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| FACILITY: HEMOPHILIA TREATMENT CENTER |
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| SOP NO: 0001 | REVISION: |
| TITLE: BBPSP Counseling SOP | FILE: BBPSP Counseling Document |
| PAGE: OF 6 | EFFECTIVE DATE: |
| RELATED PROCEDURES: BLOOD BANK RECALL SOP | |

**Patient Notification and Counseling Protocol for
New Blood Borne Pathogens
Discovered through the Blood Borne Pathogens Project**

Definitions:

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| SOP | Standard Operating Procedure |
| AHCDC | Association of Hemophilia Clinic Directors of Canada |
| BBPP | Blood Borne Pathogens Project |
| CHARMS | Canadian Hemophilia Assessment and Resource Management information System |

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SOP HISTORICAL RECORD

| DATE | WRITTEN/REVISED BY | APPROVED BY | SUPERVISOR REVIEW | MD REVIEW |
|-------------|---|-------------|-------------------|-----------|
| WRITTEN: | | | | |
| 8 July 2002 | Bruce Ritchie, Nancy McCombie, Tony Glulivi | | | |
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1.0 PRINCIPLE

People identified as having been exposed to a new blood borne pathogen will be notified and counseled in a timely fashion by a member of the medical staff of the bleeding disorder clinic. Because of confidentiality, only the clinic can counsel individual patients in the first instance. Counseling will be coordinated through the clinic, with support from the Research Committee of AHCDC, and Health Canada. Notification and counseling of the bleeding community will be through public teleconference, videoconference, or other public forum.

2.0 SCOPE/RELATED POLICIES

This procedure applies to all studies done on samples archived through the Blood Borne Pathogens Project.

3.0 SPECIMEN

Archiving of specimens is described in the BBPP manual.

4.0 MATERIALS

Notification of the research lab by the investigator doing the testing will trigger coordinated notification and counseling of positive patients. Records will be kept on CHARMS of the notification process.

5.0 SAFETY/CONFIDENTIALITY

Refer to institutional safety and confidentiality policies and procedures. The clinic will be notified of results electronically, with confirmation of receipt by telephone.

6.0 RECORDS/FORMS/DOCUMENTS

Product Recall Summary Log Book
Worksheet 1: Notification of clinic of results
Worksheet 2: Notification of patient's results

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7.0 QUALITY CONTROL/ASSURANCE

1. Notification provided through this SOP will be reviewed by the research committee of the AHCDC on weekly teleconference held during the notification period.
2. Notification provided through this SOP will be reviewed once yearly by the oversight board of the project, which includes broad representation by stakeholders.
3. Yearly verification and update of this SOP.

8.0 PROCEDURES

1. When the Research Committee of AHCDC receives a request to perform assays on archived blood samples, a strategy will be discussed and decided upon by the committee with respect to notification and counseling of affected study subjects.
2. Individual notification and counseling will be provided by the clinics based on information provided by the Research Subcommittee and Health Canada.
3. Support for the clinic members providing counseling will be provided by teleconference, videoconference, or by the World Wide Web depending upon the situation. A member of the Research Committee and/or Health Canada will be available by telephone for consultation, upon request.
4. Information sessions will be available, with support from Health Canada, to the bleeding disorder community at large. Support for the bleeding disorder community at large will be provided by teleconference, videoconference, and by the World Wide Web depending upon the situation. Experience with this approach during the "Utah Donor" notification will be followed.
5. A transcript of all information sessions will be posted on the AHCDC and Health Canada websites.

9.0 INTERPRETATION

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[Not applicable.]

10.0 RESULT REPORTING

Samples are encoded with a sample inventory number. Results associated with this number will be reported to the surveillance lab by the investigator. This number will then be translated into a CHR registry number and the results sent electronically (secure ftp), and by surface mail to the local investigator(s). Local investigators will also be contacted by telephone and or email to confirm receipt. Summary results of the investigation will be simultaneously reported to the Research Committee, the local investigator, and Health Canada.

11.0 LIMITATIONS/PRECAUTIONS

The information provided to the patients at the time of a recall may be partial and may require updating, which should be documented when done. The information provided to the patients should be the same or similar to that provided at all bleeding disorder clinics across the country.

12.0 REFERENCES

Blood Borne Pathogens Project Manual.