

## CANADIAN THALIDOMIDE SURVIVORS SUPPORT PROGRAM (“CTSSP”) RECONSIDERATION PROTOCOL

This reconsideration protocol is intended for use by Applicants to the CTSSP who wish to request reconsideration of an application determination issued by the CTSSP Administrator (“Administrator”) at any step of the CTSSP application process.

The protocol identifies the requirements to request reconsideration and the corresponding process that the Administrator will follow in reviewing each request.

Requests for Reconsideration must be postmarked by June 3, 2024 (the “Application Deadline”).

Applications still in progress at any stage of the CTSSP application process as of the Application Deadline will have one (1) year post the Application Deadline to complete the Application process; after which time the application review process will end.

The Forms mentioned throughout this protocol can be downloaded via the CTSSP website (<https://tsspcanada.ca/>) or requested from the Administrator.

### Defined Terms

**Applicant** – An individual who has submitted an application to the CTSSP and whose application has been received by the Administrator.

**Application** – Refers to any form throughout the application process which requires completion by the Applicant.

**Application Deadline** – For the purposes of this protocol, the postmark date by which a Request for Reconsideration Form must be sent to the CTSSP Administrator. The Application Deadline is postmarked by June 3, 2024.

**Completed File** – A claimant submission that the Administrator deems complete when all questions have been answered in an Application Form(s) and requested supporting documents have been provided or a response from the Applicant has been received advising the requested supporting documents will not be submitted.

**Deficiency Letter** – A letter from the CTSSP Administrator to the Applicant identifying what information is missing or needed from the Applicant to enable the completion of an Application review.

**Determination Letter** – A letter issued by the CTSSP Administrator to an Applicant providing an Applicant with the determination following the review of their application at any stage of the CTSSP application process.

**File** – A term used to mean all of the Applications and supporting documents submitted by the Applicant in support of their application to the CTSSP which have been received by the Administrator at the point in time an application review and determination is undertaken.

**Methodology** – The process by which the medical-legal committee reviews a File and makes a recommendation to the CTSSP Administrator.

**Oral Hearing** – Is a form of reconsideration available to Applicants denied at Step 3 whereby an Applicant can request reconsideration of the Step 3 determination by providing Reconsideration Information via a combination of written and virtual or in-person submissions with at least one (1) clinical member of the Committee present, but typically one (1) clinical member and one (1) non-clinical member of the Committee, and representatives of the Administrator. An Oral Hearing is not a formal legal proceeding and is meant to be informal.

**Reconsideration Information** – Reconsideration Information is a) any additional medical information. X-rays, pictures or records of the Applicant not previously identified that speaks to their Thalidomide related birth differences, or b) identification of a specific consideration, document, medical record or submission not addressed in the Determination Letter that the Applicant believes has the potential to change the determination regarding the person's eligibility under the CTSSP previously made.

**Request for Reconsideration** – The form and process used by an applicant to request reconsideration of the determination at any stage of the CTSSP application process.

**Written Submission Deadline** – The postmark deadline by which an Applicant at Step 3 must provide additional written Reconsideration Information submissions in regard to their Step 3 Request for Reconsideration.

Any reference to days in this protocol refers to calendar days unless otherwise specified. In the event that a date pertaining to a deadline referred to herein falls on a Canadian holiday or a weekend, then the deadline date will be the next business day thereafter.

The following pages outline the steps and requirements regarding reconsideration at each stage of the CTSSP.

## **STEP 1 Reconsideration – Preliminary Screening**

1. Applicants who receive a Determination Letter that indicates they did not meet one (1) or more of the three (3) Step 1 eligibility criteria identified in the Order in Council may request reconsideration by completing and submitting a Request for Reconsideration Form to the Administrator postmarked by the Application Deadline. The Administrator will consider any Request for Reconsideration that contains Reconsideration Information regarding the eligibility criteria that was not met as identified in the Determination Letter sent to the Applicant.
2. Within two (2) business days of receipt of the Request for Reconsideration Form, the Administrator will send the Applicant an acknowledgement letter confirming receipt of the Request for Reconsideration Form.
3. The Administrator will review the Request for Reconsideration Form for completeness and to confirm if Reconsideration Information has been provided:

**Incomplete Reconsideration Request:**

- i. If the Administrator determines that the Request for Reconsideration Form has not been completed in full, the Administrator will send the Applicant a Deficiency Letter explaining what information is missing.

- ii. The Applicant's Request for Reconsideration will then be placed on hold pending receipt of the missing information by the Administrator or confirmation from the Applicant that they will not be submitting the missing information.
- iii. The Administrator will follow-up with the Applicant in writing, using existing contact information on file, every 60 days until the Application Deadline if a response to the Deficiency Letter has not been received.
- iv. Upon receipt of the requested missing information or receipt of the Applicant's response that all or some of the missing information will not be provided, the Administrator will complete its review and issue a Determination Letter to the Applicant based on the File information received as of that time. In the event, that a response to the Deficiency Letter is not postmarked by the Application Deadline, then the Administrator will base its review and issue the Determination Letter based on the File information received as of the Application Deadline.

**Reconsideration Information *Not* Submitted:**

- i. If the Administrator determines that the information submitted with the Applicant's Request for Reconsideration Form is not Reconsideration Information, the Request for Reconsideration Form will be rejected, and the Applicant will be notified in writing that their Application will not proceed any further. The Applicant may request reconsideration again if they so wish before the Application Deadline. There is no limit to how many Requests for Reconsideration an Applicant may submit prior to the Application Deadline.

**Reconsideration Information Submitted:**

- i. A Request for Reconsideration Form that the Administrator determines is complete and contains Reconsideration Information will be reassessed at Step 1 to determine if the Reconsideration Information changes the Administrator's previous determination regarding the Applicant's eligibility to advance to Step 2 under the CTSSP. The Applicant will receive the Administrator's Determination Letter in writing within 30 calendar days of the Applicant's Request for Reconsideration Form being deemed completed in full and containing Reconsideration Information by the Administrator.
- ii. Should the determination results indicate that the Applicant meets the Step 1 eligibility criteria, the Determination Letter will provide the Applicant with information on how to proceed through Step 2 of the CTSSP application process.
- iii. Should the determination results indicate the Applicant does not meet the Step 1 eligibility criteria, the Determination Letter will explain why the Applicant does not meet the criteria. The Applicant will then have the right to request reconsideration again by completing and submitting a new Request for Reconsideration by the Application Deadline. There is no limit to how many Requests for Reconsideration an Applicant may submit prior to the Application Deadline.

## STEP 2 Reconsideration – Probability Assessment

1. Applicants who receive a Step 2 Determination Letter with a valiDATE result of “Unlikely” or “Uncertain” will automatically receive a Selection Form, which provides the Applicant with four (4) options:
  - Option 1: The Applicant may choose to have their File reviewed by a committee of medical and legal experts (“Committee”).
  - Option 2: The Applicant may choose to do nothing at this time but reserve their choice to request that their File be sent to the Committee at a later date by submitting a new Selection Form to the Administrator prior to the Application Deadline.
  - Option 3: The Applicant may choose to do nothing and to not have their File proceed through the CTSSP process any further.
  - Option 4: The Applicant may request reconsideration by completing and submitting a Request for Reconsideration Form to the Administrator by the Application Deadline.
2. Applicants who want their Application to continue through the CTSSP Application process must complete and submit the Selection Form to the Administrator postmarked by the Application Deadline. The Administrator will follow-up with Applicants in writing, using existing contact information on file, every 60 days until the Application Deadline if a Selection Form has not been returned to the Administrator.
3. Within two (2) business days of receipt of the Selection Form, the Administrator will send the Applicant an acknowledgement letter confirming receipt of the Form.
4. The Administrator will then review the Selection Form for completeness and to verify the Applicant’s choice.

### Incomplete Section Form Submission:

- i. If the Administrator determines that the Selection Form was not completed in full, the Administrator will send the Applicant a Deficiency Letter explaining what information is missing.
- ii. The Applicant’s Selection Form will then be placed on hold pending receipt of the missing information by the Administrator.
- iii. The Administrator will follow-up with the Applicant in writing, using existing contact information on file, every 60 days until the Application Deadline if a response to the Deficiency Letter has not been received.
- iv. In the event, that a response to the Deficiency Letter is not postmarked by the Application Deadline, then the Administrator will issue a Determination Letter informing the Applicant that their application will proceed no further.

### Fully Completed Section Form:

#### **Option 1: The Applicant chooses to have their application reviewed by a committee of medical and legal experts (“Committee”).**

- i. The Administrator will send an Attestation Form to the Applicant’s health care practitioner identified in the Applicant’s Step 2 Application Form to request that they

- verify that the responses to the questions in the valiDATE report are an accurate account of the Applicant's Thalidomide related birth differences. They will have a space in the Form to note any additional information if applicable. The completed Attestation must then be submitted to the Administrator postmarked by the Application Deadline.
- ii. Within two (2) business days of receipt of the completed Attestation Form, the Administrator will send the Applicant an acknowledgement letter confirming receipt of the Form.
  - iii. The Administrator will then review the Attestation Form for completeness.

*Incomplete Attestation Form Submission:*

- a. If the Administrator determines that Attestation Form was not completed in full, the Administrator will send the health care practitioner a Deficiency Letter explaining what is missing with a copy to the Applicant.
- b. The Applicant's Application will then be placed on hold pending receipt of the missing information by the Administrator.
- c. The Administrator will follow-up with the healthcare practitioner and the Applicant in writing, using existing contact information on file, every 60 days until the Application Deadline if a response to the Deficiency Letter has not been received.
- d. If a response to the Deficiency Letter is not postmarked by the Application Deadline, then the Attestation Form will be rejected, and the Applicant will be notified in writing that their Application will not be proceeding any further.

*Complete Attestation Form Submission:*

- a. The Administrator will review the Applicant's entire File for completeness. If information is missing, the Administrator will contact the Applicant to obtain the same.
- b. Once the Administrator determines the File is complete, the File will then be forwarded to the Committee for review and recommendation to the Administrator as to whether the Applicant should be found eligible under the CTSSP.
- c. The Committee will look at the totality of the information provided by the Applicant and anything else it might find relevant to make its recommendation to the Administrator. The Committee may also request additional information and/or tests it deems necessary in order to make its recommendation. The Committee will have a **maximum of 90 days** to provide its written recommendation to the Administrator unless there is a delay in receiving the additional information or tests requested by the Committee from the Applicant which makes that timeline impossible. If there is a delay for that reason, the Applicant will be notified in writing.
- d. Upon receipt of the recommendation from the Committee, the Administrator will review the recommendation and issue a Determination Letter to the Applicant within 5 days of receipt.
- e. An Applicant who receives a Determination Letter containing an eligible determination will be provided with additional information as to next steps.
- f. An Applicant who receives a Determination Letter containing an ineligible determination may request reconsideration of the Administrator's

determination following the process outlined in the section labeled “Step 3 Reconsideration - Medical Legal Panel Review”.

***Option 2: Selecting to do nothing at this time:***

- i. Should the Applicant select that they are undecided at this time if they want their File to be reviewed by the Committee, no further action will be taken on the part of the Administrator regarding the Applicant’s CTSSP Application or Selection Form until such time that the Applicant submits a new Selection Form to the Administrator postmarked by the Application Deadline.

***Option 3: Selecting to stop the application process and not proceed any further through the CTSSP process:***

- i. Should the Applicant select that they do not wish their File to proceed any further through the CTSSP process, no further action will be taken on the part of the Administrator regarding the Applicant’s CTSSP Application or Selection Form and the Applicant will be notified in writing that their Application will not proceed any further.

***Option 4: Selecting to Submit a Request for Reconsideration Form:***

- i. Applicants who choose to request reconsideration at Step 2 must complete and submit a Request for Reconsideration Form to the Administrator postmarked by the Application Deadline. The Administrator will consider any reconsideration request that contains Reconsideration Information.
- ii. Within two (2) business days of receipt of the Request for Reconsideration Form, the Administrator will send the Applicant an acknowledgement letter confirming receipt of the Form.
- iii. The Administrator will then review the Applicant’s Request for Reconsideration Form for completeness and to confirm if Reconsideration Information has been provided.

***Incomplete Request for Reconsideration Form Submission:***

- a. If the Administrator determines that Request for Reconsideration Form was not completed in full, the Administrator will send the Applicant a Deficiency Letter explaining what is missing.
- b. The Applicant’s Request for Reconsideration will then be placed on hold pending receipt of the missing information by the Administrator or confirmation from the Applicant that they will not be submitting the missing information.
- c. The Administrator will follow-up with the Applicant in writing, using existing contact information on file, every 60 days until the Application Deadline if a response to the Deficiency Letter has not been received.
- d. If a response to the Deficiency Letter is not postmarked by the Application Deadline, then the Request for Reconsideration Form will be rejected, and the Applicant will be notified in writing that their Application will not proceed any further.

*Reconsideration Information Not submitted:*

- a. If the Administrator determines that the information submitted with the Applicant's Request for Reconsideration Form is not Reconsideration Information, the Request for Reconsideration Form will be rejected, and the Applicant will be notified in writing that their Application will not proceed any further. The Applicant may request reconsideration again if they so wish before the Application Deadline in response. There is no limit to how many Step 2 Requests for Reconsideration an Applicant may submit prior to the Application Deadline.

*Reconsideration Information Submitted:*

- a. If the Administrator determines that a Request for Reconsideration Form is complete and contains Reconsideration Information, the Administrator will forward the Applicant's File to qualified medical staff who will use the information provided by the Applicant to re-answer the questions in the valiDATE diagnostic algorithm and generate a new valiDATE report.
- b. Upon receipt of the new valiDATE report, the Administrator will issue a new Determination letter to the Applicant. An Applicant who receives a Determination Letter with a valiDATE result of "probable" will advance to Step 3 of the CTSSP process: see next section, "Step 3 Reconsideration – Medical-Legal Panel Review". An Applicant who receives a Determination Letter with a valiDATE result of "unlikely" or "uncertain" will receive a new Selection Form: see "STEP 2 Reconsideration – Probability Assessment" above.

### **STEP 3 Reconsideration – Medical-Legal Panel Review**

The Request for Reconsideration process at Step 3, either in writing or by an informal Oral Hearing, is **not** a formal legal proceeding. Its purpose is to provide a forum for an Applicant to present Reconsideration Information to the Committee representatives and the Administrator because the Applicant believes the Reconsideration Information has the potential to change the determination regarding the person's eligibility under the CTSSP previously made. It is not a forum for challenging the Methodology by which the Committee rendered its recommendation.

**A maximum of one (1) Step 3 Request for Reconsideration per Applicant is permitted, whether in writing or by informal Oral Hearing, that results in the medical-legal committee reviewing the Request for Reconsideration and making a recommendation regarding the eligibility of the Applicant under the CTSSP.**

An Applicant who receives a Step 3 Determination Letter containing an ineligible determination may request reconsideration in one of two (2) ways:

- Option 1: Request reconsideration conducted entirely in **writing** on the basis of the information the Applicant provides with the Request for Reconsideration Form and any written submissions an Applicant submits to the Administrator by the Written Submission Deadline; or;

Option 2: Request reconsideration conducted in the form of an informal **Oral Hearing** on the basis of the information the Applicant provides in the Request for Reconsideration Form and any written submissions an Applicant submits to the Administrator by the Written Submission Deadline.

An informal Oral Hearing will take place as:

(i) a **Virtual Hearing** via “Zoom” or other virtual meeting format,

or,

(ii) an **In-Person Hearing** at the Administrator’s premises located in Ottawa, Ontario. Applicants are responsible for any and all of their costs associated with attending the In-Person Hearing, including travel and accommodation costs where applicable. Please note that due to the geographic diversity of the Committee members, their physical presence at an In-Person Hearing will not be feasible.

1. To submit a Request for Reconsideration at Step 3, an Applicant who was found ineligible at Step 3 must:
  - i. Complete and submit a Request for Reconsideration Form to the Administrator postmarked by the Application Deadline indicating their preference for reconsideration in writing or by informal Oral Hearing.
  - ii. The Applicant must provide Reconsideration Information in order for their reconsideration request to be considered.
  - iii. The Applicant must indicate if they intend to provide additional Reconsideration Information, beyond what was provided in their initial Request for Reconsideration Form submitted. Applicants intending to provide additional Reconsideration Information will have an additional sixty (60) days from the date the Reconsideration Form is received by the Administrator (“Written Submission Deadline”) to provide additional Reconsideration Information in support of the Request for Reconsideration. The following requirements must be met when submitting additional Reconsideration Information:
    - a. Additional Reconsideration Information may be a maximum of 30 pages in length, exclusive of medical records and reports.
    - b. The reasons relied upon as the basis for reconsideration must be clearly specified and that any elements to be considered for review by the medical-legal committee are clearly stated.
    - c. No further written submission will be accepted once the 60-day Written Submission deadline passes.
2. Within two (2) business days of receipt of the Request for Reconsideration Form, the Administrator will send the Applicant an acknowledgement letter confirming receipt of the form.

3. The Administrator will then review the Applicant's Request for Reconsideration Form for completeness and to confirm if Reconsideration Information has been provided. The Administrator may consult the Committee in determining if the information provided is Reconsideration Information in the case of medical documentation.

*Incomplete Request for Reconsideration Form Submission:*

- i. If the Administrator determines that the Request for Reconsideration Form was not completed in full, the Administrator will send the Applicant a Deficiency Letter explaining what is missing.
- ii. The Applicant's Request for Reconsideration will then be placed on hold pending receipt of the missing information by the Administrator or confirmation from the Applicant that they will not be submitting the missing information.
- iii. The Administrator will follow-up with the Applicant in writing, using existing contact information on file, every 60 days until the Application Deadline if a response to the Deficiency Letter has not been received.
- iv. If a response to the Deficiency Letter is not postmarked by the Application Deadline, then the Request for Reconsideration Form will be rejected, and the Applicant will be notified in writing that their Application will not proceed any further.

*Reconsideration Information not submitted:*

- i. If the Administrator determines that the information submitted with the Applicant's Request for Reconsideration Form is not Reconsideration Information, the Request for Reconsideration Form will be rejected, and the Applicant will be notified in writing that their Application will not proceed any further. The Applicant may request reconsideration again if they so wish before the Application Deadline in response. There is no limit to how many Requests for Reconsideration an Applicant may submit prior to the Application Deadline **when** their Request for Reconsideration is rejected for not providing Reconsideration Information.

*Reconsideration Information Submitted:*

- i. Once it has been determined that the Request for Reconsideration contains Reconsideration Information, if the Applicant indicates that they would like to submit additional information beyond what was submitted with their Reconsideration Form, the Applicant's Request for Reconsideration will be placed on hold pending receipt of the additional Reconsideration Information by the Administrator.
- ii. The Administrator will follow-up with the Applicant in writing, using existing contact information on file, 30 days before the Written Submission deadline if no response is received beforehand.
- iii. If the Applicant indicates that they will not be submitting further Reconsideration Information, the Request for Reconsideration will directly advance to the next Step (iv).
- iv. The Administrator will review the Request for Reconsideration and any Reconsideration Information submitted to verify the content is within the scope of the reconsideration process: out of scope would mean anything that

challenges the methodology by which the Committee rendered its recommendation. The Applicant will be notified in writing if anything falls outside the scope as that content will not be subject for review by the medical-legal committee.

**Requests for Reconsideration in Writing:**

- i. If the Administrator determines that the Request for Reconsideration Form is complete and contains Reconsideration Information, the File will then be forwarded to the Committee for review and recommendation to the Administrator as to whether the Applicant should be found eligible under the CTSSP.
- ii. The Committee will look at the totality of the information, including the Reconsideration Information provided by the Applicant along with their Request for Reconsideration and anything else it might find relevant to make its new recommendation to the Administrator. The Committee may also request additional information and/or tests it deems necessary in response to the Reconsideration Information received in order to make its recommendation. The Committee will have a **maximum of 90 days** to provide its written recommendation to the Administrator unless there is a delay in receiving the additional information or tests requested by the Committee from the Applicant which makes that timeline impossible. If there is a delay for that reason, the Applicant will be notified in writing.
- iii. Upon receipt of the recommendation from the Committee, the Administrator will issue a Determination Letter to the Applicant within 5 days of receipt.
- iv. An Applicant who receives a Determination Letter containing an eligible determination will be provided with additional information as to next steps.
- v. An Applicant who receives a Determination letter containing an ineligible determination will be advised that the determination is **final, and the application process has concluded.**

**Requests for Reconsideration by Informal Oral Hearing:**

- i. An applicant who requests reconsideration via an informal Oral Hearing will be provided in writing with a selection of meeting dates to choose from.
- ii. Upon confirmation of the meeting date and time, the Administrator will send the Applicant the meeting details (e.g., Zoom invite if virtual or physical address if in person) in writing.
- iii. The Administrator will provide the File to the Committee at minimum 15 days in advance of the hearing to assist in streamlining the informal Oral Hearing so that issues can be identified ahead of time and allow all parties to better prepare for the informal Oral Hearing.

**During the Informal Oral Hearing:**

- a. The representative of the Administrator will act as the facilitator.
- b. At least one (1) clinical member of the Committee will be present, but typically one clinical member and one (1) non-clinical member of the Committee will be present.

- c. The informal Oral Hearing will be informal. Legal representatives for the Applicant are permitted but are not required. In addition, the Applicant may choose to have one additional support person present (e.g., family member, guardian). Both the Applicant and their accompaniment(s) may speak on behalf of the Applicant at the informal Oral Hearing if that is the Applicant's choosing.
- d. The Facilitator will introduce all parties.
- e. The Applicant will then have the opportunity to present their Reconsideration Information as identified in their Request for Reconsideration. They are not permitted to present additional Reconsideration Information not previously disclosed.
- f. The Committee representative(s) will then have an opportunity to respond.
- g. The Applicant will then have an opportunity to ask any follow up questions in brief.
- h. The Committee representative(s) may choose to respond or defer their response if further review may be required.
- i. The informal Oral Hearing will be scheduled for a maximum of one (1) hour.
- j. Subject to the consent of the Applicant, the informal Oral Hearing will be recorded.
- k. The Committee will look at the totality of the information, including the Reconsideration Information provided by the Applicant along with their Request for Reconsideration and anything else it might find relevant to make its new recommendation to the Administrator. The Committee may also request additional information and/or tests it deems necessary in response to the Reconsideration Information received in order to make its recommendation. The Committee will have a **maximum of 90 days** to provide its written recommendation to the Administrator unless there is a delay in receiving the additional information or tests requested by the Committee from the Applicant which makes that timeline impossible. If there is a delay for that reason, the Applicant will be notified in writing.
- l. Upon receipt of the recommendation from the Committee, the Administrator will issue a Determination Letter to the Applicant with 5 days of receipt.
- m. An Applicant who receives a Determination Letter containing an eligible determination will be provided with additional information as to next steps.
- n. An Applicant who receives a Determination letter containing an ineligible determination will be advised that the determination is **final, and the application process has concluded.**