

Traceback Protocol For Primarily-Infected Persons

1. In addition to the defined terms contained in the Pre-1986/Post-1990 Hepatitis C Settlement Agreement (which appear herein as capitalized words), the following defined terms are used in this Protocol:

a. “Traceback Procedure” means a targeted search for and investigation of the donor and/or the units of Blood received by a Primarily-Infected Person in Canada and, for the purpose of this Protocol, includes any one or more of the following stages of search: a Unit Number Search, a Records Search, and/or a Class Period Search;

b. “Traceback Procedure Information” means any documentation from or contained in the files of The Canadian Red Cross Society, Canadian Blood Services, Héma-Québec or Health Canada arising from a Traceback Procedure or otherwise which confirms that the donor of a unit of blood or a unit of blood received by a claimant was HCV antibody positive;

c. “Unit Number Search” means a search of medical, clinical, laboratory, blood bank or hospital records requested by Canadian Blood Services (“CBS”) or Héma-Québec at the request of the Administrator to determine the unit numbers of Blood received by a Primarily Infected Person;

d. “Records Search” means that stage of the Traceback Procedure where a search is conducted to match the units of Blood received by a Primarily-Infected Person at any time against the records of CBS and Hema-Quebec to determine if the HCV antibody status of the donor of some or all of the units received is known;

e. “Class Period Search” means that stage of Traceback Procedure where attempts are made to locate the donors of the units of Blood received by a Primarily-Infected Person during the Class Period and, where necessary, to have the donor tested to determine his or her HCV antibody status;

f. “Lookback Notification” means notification that the person claimed to be a Primarily-Infected Person received Blood from a donor who, on subsequent donation or testing, is confirmed to be HCV antibody positive.

2. For the purposes of this Protocol:

a. a Traceback Procedure shall be deemed complete and all further Traceback Procedure efforts under this Protocol relating to a Claim discontinued where:

i. the person claimed to be a Primarily-Infected Person received Blood during the Class Period and:

A one of the donors or units of the Blood he or she received during the Class Period is determined to be HCV antibody positive; or

- B. all of the donors or units of the Blood he or she received during the Class Period are determined not to be HCV antibody positive;
- b. all further Class Period Search efforts under this Protocol relating to a Claim shall be discontinued once the Administrator has made its decision to accept or reject that Claim. Subsequent periodic Record Search updates may be required in respect of some Claims as provided in paragraph 9 of this Protocol.
- c. Traceback Procedures shall not be conducted on Blood received after September 28, 1998

The Administrator's Decision To Accept Or Reject A Claim

- 3. In making its decision whether the Claim in respect of a person claimed to be a Primarily-Infected Person should be approved, the Administrator shall:
 - a. obtain and assess the results of the stage or stages of the Traceback Procedure required by such of paragraphs 5 through 9 of this Protocol as are applicable to the claim in question;
 - b. carry out additional investigation where one or more of the type of indicia enumerated at paragraph 9 of this Protocol are present; and
 - c. where the Administrator undertook additional investigation as required by paragraph 3(b) of this Protocol, consider whether all of the information available to the Administrator when weighed together establishes to the satisfaction of the Administrator on the balance of probabilities, that the person claimed to be the Primarily-Infected Person was infected with HCV for the first time during the Class Period (the "Balance of Probabilities Analysis").
- 4. Subject to the other requirements in paragraph 3 of this Protocol, the Administrator shall make its decision to accept or reject the Claim, notwithstanding that a Class Period Search may not have been completed:
 - a. when the Administrator is of the view that in all of the circumstances a Class Period Search is unlikely to yield any further information that will assist in assessing the Claim; and
 - b. notwithstanding subparagraph (a) above, no later than 6 months after the date on which the claimant has met the requirements of Sections 2.01(1)(a) and (b) of the Settlement Agreement and provided *** Forms unless:
 - i. the Blood transfusion information concerning the person claimed to be a Primarily-Infected Person provided on or with *** Form was incomplete or inaccurate, in which case the 6 months will begin to run from the time the

Administrator determines the Blood transfusion information is complete; or

- ii. the time is extended with the consent of the claimant or by the Monitor on a teleconference motion made by the Administrator on notice to the claimant;
- iii. the administrator will consider the appropriateness of seeking an extension pursuant to paragraph 4(b)(ii) where the traceback can be completed without an unreasonable delay and the amount of compensation to be paid is significant.

Obtain And Assess Available Lookback Notification or Traceback Procedure Information

5. The Administrator shall obtain and assess the results of any Lookback Notification or Traceback Procedure Information in respect of a person claimed to be a Primarily-Infected Person initiated without the involvement of the Administrator.

6. If the Lookback Notification or Traceback Procedure Information is complete or can be deemed complete as provided in paragraph 2 herein, the Administrator shall accept or reject the Claim where Blood transfusions were received during the Class Period, by applying the appropriate subparagraph of paragraph 8 below.

Initiating Records Search, Unit Number Search and Traceback

7. Where there is no Lookback notification or where the available Traceback Procedure Information regarding the Primarily-Infected Person is not sufficient to allow the Administrator to accept the claim, the Administrator shall follow steps 1 to 8 of this paragraph, in the order set out, until the claim can be accepted or rejected or there is sufficient information available to conduct a Traceback Procedure:

1. determine, on the basis of a Records Search of the Unit Numbers in the medical records provided in support of the claim, whether the claim can be accepted or rejected and if so, accept or reject the claim;
2. determine the dates on which Blood was received and where any Blood was received prior to 1982, accept the claim;
3. determine whether more than four units of Blood in total were received prior to 1986 and if so, accept the claim;
4. review the medical, clinical, laboratory, blood bank or hospital records to determine if they contain the Unit Numbers of the Blood received and if any Unit Number is missing, request that CBS or Héma-Québec request a search of the hospital or other records to find the Unit Number of that Blood;

5. if any Unit Number cannot be found, accept the claim;
6. if all of the Unit Numbers can be found, initiate a Records Search for each Unit Number and
 - a. where the HCV antibody status of any of the donors is known to be positive, accept the claim; or
 - b. where the HCV antibody status of all of the donors is known to be negative, reject the claim; or
 - c. where the HCV antibody status of any of the donors is unknown, and the claim is Disease Level 1, accept the claim;
7. if step 4 above establishes that any Blood was received before 1982 or that more than 4 units of Blood were received before 1986, accept the claim;
8. where the claim is Disease Level 2 to 6 and the antibody status of one or more of the donors is unknown and all others are negative, proceed as directed in paragraph 8 below.

Where this paragraph directs that the Administrator accept the claim, that acceptance is subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 3 (c) of this Protocol and all other applicable requirements of the Settlement Agreement.

8. After reviewing the available Traceback Procedure Information, if any, and the results of the Unit Number Search or Records Search, if such were required, the Administrator shall:
 - a. where all of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period are determined not to be HCV antibody positive, reject the Claim as provided in Section 5.04(1) of the Settlement Agreement, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in Section 5.04(2) of the Settlement Agreement and paragraphs 15 to 18 of this Protocol;
 - b. where one or more of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period is determined to be HCV antibody positive, accept the Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 3 (c) of this Protocol; or
 - c. where the Claim can neither be accepted nor rejected as provided in subparagraph (a) or (b) of this paragraph, the HCV antibody status of one or more of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the

Class Period remains unknown, initiate a Class Period Search and after reviewing the results proceed as follows:

- i. where all of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period are determined not to be HCV antibody positive by the Class Period Search, reject the Claim as provided in Section 5.04(1) of the Settlement Agreement, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in Section 5.04(2) of the Settlement Agreement and paragraphs 15 to 18 of this Protocol;
- ii. where one or more of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period is determined to be HCV antibody positive by the Class Period Search, accept the Claim, subject to the effect, if any, of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 3(c) of this Protocol; or
- iii. where the Claim can neither be accepted nor rejected as provided in subparagraph (c)(i) or (c)(ii) of this paragraph and the HCV antibody status of one or more of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period remains unknown following the Class Period Search, accept the Claim in reliance on the presumption provided for in the definition of Primarily-Infected Person in the Settlement Agreement, subject to the effect, if any, of the results of the Balance of Probabilities Analysis the Administrator may be required to perform as provided in paragraph 3(c) of this Protocol.

Indications For Additional Investigation

9. The Administrator shall review such records, Forms, documentation and/or information it receives pertaining to the person claimed to be a Primarily-Infected Person to determine if there is any indication for additional investigation, including:
 - a. any indication of non-prescription intravenous drug use by the person claimed to be a Primarily-Infected Person, notwithstanding that the claimant provided the required declaration;
 - b. a prior application to another government HCV compensation program or plan and/or a declaration of knowledge, information or belief that the person claimed to be a Primarily-Infected Person was infected with HCV by blood received between January 1, 1986 and July 1, 1990;
 - c. any indication of Blood transfusion information that conflicts with the information provided on the Forms submitted;

- d. a relationship with the Treating Physician which appears to be of a transitory nature;
- e. any indication of the existence of Hepatitis B, a previous unspecified Hepatitis or liver irregularity by the person claimed to be a Primarily-Infected Person prior to his or her first Blood transfusion during the Class Period;
- f. any indication of the existence of a major surgical procedure, disease, treatment or trauma that was likely to have required a Blood transfusion but which was not detailed in the answers provided in the Forms submitted to the Administrator;
- g. any indication of one or more of the risk factor(s) outlined at Section * of the Treating Physician Form either from the Treating Physician or in the other documentation received;
- h. receipt of any Blood transfusions outside Canada at any time prior to his or her diagnosis with HCV; and/or
- i. an inconclusive Traceback Procedure result;

and conduct such additional investigation as to it seems appropriate for the Claim in question, which may include obtaining additional documentation and/or medical examination as provided in Section 2.03 of the Settlement Agreement.

Periodic Update Of The Records Search In Some Cases

10. The Administrator shall, after having made its decision to accept or reject a Claim as provided in paragraph 8(c)(iii) of this Protocol, periodically update the Records Search of the relevant units of Blood received by the person claimed to be a Primarily-Infected Person for which the HCV antibody status remains unknown to determine if there is any additional information with which to re-assess its decision in respect of the Claim.

11. Where a Claim is accepted, it may later be rejected if information concerning the HCV antibody status of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person or other means of infection becomes known which would have resulted in rejection of the Claim had that information been considered at the time the Administrator's decision was taken. The claimant shall thereafter become disentitled to future payments under the Settlement Agreement. Absent fraud on the part of the claimant, the claimant shall not be obligated to repay any monies received under the Settlement Agreement prior to becoming disentitled under the Settlement Agreement.

12. Where a Claim is rejected, it may later be accepted if information concerning the HCV antibody status of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person becomes known which would have resulted in acceptance of the Claim had the information been considered at the time the original decision was taken. The claimant shall become entitled to the relevant payments under the Settlement Agreement.

Reporting

13. The Administrator shall, where it has received sufficient Traceback Procedure Information from CBS or Hema-Quebec to make its decision to accept or reject a Claim, request CBS or Hema-Quebec to provide a report of available Traceback Procedure Information to the claimant.

Confidentiality

14. The Administrator shall not use or disclose the information obtained pursuant to the Traceback Procedure other than for the purpose of performing its obligations under the Settlement Agreement and any relevant Court orders or pursuant to section 18.05 of the Settlement Agreement and for no other purpose. Any person to whom the Administrator discloses the information obtained pursuant to the Traceback Procedure in performing its obligations pursuant to the fulfillment of the Settlement Agreement and relevant Court orders shall not use the Traceback Procedure information for any purpose other than the fulfillment of the Settlement Agreement and relevant Court orders.

Section 5.04(1) – Rejection Of Claim

15. The Administrator shall, after determining in accordance with the provisions of Section 5.04(1) of the Settlement Agreement and paragraph 8(a) or 8(c)(i) above that a Claim must be rejected based upon the Traceback Procedure result, advise the claimant that, unless the claimant provides further evidence of first infection ("Further Evidence of First Infection") which establishes to the satisfaction of the Administrator that the person claimed to be the Primarily-Infected Person was infected for the first time with HCV by a Blood transfusion received in Canada during the Class Period notwithstanding the Traceback Procedure result in accordance with Section 5.04(2) of the Settlement Agreement, his or her claim shall be rejected (a "Section 5.04 Letter").

16. A Section 5.04 Letter shall advise the claimant that he or she may elect to provide Further Evidence of First Infection by returning the election form provided to the Administrator within thirty days from the date of receipt of the Section 5.04 Letter, failing which his or her claim shall be rejected.

17. If the claimant elects to provide Further Evidence of First Infection and returns the prescribed election form in the prescribed time, he or she must provide, within the following six months, his or her Further Evidence of First Infection, unless that time is extended with the consent of the Administrator or by the Court on a teleconference motion arranged at the request of the claimant.

18. The Administrator shall, following receipt and consideration of the Further Evidence of First Infection received from a claimant, accept or reject his or her Claim based upon all of the information available to the Administrator and Section 5.04 of the Settlement Agreement. If the claimant who elected to provide Further Evidence of First Infection does not provide the Further

Evidence of First Infection within the six months following his or her election, or such further time as has been agreed or ordered, his or her Claim shall be rejected.

Appeal Rights

19. Where the Administrator rejects a Claim, it shall advise the claimant of his or her appeal rights in relation thereto.

20. Notwithstanding the foregoing provisions of this Protocol, no test result in respect of a frozen blood sample maintained by CBS shall be taken into consideration for the purpose of including or excluding any HCV Infected Person under the Settlement Agreement.