outcome of the application to the Clinical Research Committee.

**NOTE:** Often, if the project does not require direct patient contact and only a chart review, the Department Head will approve this project administratively so that the applicant can begin work. This approval is provisional and requires confirmation by the full CRC Committee at its next meeting plus UBC/C&W REB approval.

## II. Department Forms

### C. Clinical Research Committee (CRC) Application for Directed Study Projects by Genetic Counselling Students (MEDG 548)

#### i. Purpose of Application Form:

This application form (**CRC Form 3** - attached) is completed **for all Directed Study Projects undertaken by students in the Genetic Counselling Program** – regardless of purpose, supervisor(s), intended use or content. Requests for queries of the patient database or access to patient records, will not be provided until approval is obtained. The student must be present at the meeting to present their project. It is strongly recommended that the Principal Supervisor also be present at the CRC meeting.

#### ii. Process of Obtaining Approval:

- a) Obtain application form from the Department Head's Administrative Assistant or Graduate Advisor/Program Director of the Genetic Counselling Program.
- b) Complete form and submit **electronically** to the Department Head's Administrative Assistant for review. It will then be given to the Department Head to take forward to the CRC for approval.
- c) Submit application for UBC/C&W REB approval using the online RISE application process. Submit the appropriate utilization forms to UBC C&W REB.
- d) The Principal Supervisor, Medical Director (PMGP), Program Manager (PMGP), and Records Clerk will receive notification of the outcome of the application to the CRC.

**NOTE:** Often, if the project does not require direct patient contact and only a chart review, the Department Head will approve this project administratively so that the applicant can begin work. This approval is provisional and requires confirmation by the full CRC Committee at its next meeting plus UBC/C&W REB certificate of approval.

### III. UBC/C&W Research Scientific & Ethics Approval

#### A. Summary/General Information

All research involving investigators with UBC appointments and/or UBC staff or students and which involve human subjects, including chart review, must be approved by the UBC/C&W Research Ethics Board (REB). As part of the UBC/C&W REB review process, the application will also be reviewed for scientific merit.

#### B. UBC/C&W forms – Information on forms for Ethical Review:

UBC/C&W Research Ethics Board	OR	Marion Thomas, PhD
Room A2-136		Research Program Manager
950 West 28 <sup>th</sup> Avenue		Dept. Medical Genetics, C352
Vancouver, B.C. V5Z 4H4		Phone: 604 875-2000 Ext. 4927
Phone: 604-875-3103		Email: <a href="mailto:mthomas@cw.bc.ca">mthomas@cw.bc.ca</a>
Fax: 604-875-2496		
Email: <a href="mailto:cwreb@cw.bc.ca">cwreb@cw.bc.ca</a>		
RISe: <a href="https://rise.ubc.ca">https://rise.ubc.ca</a>		

#### C. Ethical Review Information (2 types)

- i) Ethical Review of Activities Involving Human Subjects in Questionnaires, Interviews, Observations, Testing, Video and Audio Tapes, etc. Any project which involves these activities must be reviewed and approved by the UBC/C&W REB before any work is started.

For more information:

UBC/C&W Research Ethics Board	
Maryam Ghourfour, Administrative Coordinator	
Room A2-136	Phone: 604-875-3103, Fax: 604-875-2496
950 West 28 <sup>th</sup> Avenue	Email: <a href="mailto:cwreb@cw.bc.ca">cwreb@cw.bc.ca</a>
Vancouver, B.C. V5Z 4H4	RISe: <a href="https://rise.ubc.ca">https://rise.ubc.ca</a>

- ii) Ethical Review of Activities Involving Human Subjects Clinical Procedures. Any project which involves surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of medical records, etc must be reviewed and approved by the UBC/C&W REB before any work is started.

Help/Questions – Call:

UBC/C&W Research Ethics Board	
Maryam Ghafouri, Admin. Coordinator	Phone: 604-875-3103, Fax: 604-875-2496
Room A2-136, 950 West 28 <sup>th</sup> Avenue	Email: <a href="mailto:cwreb@cw.bc.ca">cwreb@cw.bc.ca</a>
Vancouver, B.C. V5Z 4H4	RISe: <a href="https://rise.ubc.ca">https://rise.ubc.ca</a>

Or

Contact Dr. Barbara McGillivray	Phone: 604-875-2819
	Email: <a href="mailto:bmcgillivray@cw.bc.ca">bmcgillivray@cw.bc.ca</a>

#### D. UBC Policy #89

i) UBC Policy #89 (<http://www.universitycounsel.ubc.ca/policies/policy89.pdf>) is intended to create a research environment in which human subjects are protected, and to ensure responsibilities are discharged according to the relevant ethical standards, by promoting awareness of research ethics amongst faculty, staff and students, establishing an independent research ethics review process, and putting in place mechanisms for the protection of human subjects in ongoing research including monitoring. This document is supplementary to the Canadian Tri-Council Policy Statement (TCPS) guidelines (<http://pre.ethics.gc.ca/eng/policy-politique/tcps-eptc/readtcps-lireeptc/>).

#### E. UBC/C&W REB Deadlines

i) Deadline for the online RISE ethics application submission is the **second Wednesday of each month**. The UBC/C&W REB will meet two weeks after this deadline to discuss any changes required.

ii) *PLEASE NOTE:* When the RISE application has been submitted by the PI an automatic email is generated that goes to the Department Head for approval. Only after this application is approved at the departmental level, only then will UBC/C&W REB receive your application. You may wish to notify the Departmental Head or his/her administrative assistant that you have submitted an application.

**IV Clinical Research Committee (CRC) FORMS 1, 2 and 3.**

<p><b>CRC Form 1</b>                  Department of Medical Genetics                  Children's &amp; Women's Health Centre of BC – Oak Street                  CLINICAL RESEARCH COMMITTEE  <b>APPLICATION FOR ACCESS TO CHARTS FOR SERVICE PROJECTS</b></p>	
PRINCIPAL INVESTIGATOR:	DATE:
APPROXIMATE NUMBER OF CHARTS TO BE REVIEWED:	DATE CHARTS REQUIRED:
PARTICIPANTS IN PROJECT:	
TYPE OF PROJECT:	
PURPOSE OF PROJECT: <input type="checkbox"/> Quality Assurance <input type="checkbox"/> Other (explain)	

<b>MEDICAL DIRECTOR'S ACTION:</b>	
Approved	
Not Approved	
Refer to Clinical Research Committee	
Medical Director's Signature:	Date:

<b>PRINCIPAL INVESTIGATOR'S SIGNATURE:</b>
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***No patient contact permitted for service projects. If patient contact is required, approval should be requested as a research project.***

cc:      Original to Department Head  
          Applicant (PI)  
          Records Clerk

<p><b>CRC Form 2</b>  <b>Department of Medical Genetics</b>  <b>Children's &amp; Women's Health Centre of BC</b>  <b>CLINICAL RESEARCH COMMITTEE</b>  <b>APPLICATION FOR RESEARCH PROJECT</b></p>	
PRINCIPAL INVESTIGATOR:	
OTHER PARTICIPANTS:	
TITLE OF PROJECT:	
EXPECTED START DATE:	EXPECTED COMPLETION DATE:

Attach a brief (1-2 page) summary of project or a copy of the UBC/C&W Research Ethics Board application.

1. Does project require use of Medical Genetics Records? Y\_\_\_ N\_\_\_  
 If yes: Estimated number of charts \_\_\_\_\_ Dates \_\_\_\_\_
2. Does project require direct patient contact? Y\_\_\_ N\_\_\_  
 If yes, attach copy of contact letter to family. **NB:** families/patients cannot be contacted except with prior approval of attending geneticist and referring physician.
3. Is funding available for project? Y\_\_\_ N\_\_\_  
 If yes, indicate accounts available to defer costs of using Department of Medical Genetics clinical resources and personnel.

If no, itemize expected requirements for Department of Medical Genetics clinical resources and personnel.

4. Has approval by UBC/C&W Research Ethics Board been sought or obtained for this project? Y\_\_\_ N\_\_\_

PRINCIPAL INVESTIGATOR'S SIGNATURE:	DATE:
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cc: Original to Department Head  
 Applicant (PI)  
 Records Clerk

**CRC Form 3 – Directed Study Projects**  
**Department of Medical Genetics**  
**Children's & Women's Health Centre of BC**  
**CLINICAL RESEARCH COMMITTEE**  
**APPLICATION FOR DEPARTMENTAL APPROVAL**

INVESTIGATOR (student's name):

PRINCIPAL SUPERVISOR:

Other supervisors/investigators:

TITLE OF PROJECT:

EXPECTED  
START DATE:

EXPECTED  
COMPLETION DATE:

OTHER PARTICIPANTS IN PROJECT (e.g. consumer groups, support organizations, etc.):

TYPE OF PROJECT (check all that apply):

Chart Review     Unique research     Part of a larger project already having all approvals

Educational     Patient/client survey     Other \_\_\_\_\_

PURPOSE OF PROJECT:

OVER

1. Does project require use of Medical Genetics' charts? Y\_\_\_\_ N\_\_\_\_

If yes: Estimated number of charts \_\_\_\_\_ Chart Years: \_\_\_\_\_

2. As per the CRC guidelines "It is the responsibility of the primary investigator (student) to schedule a meeting with the Medical Director and Program Manager of the Provincial Medical Genetics Program prior to implementation of the project, to discuss the impact of the research project on the workload of the clinic staff and to ensure that systems are in place."

Meeting Date: \_\_\_\_\_ Signature: Medical Director / Program Manager

Not Required: \_\_\_\_\_

3. Does project require direct patient contact? Y\_\_\_\_ N\_\_\_\_

If yes, attach copy of contact letter to family. NB: Medical Genetics families/patients cannot be contacted except with prior approval of attending geneticist and referring physician.

4. Is external funding available for project? Y\_\_\_\_ N\_\_\_\_

If yes, indicate monies available to defer costs.

If no, itemize expected requirements for Department of Medical Genetics clinical resources and personnel. Attach an additional sheet if necessary.

5. Has approval by any UBC Research Ethics Board been obtained for this project?

Y\_\_\_\_ Which one? \_\_\_\_\_ Submitted (date) \_\_\_\_\_

Not Required: \_\_\_\_\_

6. Attach a 1 – 2 page summary of the project.

INVESTIGATOR'S (STUDENT'S) SIGNATURE:	DATE:
PRINCIPAL SUPERVISOR'S SIGNATURE:	DATE:
ADDITIONAL SUPERVISOR'S SIGNATURE:	DATE:

cc: Original to Department Head  
Investigator (Student)  
Records Clerk