Ontario's Community Health Centres

BLACK CREEK COMMUNITY HEALTH CENTRE

Research Policy and Protocols

Preamble:

The term "*research,"* is often used very broadly. This policy relies on a definition developed by the Tri-Council Policy Statement, Government of Canada, 1998, in which research is defined as involving:

> **"A systematic investigation to establish facts and principles of generalizable knowledge."**

Research Ethics

Black Creek Community Health Centre's Research Policy and Protocols[1] focus more on what could be referred to as "moral imperatives," than on the mechanics of research. Moral imperatives focus on ethics and would include such things as:

- Respect for human dignity
- Respect for vulnerable persons
- Respect for privacy and confidentiality including data maintenance, storage, release of information, use of names or codes, destruction of data at the conclusion of the research.
- Balancing harms and benefits
- Respect for free and informed consent

These and other related moral imperatives serve as the foundation from which our Centre's research endeavours will proceed.

Research Priorities

Black Creek Community Health Centre is committed to engaging in research geared at generating knowledge, community capacity and advocacy for overcoming health disparities and improving health outcomes. The Centre promotes community-based participatory research as a way to empower residents to become agents of change in their own communities.

The approval of ***research projects*** will be guided by the following priorities:

- To focus on client-centred research with an emphasis on the determinants of health
- To assess the Centre's success in delivering programs and services as a community health centre.
- To contribute to the body of knowledge relevant to the philosophy and goals of community health centres.

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[1] Portions of this Policy and Protocols document have been adapted, with kind permission, from Access Alliance Multicultural and Health Services' "Research Policies and Protocols"(2012).

- To focus on projects that contribute to the enhancement of clinical knowledge and effective treatment modalities.

Process

External researchers who are interested in collaborating with Black Creek CHC on a research study are required to complete and submit the "Application from External Researchers for Black Creek Community Health Centre to Assist, Collaborate or Participate in a Research Study" form (APPENDIX 1).

Written research proposals will be evaluated by the Management Team and Executive Director in order for discussion, approval and identification of possible resources. The following criteria will be considered in the decision making process:

Criteria

- the research project is consistent with BCCHC's mission, values, and policies
- the research would be relevant and beneficial to the Centre's programs, services or client population and contribute to knowledge of best practices for working with marginalized groups.
- the project has appropriate confidentiality mechanisms in place which are consistent with legal requirements and internal policies.
- the research proposal must clearly state the type of resources required, material, human and financial.
- the project respects and offers fair treatment to the participants at all times
- the risks for participants are minimal
- the project has appropriate consent mechanisms in place which are consistent with Black Creek policies
- the project will ensure anonymity in the presentation of results
- the research project must have been successfully reviewed by a research ethics committee
- the research proposal meets the Ethical Standards outlined in the Tri Council Policy Statement on Ethical Conduct for Research Involving Humans established jointly by Canadian Institute of Health Researchers (CIHR), Social Sciences and Humanities Research Council of Canada (SSHRS), and Natural Sciences and Engineering Research Council of Canada (NSERC), and adopted by Research Ethics Boards in Universities and other institutional settings.
- In those cases where Black Creek CHC is not the Principal Investigator, a specific description of its roles and responsibilities must be defined in the proposal.

Declining to participate in or withdrawing from a Black Creek CHC research project will not affect the participant's access to programs and/or services.

Verbal or written reports on the project will give appropriate credit to Black Creek CHC, and will be made available to all stakeholders and project participants.

See **APPENDIX 3: Policy for Dissemination of Research Findings (delete)**

Ethical Conduct in Research

The intent of the ethics review process is to ensure that all investigations involving Human participants are consistent with the Centre's Research Policy and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (1998) as well as ethics guidelines of professional associations.

Staff involved in research projects must complete the Tri-Council Policy Statement: ethical conduct for research involving humans tutorial (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)

This process offers a level of assurance to the research participants, the investigators, and the Centre that participants will be involved in a consent process which is fully informed[2][3] and voluntary. The review process also ensures adequate provisions for protection of an individual's privacy. Client confidentiality will also be maintained in accordance with Black Creek CHC's Confidentiality and Mandatory Reporting Policy (***See APPENDIX 2: Research Data Security and Management).***

In addition, the process makes certain that known and anticipated risks will be adequately communicated prior to participation, and do not outweigh potential benefits for research participants. Procedures used to recruit participants are examined to ensure they are free of explicit or implicit coercion and enable participants to withdraw their consent at any time without fear of reprisal.

BCCHC will ensure all participants are informed as to their understanding of their participation in the research project.

Actions that violate the standards of the Research Ethics Board may lead to the imposition of sanctions. If staff, students, or research collaborators have reasons to believe that misconduct has occurred, the individual has a responsibility to report to the Executive Director, who will initiate an investigation and set the appropriate sanction according to the severity of the misconduct (i.e. reprimand, censure, suspension).

[2] Given the diverse nature of the community within BCCHC's catchment area, every attempt will be made to provide appropriate cultural and language interpretation to participants and those offering consent for minors.

[3] Health Canada: Research – Requirements for Informed Consent: http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php

Publication and Authorship

BCCHC recognizes that as producers of research, we have an ethical obligation to publish and disseminate findings so that they may benefit the community. Sharing findings with staff, other service providers, community residents and policy makers is encouraged. The findings may used to improve programs, services and public policy.

Procedures

The following procedures are intended to provide direction in the authoring of research related publications and recognition of intellectual property. Authorship of external publications (e.g., journal articles, book chapters, abstracts, reports and conference presentations)

The Centre will ensure that any person who has substantially contributed to the concept or design of the publication, the generation of its content, and its writing is listed as an author. Reviewers and copy editors will be acknowledged but not listed as authors. In the case of a research project, anyone who has substantially contributing to carrying out the study and/or interpreting the data must be duly acknowledged. Before agreeing to be listed as an author, individuals should be made aware that:

- Anyone accepting authorship accepts responsibility for ensuring the validity of the whole manuscript;
- The principal author(s) are responsible for verifying the accuracy of the information reported in the publication;
- All authors must be involved in making decisions about the publication and its distribution and should have the opportunity to review research results, analyses and interpretations used in preparing the publication;
- Each author should have access to the full manuscript prior to its submission for publication and should agree to being listed as a co-author;
- All authors should be involved in deciding the order of authorship. In general, the principal author(s) will be the person(s) who have made the greatest contribution to the writing of the article. In the case where authors have contributed equally, alphabetical order will be used;
- Authors that were Black Creek CHC staff members at the time the publication was submitted for publication will list Black Creek CHC as their affiliation on the publication. In the case of students that contributed to a publication while completing a placement or practicum, a note will be included to indicate that the research was completed in the context of a placement at BCCHC.

Authorship internal publications

In general, the guidelines described above will also apply to reports and other publications produced for internal use or for limited circulation (e.g. funders or partners). In this case, BCCHC will appear as the publisher or the author, unless otherwise approved by the Executive Director.

Placement students may submit publications written during the placement for academic credit or as examples of work completed provided that:

- They were the principal author of the publication;
- They acknowledge the contribution of any staff, other students or research collaborators that provided direct guidance, feedback or advice on the publication;
- The publication does not contain sensitive or confidential information about the agency or its clients;
- The publication will not be shared outside of their academic setting (unless prior approval has been received by the Executive Director to do so).

Addressing misconduct in publications

Integrity is fundamental to the research and publication process. Misconduct of any sort will not be condoned and may result in disciplinary action. In the context of research and publishing, misconduct sometimes takes the form of academic dishonesty. Examples of academic dishonesty include, but are not limited to: falsification or fabrication of research results and plagiarism (i.e., copying another person's work and passing it off as one's own).

If staff, students or research collaborators have reasons to believe that misconduct has occurred, the individual has a responsibility to report it to the Executive Director, who will initiate an investigation and set the appropriate sanction according to the severity of the misconduct. If the complaint is about the Executive Director, the complaint will be filed with the President of BCCHC's Board of Directors.

Dissemination of Research Findings

As a commitment to ethical research practice and to community-based participatory action research, Black Creek Community Health Centre is committed to carrying out research projects that lead to positive benefits/changes for community members, including:

- the recognition, dissemination, expansion of knowledge that immigrant, refugees and racialized other marginalized groups hold;

- mobilizing evidence-based improvements in direct services at the local/immediate level for clients; and
- mobilizing evidence-based improvements in policies for positive systemic changes.

Results and reports will be actively shared within Black Creek CHC (with staff, managers and the Executive Director and Board of Directors) to inform positive changes in internal policies and practices. Results and reports will also be shared strategically to policy makers to inform policy changes geared at promoting health equity. Particular attention will be paid to disseminating findings/reports at the community level through popular knowledge exchange tools and using accessible language. Whenever possible, peer researchers will be invited to play an active role in developing communication materials and disseminating research findings and recommendations.

Reports that are available to the public will be posted on the BCCHC website on a timely bais. Media inquiries about research projects and findings will be addressed by the Principal Investigator, Executive Director or by a designated research team member (e.g, Research Coordinator). Peer Researchers and other participants will respond to media inquiries on behalf of Black Creek CHC only after they have completed appropriate training and have consulted with the Principal Investigator, Executive Director, or Research Coordinator in advance.

All reports and publications will observe the guidelines outlined in the "Publication and Authorship" section of the Black Creek Community Health Centre Research Policy. Any reports or publication will be submitted to the Executive Director prior to the distribution or submission and the Centre will have the right to request and receive acknowledgement or to include a disclaimer in the report publication (i.e., "The views contained in this report are not representative of the views of Black Creek Community Health Centre").

All research team members will act in accordance with this policy and associated protocols. Failure to do so will lead to any or all of the following actions, including sanction, reporting to the appropriate organization and any appropriate reporting or disciplinary processes.

I have read the above document and agree with all the stated policies and protocols.

_____	_____
Name	Agency
_____	_____
Signature	Date

Appendices:

1. Application from External Researchers for Black Creek Community Health Centre to Assist, Collaborate or Participate in a Research Study
2. Protocol: Security and Management of Research Data

Developed: June 2005
Reviewed: July 19, 2005, Aug 2007, April 2011, April 2013 (Research Advisory Committee), Dec 2014
Approved: Sep 2007, June 2011, Nov 2011, Jan 2015

APPENDIX 1:

Application from External Researchers for Black Creek Community Health Centre to Assist, Collaborate or Participate in a Research Study

This form is for external researchers (academics, policy researchers, graduate students) interested in collaborating/partnering with Black Creek Community Health Centre in conducting their study. It is also for researchers inviting Black Creek CHC to participate in their study or for those requesting assistance from Black Creek CHC in recruiting participants, sharing of study findings, or any other aspects of their study.

Please provide detailed answers to the questions below so we can better understand your study. The information in this form will be used by Black Creek CHC to assess whether to collaborate/assist/participate in your study based on relevance and fit with agency goals and operational framework. We get numerous requests throughout the year. We prioritize research projects that have tangible goals and commitment to building healthy public policies and improving programs/services to promote newcomer health equity.

Genuinely ethical research protocol is also an important criterion with proactive steps to understand and address ethical concerns faced by vulnerable newcomers in participating in your study.

1. Administrative:

a. Title of your study:

b. Names of the main investigators and their institutional affiliations:

c. Partners/collaborators:

d. Duration of the study (start date and end date)

e. Study funded by (if you have received funding):

f. If study is being led by a graduate student as part of thesis/dissertation research, please list name of main supervisor:

g. Has this study received approval from Research Ethics Board?

o Yes. Which REB?: _____ Date received: _____

o No. Which REB are you applying to?:_____

2. Goals and Impacts:

a. What are the key goals of your study?

b. How will the study goals and findings contribute to strengthening services/programs offered at Black Creek CHC and/or to improving health of clients we serve?

c. What are the expected policy, program/service planning or social impacts from the study (please be as specific as possible and identify tangible policy/social outcomes)?

d. Which public policies specifically will this study help to inform (identify specific government agency or decision making body and where possible the particular legislation)?

3. Research Methods

Describe your research methods?
List all data collection instruments/methods (survey, interviews, focus groups, arts-based method) you will use, and the target population and sample size for each.

4. Research Ethics:

What proactive and extra steps will you take to ensure that vulnerable population groups that may be participating in the study do so in genuinely informed ways, their confidentiality/privacy is fully ensured, and harm/risk is minimized to fullest extent. *(for instance, vulnerability facing newcomers may be linked to limited English language fluency, refugee claimants or non-status, isolated or easily identifiable newcomers communities, or just being new and unfamiliar with how research ethics works. Please discuss how these will be overcome).* **Attach a copy of your consent form with this application.**

5. Community Empowerment through Research:

Black Creek Community Health Centre actively practices and promotes community-based research in which members of target community are engaged in a participatory, or, if possible, leadership capacity in the knowledge production process (and not just as research subjects).

Indicate what steps you are taking, if any, to involve target community members as collaborators in the knowledge production and sharing process of your study (e.g. in identifying research questions, conducting research, helping to analyze/interpret data, and in knowledge translation activities). If none, discuss why not?

6. Requested Assistance, Collaboration or participation from Black Creek Community Health Centre:

Indicate what types of assistance, collaboration or participation you are requesting from Black Creek Community Health Centre, and why?

7. Knowledge Translation and Impact:

a. What do you intend to do with the findings of this project?
To achieve stated policy/social impact goals of your study, how will you share your research findings with

(i) study participants/community and with
(ii) relevant policy/decision makers.

b. How and when will you share study findings with Black Creek Community Health Centre?
We strongly recommend that you us provide a hard copy of your study report/publication and also consider giving presentation to relevant teams within Black Creek Community Health Centre on the study findings with tangible program planning recommendations.

_____
Name of Principal Investigator

_____
Signature of Principal Investigator

_____
Date

Appendix 2:
Protocol: Research Data Security and Management
Black Creek Community Health Centre regularly collects and stores data as part of its ongoing research and evaluation activities. Data may be in written form (e.g., completed surveys or evaluation forms), electronic documents (e.g., interview transcripts), audio, video recordings, or digital photographs. This policy also applies to related documents that may contain personal or sensitive data (e.g., consent forms, screening forms).

For all kinds of research and evaluation data Black Creek Community Health Centre will take all reasonable measures to ensure that:

- Identify and communicate various roles and responsibilities of the individual research team members (both internal and external), including Research Coordinator, research administrative staff, etc.
- The data is **securely and properly categorized and appropriately stored.**
- Designated research team members have t**imely access to well organized and security-processed research data** that is directly relevant to their work;
- Designated research team members **effectively monitor/manage the access, reproduction, and utilization** of data and related research documents.

All research team members, research assistants, transcribers, translators, and consultant/contract staff who will be working with data will be required to sign the Confidentiality Agreement Form.

1. Data Security Levels

A research project produces different kinds of datasets and documents that require different levels of security. Also, security level for data/document may change after processed/analyzed. The level of data security is mainly based on the extent to which data/documents contain information that can identify a particular person, group, place, and institution. In general, all raw, unprocessed research data and documents that contain demographic information are to be considered of high security. The latter include consent forms, Demographic Information Form and Participant Intake/Screening Forms should be considered high security and Honourarium Forms for research participants. However, the Finance Department staff can have access to this information along with designated research team members. The level of data security determines which members of the research team have access to particular sets of datasets and research documents. While data security levels may vary by project, the following table categorizes typical research data and documents by their level of security:

High Security Data and Documents	**Medium Security Data and Documents**	**Low Security Data and Documents**	**Transparent/Open Data and Documents**
Only Project Leads (PIs) and Co-investigators have access	*Only PIs, co-investigators, and collaborators have access*	*PIs, co-investigators, partners and research participants have access*	*Open to all*
Consent Forms			Confidentiality Agreements; Partnership Agreement

Intake/Screening Forms	Honourarium Forms (Finance Staff can have access)		
Demographic Information Form	Aggregate level data with all potential identifiers removed	Aggregate level analyzed data with all potential identifiers removed	Aggregate level data that has been summarized and presented in the context of a report/workshop
All digital recordings from focus groups			
All verbatim raw transcripts	Transcripts with all potential identifiers removed	Coded quotes and narratives with potential identifiers removed	Coded quotes and narratives (with potential identifiers removed) presented as part of a report/workshop
All verbatim raw translations	Translated data with all potential identifiers removed	Coded quotes and narratives with potential identifiers removed	Coded quotes and narratives (with potential identifiers removed) presented as part of a report/workshop
Completed survey and evaluation forms with names included (in most cases, participants will not be asked to provide their name when completing a survey or evaluation form)	Completed survey and evaluation forms with names removed	Aggregate level analyzed data with all potential identifiers removed	Aggregate level data that has been summarized with all relevant context provided (e.g., background/rational of project, overview of participant characteristics, etc)
Survey data files (e.g., Excel, SPSS) still containing potential identifiers	Aggregate level data with all potential identifiers removed	Aggregate level analyzed data with all potential identifiers removed	Aggregate level analyzed data presented as part of report/workshop
Photos, Films, Drawings etc, that can identify any particular person, place, agency	All shots, footage with potential identifiers removed	All shots, footage with potential identifiers removed	All shots, footage with potential identifiers removed and presented as part of a report/workshop
Focus group, interview notes/field logs	Focus group, interview notes/field logs with all potential identifiers removed	Focus group, interview notes/field logs with all potential identifiers removed	

2. Transporting data

It is sometimes necessary to transport confidential files from one physical location to another (e.g., from where data is collected at Black Creek Community Health Centre offices). When travelling with data the researcher will take all reasonable measures to keep the data secure by:

i. Password protected laptop computers, USB memory devices, and external hard drives that contain confidential information;
ii. Sealing notes, consent forms and recordings in one or more sealed envelop that is labelled "Confidential";
iii. Storing that envelope in a secured travel case;
iv. keeping the material in their possession at all times;
v. Transferring the materials to a secure storage location as soon as reasonably possible.

3. Use of Centre Nightingale on Demand (NOD) FOBs

If access to the Centre's EMR system, Nightingale on Demand (NOD) is required for the research study, all research team members are required to receive appropriate training on the NOD system from the Centre's Data Management Coordinator (DMC) and to review, complete and abide by the terms of the Centre's "EMR FOB Custody Agreement".

3. Using FOB to access EMR - abiding by the FOB policy

4. Security-processing of Raw Data

All raw data must be "security-processed" before it can be used or distributed to designated members of the research team. Security Processing of raw data involves the following steps

i. Carefully review all transcripts/notes/photos/film footage and ***assign a level of data security for this dataset***
ii. Delete or white-out all data/info that directly includes names of people, easily identifiable groups, institutions, or specific location; Assign pseudo-name or code.
iii. Identify all data (excluding names) that potentially identify a particular person, group, institution, or specific location and develop a way to remove the identifiable information
iv. Password protect all electronic copies of data so only designated research team members can access them.
v. Process/Code/Analyze data to bring to ***aggregate leve***l such that individual persons, easily identifiable groups, institutions cannot be identifiable.
vi. Save photos and film footage of interviews and focus groups in the Raw Data folder (secure network drive with access limited to Project Leaders and Co-Investigators). Photos and film footage should be given to the designated research team member to be archived for storage.

5. Data Backup

The Research Coordinator will need to make back-up copies of all research data and documents (hard and electronic copies) and securely store the originals and then use only the copies for analysis. Back-up copies of the following research data and documents do not necessarily need to be made:

- Signed Consent Forms
- Completed Survey Forms
- Confidentiality Agreements

6. Data Storage

A. **Hard Copy -** Consent form, paper copy of focus group/interview transcript, field note, questionnaire, paper copy of participant contact list/master list, job application

- The interim secure storage of documents is the responsibility of Research Coordinator
- These documents must be stored in a locked cabinet at all times.
- All documents will be transferred to the designated research team member for secure long-term storage in a centralized locked cabinet. Only the Principal Investigator, Research Coordinator, and designated research administrative staff will have access to the centralized archive. Other research staff may access these data by contacting one of these individuals.
- All documents will be filed in an organized manner. They will be placed in envelopes; labeled appropriately with project information, date and location of data collection; and sealed.

B. Electronic Files - Transcripts, typed filed notes, survey data (entered in Excel, SPSS, etc..), electronic contact list/ master list, job application

- of study-data collection event number
- The Research Coordinator must ensure that electronic folders containing sensitive data such as data collection, data analysis and hiring folders are not accessible to all staff. Specific files containing name and sensitive information about research participants, peer researchers and potential candidates must be protected by a password. Software such as Microsoft Word, Excel, and computer platforms , include an option to set passwords for documents, and folders. The password must be communicated to relevant members of the research team and Research Coordinator in writing upon creation and any subsequent modification
- Raw data should not be transferred by external email (i.e., within the body of an email as an attachment). Internal email attachments may be sent as a password-protected attachment. Care should be taken to communicate passwords in a secure way.

C. Voice recordings, video recordings, digital photographs

- Recordings must be erased from digital recording device as soon as the event has been transferred, verified and saved on a computer in the Raw Data folder.
- After transcription is completed, verified, and validated recordings must be deleted from the computer on which the transcriptions were typed up.
- All transcriptions are stored in a secure network folder and access is limited to the designated research team members
- The deletion of specific recordings stored will be upon such instruction by the Research Coordinator
- Recordings that need to be transferred to consultants/contract staff working offsite for transcribing will be transferred according to the steps identified in this protocol, ***section 2, "Transporting data".***

D. Other Portable Data Storage Device

- All files must be erased from devices (e.g., voice recorders, video cameras) as soon as the data transfer is complete and the accessibility of files is checked.

7. Data Access, Sharing and Use

Requests for data will be authorized by the designated Research Coordinator or the Principal Investigator. All requests should be made in writing and is subject to the terms of the relevant Partnership Agreement. A record will be maintained by the Research Coordinator, or designate of all data being stored and will track all requests and use of research data and documents.

8. Destroying Data

The Research Coordinator will need to consult all members of the research team, and Executive Director and ensure all research data and documents are properly destroyed at the specified data as follows:

- Hard copies of data and documents must be shredded (through an official shredding company)
- Soft copies and digital recording files (voice recordings, video, photographs) need to be deleted.

Research Coordinators must follow up with each member of the research team and ensure that all hard and soft copies of research data that they have or may have reproduced are deleted.