

Subject: DOH Incident Reporting Management and Investigation of Serious Reportable and Recordable Incidents for the TBI and NHTD Waiver Programs  
Section: 7.1  
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Approval: 

1.0 **PURPOSE:**

To set forth Head Injury Association's policy and procedure regarding Incident Reporting Management and Investigations of Serious Reportable and Recordable Incidents for the TBI and NHTD Waiver Programs

2.0 **SCOPE:**

This policy and procedure applies to all employees, interns, volunteers, consultants, and contractors of Head Injury Association.

3.0 **RESPONSIBILITY:**

The responsibility of interpretation and administration of this policy and procedure shall be vested with the agency administrators.

4.0 **POLICY:**

4.1 Head Injury Association has developed policies and procedures in accordance with New York State Department of Health regulations.

4.2 The purpose of reporting, investigating, reviewing, correcting and/or monitoring certain events or situations is to enhance the quality of care provided to participants and to protect (to the extent possible) them from further harm and ensure that participants are free from mental and physical abuse. In addition, to enable program administrators to become aware of problems, ensure corrective action, minimize the potential for re-occurrence and identify trends. The reporting of certain events or situations in a uniform orderly manner facilitates identification of trends, which ultimately allows for the development and implementation of preventive strategies.

The process begins with the occurrence of an 'Event', which is defined as an occurrence with a negative impact to the participant, or actual harm to the participant that has come to the attention of a waiver service provider. Once Head Injury Association has become aware of an

'Event,' Head Injury Association will evaluate what has occurred to determine at what level an investigation must be conducted. The safety of the participant must be immediately assured upon discovering an event.

- 4.3 Whenever an accident, situation, condition, or event not routine to normal treatment or activity occurs that endangers the health or safety of program members occurs as part of program activities, the incident reporting procedure will be utilized and the appropriate incident report form will be used.

#### 4.4 **Incident Categories**

DOH regulations designate two categories of incidents for the TBI and NHTD waiver programs, recordable and serious reportable incidents.

A Serious Reportable Incident is defined as any significant event or situation endangering a participant's well-being. Serious Reportable Incidents can also include any situation in which the participant experiences a perceived or actual threat to his/her health and welfare or to his /her ability to remain in the community. These incidents must be reported to the RRDS and / or NYS DOH using the process outlined in this policy. Program Management in conjunction with the Sr. Director of Corporate Compliance and QA and if indicated the Executive Director and the RRDS will determine if the incident must also be reported to Adult Protective Services and the police.

Serious Reportable Incidents Categories Include:

Abuse: the maltreatment or mishandling of a participant that would endanger his/her physical or emotional well-being through the action or inaction of anyone associated with the participant, whether or not he/she is or appears to be injured or harmed.

Subcategories include:

- Physical
- Sexual
- Psychological
- Seclusion
- Restraint
- Mistreatment (an allegation of financial or material exploitation that can compromise the safety and well-being of a participant should be filed as an allegation of abuse subcategory Mistreatment).
- Aversive conditioning

Neglect: a condition of deprivation in which the participant receives insufficient, inconsistent, or inappropriate services, treatment or care to meet their needs; failure to provide an appropriate and/or safe environment for receiving services; and/or failure to provide appropriate services, treatment or care by gross error in judgment, inattention or ignoring.

Violation of a participant's civil rights – Any action or inaction that deprives a

participant of the ability to exercise their legal rights, under state or federal law

Missing person – The unexpected or unauthorized absence of a participant, taking into consideration his/her habits, deficits, health problems and capabilities.

Death of a participant: All deaths should be reported to the RRDC, and the RRDC will decide if the death is an SRI or Recordable.

Death of a waiver participant due to circumstances unrelated to the natural cause of illness or disease or proper treatment in accordance with accepted medical standards; an apparent homicide or suicide; or an unexplained or accidental death.

Deaths due to natural causes must be reported to the RRDC within 24 hours; the RRDC will determine if it will be categorized as an SRI.

Unplanned hospitalization – Any injury or illness which results in a hospital admission of a participant for treatment or observation for greater than 24 hours due to the injury/illness.

- Unplanned Hospitalization: Psychiatric facility admissions should be filed under Unplanned Hospitalization.
- Unplanned Hospitalization: regardless if a person was a 'full admit' or on 'observation status,' the standard is that if they are in the hospital over 24 hours, then an SRI should be filed.

Possible criminal action – Actions by participants which are or appear to be a crime under New York State or Federal law.

- Possible Criminal Action is not a category to file an SRI if it is suspected that a waiver staff has committed a crime. There are other possible categories that situation may fall under; this category is used if the participant commits a crime.

Medication error/refusal – A situation in which a participant displays marked adverse effects or his/her health or welfare is in jeopardy due to incorrect dosage, administration or refusal to take prescribed medication. The participant must have an adverse reaction or have his/her health or welfare jeopardized due to the error/refusal.

Recordable Incidents are events that do not pose an immediate threat to the participant and does not meet the level of severity of a Serious Reportable Incident but may compromise his/her safety and well-being if not noted, reported and addressed.

Recordable Incidents:

- Do not meet the level of severity of SRIs, but impact the participant's life in the community.

- Are not reported to NYSDOH; however, NYSDOH reserves the right to review these incidents at any time.
- Are reported annually to the Regional Resource Development Center (RRDC) and are subject to review upon site visits by the RRDC and /or NYSDOH Office of Primary Care and Health Systems Management (OPCHSM)

Recordable Incidents Include:

- Injury – Any suspected or confirmed harm to a participant caused by an act or person, accidental in nature or one that the cause cannot be identified, which results in a participant requiring medical or dental treatment and such treatment is more than first aid.
- Natural Death of a waiver participant – Due to natural causes when in a treatment facility or hospice environment. Deaths due to natural causes must be reported to the RRDC within 24 hours and the RRDC will determine if it will be categorized as a Recordable Incident or SRI.
- Sensitive Situation – Any situation related to a participant that needs to be monitored for a potential adverse outcome. This includes events that attract media attention or inappropriate activity which could threaten the participant's ability to remain in the community

For incidents that fall into the 3 categories above, the RRDC will determine if they will be categorized as Recordable Incidents.

The first staff person who witnesses a recordable incident will document the incident using the Recordable Incident and Investigation Report form. The form will document the investigation and resolution of the incident.

On a Quarterly basis, each program is responsible for completing a quarterly report that includes both SRI' and recordable incidents. The quarterly report will include an analysis for patterns and trend. When a trend is identified, program management is responsible for making recommendations to address the trend.

The RRDC may request Recordable Incidents at any time if deemed necessary, for instance, when investigating a complaint

## 5.0 **PROCEDURE:**

- 5.1 The Training Coordinator, Department Administration and Service Coordinators shall ensure that all participants, guardians, qualified person, correspondent or advocate; program employees, interns, volunteers, consultants and contractors are familiar with all policies and procedures related to reporting and investigation of incidents.

- 5.2 Any report of a serious reportable incident or allegation of abuse shall be immediately investigated by the designee of the Executive Director
- 5.3 When an incident is discovered a participant's safety must always be the primary concern. Whatever measures appear to be reasonable and prudent to ensure the protection of a person from further harm, injury, or abuse, and to provide prompt treatment or care are taken. When appropriate, an employee, intern, volunteer, consultant, or contractor alleged to have abused a person shall be removed from immediate proximity to, or responsibility for, the participant and may not work with other participants, until the investigation is completed.

When appropriate, any waiver service provider or waiver entity may contact Adult Protective Services (APS) related to an 'Event' involving a waiver participant at any time during the SRI Reporting process.

#### 5.4 Reporting Serious Reportable Incidents

1. When it is discovered that an 'Event' has occurred, the Head Injury Association has 24 hours to:
  - Determine if the 'Event' rises to the level of an SRI;
  - Complete the 24-Hour Provider Report and send it via encrypted email\* to the RRDC; and
  - Provide a copy via encrypted email\* of the 24-Hour Provider Report to the participant's SC (if the discovering waiver service provider is not the SC agency).

If there is a question about whether the event meets the definition of an SRI, the provider must contact the RRDC to discuss the matter.

To ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA), all reports and communication containing Protected Health Information (PHI) must be sent via encrypted email.

2. Within 24 hours of receiving the 24-Hour Provider Report, the SC must:
  - Notify the waiver participant and/or his/her legal guardian that an incident has been reported and is being investigated.
  - Notify other program or waiver providers of the incident when the evidence of the injury or incident may impact services or the waiver provider.
  - Complete and submit the Service Coordinator 24-Hour Notification Report form to the RRDC.

If the SC is alleged to be involved in the incident, the Service Coordination Supervisor is responsible for handling this.

3. Within 24 hours of receiving the 24-Hour Provider Report form, the RRDC must:
  - Review the form, complete the RRDC Initial Response form and assign an

incident number. This number must be included in all future reports and correspondence relating to the incident.

- Document on the RRDC Initial Response acceptance of the original classification or, if indicated, the re-classification of the incident.
- Assign the investigation to a waiver provider responsible for conducting the investigation and provide the due dates of the expected 7 day and 30 day Follow-Up Reports.
- Send the RRDC Initial Response to the investigating provider and SC.

The RRDC must notify NYSDOH of any extraordinary events within 24 hours of receipt of the incident report

4. Within 7 days from the date of the RRDC Initial Response, Head Injury Association will submit a Provider Follow-Up Report to the RRDC. The RRDC forwards the RRDC Status Report to the investigating provider and SC.
5. If the investigation is assigned to Head Injury Association and remains open, HIA will submit a Provider Follow-Up Report form to the RRDC within 30 days, as designated on the RRDC Initial Response. The RRDC forwards the RRDC Status Report to the investigating provider and SC.
6. If open beyond the first 30 days, Head Injury Association will provide continued follow-up and investigation. For each 30 days that the case remains open, Head Injury Association will submit a Provider Follow-Up Report to the RRDC staff each month, based on the date of the first 30 day Provider Follow-Up Report. The RRDC forwards the RRDC Status Report to the investigating provider and SC.
7. For the RRDC to consider an investigation to be closed:
  - The final investigation report must be submitted to the RRDC, along with the Provider Follow-Up Report.
  - Head Injury Association's Serious Incident Review Committee (SIRC) must have met and reviewed the investigation and recommend that the incident be closed.
8. Upon review of the investigation, the RRDC will send the RRDC Status Report to the investigating provider and SC indicating the SRI is closed. If it is to remain open, the reasons for that decision must be identified by the RRDC in the report, along with directions for further investigative action.

No incident investigation may remain open for more than 90 days from the date of the initial report without the approval of the SIRC, the RRDC and/or NYSDOH. This approval will occur in only the most atypical circumstances, e.g. criminal investigation, civil litigation. Final Investigation Report: A standard investigation format is used by all providers

9. Once the Head Injury Association receives the final RRDC Status Report, HIA must send written notice to the participant/legal guardian within 7 days that the investigation

has completed, indicating the final outcome without disclosing the details of the investigation. A copy of the letter is sent to the RRDC and SC.

10. Upon closure of the SRI, the RRDC also sends the participant/legal guardian a close-out letter within 7 days, indicating that the investigation has been completed and the final outcome. Details of the investigation are not disclosed.
  - The RRDC also sends a copy of the close-out letter to the SC.
  - Any further contact with the participant will be made at the discretion of the RRDC, depending on the outcome of the investigation, consistent with the plan of corrective action or recommendations included in the final investigation report.

- 5.5 Any HIA employee witnessing any actions or lack of action that constitutes a Serious Reportable Incident as described in this policy must notify their supervisor immediately who will in turn notify Program Administration and the Sr. Director of Corporate Compliance and QA.
- 5.6 The Executive Director shall be advised immediately of all serious reportable incidents / allegations of abuse / neglect immediately upon observation or discovery.
- 5.7 In situations where no HIA staff has witnessed the Serious Reportable Incident, the employee who first became aware of the incident is responsible for filling out the incident report. A supervisor may report the incident to the RRDS and Service Coordinator.
- 5.8 The Program Management or designee will notify any other program or waiver provider when there is visible evidence of injury to the participant or when the incident or response to the incident may impact services or activities. Consideration of the individual's privacy should be balanced against the need to notify other service providers.
- 5.9 DOH has pursuant to statute, the right to review and /or investigate any reportable incident, serious reportable incident, and /or allegation of client abuse regardless of the source of the information. All relevant records, reports, and minutes of meetings at which the incident or alleged abuse was discussed shall be made available to reviewers or investigators. Program members, employees, and any other relevant persons may be interviewed in pursuit of any such review or investigation.
- 5.10 Reportable incident and abuse reports and subsequent reports or documentation of investigations shall be maintained so as to protect the privacy of program members, other individuals involved, or other persons whose names appear in the report, but shall be retrievable by program participant name and filing number or identification code.
- 5.11 When a recordable incident, serious reportable incident, or alleged abuse occurs while an individual is still directly under the auspices of HIA, but is not physically on agency property (for example: in a restaurant, at the doctor, visiting family, in school, on a vacation trip, at camp, receiving non-certified location) HIA staff is responsible for reporting the incident, completing all required forms and ensuring the RRDS and Service Coordinator is notified.

- 5.12 If a recordable incident, serious reportable incident, or abuse is alleged to have occurred while the individual was under the supervision of another agency's facility:
- a) The discovering program shall make a written record of the report.
  - b) The discovering program shall determine if the event has or will be duly reported and investigated by the other agency/facility.
  - c) The agency in whose facility or under whose auspices the serious reportable incident or abuse is alleged to have occurred shall report the situation to the RRDS.

## 6.0 **Investigation of Serious Reportable Incidents**

When an incident is discovered a participant's safety must always be the primary concern of HIA, SC and the RRDC. Whatever measures appear to be reasonable and prudent to ensure the protection of a person from further harm, injury, or abuse, and to provide prompt treatment or care are taken. When appropriate, an employee, intern, volunteer, consultant, or contractor alleged to have abused a person will be removed from immediate proximity to, or responsibility for, the participant and may not work with other participants, until the investigation is completed. When appropriate, any waiver service provider or waiver entity may contact Adult Protective Services (APS) related to an 'Event' involving a waiver participant at any time during the SRI Reporting process.

- 6.1 HIA will designate staff to be responsible for conducting a thorough and objective investigation. Investigators will have documented experience and/or training in conducting investigations. HIA will ensure that staff conducting the investigation will not be:
- Staff directly involved in the incident.
  - Staff whose testimony is incorporated in the investigation.
  - Staff who are the supervisor, supervisee, spouse, significant other or immediate family member of anyone involved in the investigation.
- 6.2 If there is concern regarding a potential conflict of interest or appearance of a conflict, the RRDC will assign another waiver provider who provides services to the individual to conduct the investigation. The RRDS and/or Nurse Evaluator will conduct the investigation if the scope of the incident goes beyond one service provider, there is an appearance of conflict of interest among the providers, the provider has demonstrated non-compliance with program manual standards or improper procedures or the NYSDOH requests the RRDC complete the investigation. The RRDC will request technical assistance from the NYSDOH at any time when necessary.
- 6.3 An investigation of a Serious Reportable Incident will contain the following information:
1. A clear and objective description of the event under investigation. A description of the people involved in the alleged incident, the names of all witnesses and the time and place the incident occurred;
  2. Identification of whether this was a unique occurrence or if this is believed to be related to previously reported incidents;
  3. Details of structured interviews with all individuals involved in the events and all witnesses;



4. The investigator's conclusions if the allegation is substantiated, unsubstantiated or whether no definitive conclusions can be reached. The reasoning behind this decision must be included; and
  5. The investigator's recommendations for action. This action may be directed towards individual employers or the participant, or may address larger program concerns such as training, supervision or agency policy.
- 6.4 If a participant is alleged to have abused another participant or member of the community (including staff), it is necessary for the investigation to take into consideration the aggressor's cognitive abilities to make a judgment as to the interventions that should follow the investigation of the incident.
- 6.5 The results of the investigation will be presented to the Serious Incident Review Committee, which will determine if the investigation is complete, the appropriate actions have been taken and necessary follow-up has been implemented.
- 6.6 Timeframe for completion of the investigation (DOH)

Head Injury Association will provide written follow up to investigations within one week of the incident and monthly thereafter until the incident is deemed closed by the RRDS.

The incident must remain open until the RRDC receives confirmation that the SIRC met, reviewed the incident and has recommended that the incident be closed, while adhering to the 90 day deadline. The SIRC must also provide the RRDC with suggestions post review.

All serious reportable incidents investigations should be completed within 30 days unless additional information is required in order to complete the investigation. All investigation summaries will be sent to the RRDS and any additional required follow up by the RRDS will be incorporated into subsequent follow up reports.

SRI investigations pertaining to unplanned hospitalizations must be closed within the timeframe (90) days from the date of the 24-Hour Provider Report, not after discharge from the hospital.

The investigation is not closed until the RRDC determines it is closed.

All requests for release of DOH incident and investigation information will be reviewed and approved by the RRDS.

### **Investigations by DOH**

- 6.7 The Department and its representative(s) (i.e., the RRDS or others identified as such by the HCBS/TBI or NHTD waiver staff) have the authority to investigate the conduct, performance and/or alleged neglect of duties of administrators or employees of any agency or individual serving as a HCBS/TBI or NHTD waiver provider. This level of intervention will occur when there are concerns that the provider has not followed the procedures described in this policy.

If HIA found to be noncompliant with these policies, the State will take appropriate action that may include terminating the Provider Agreement.

6.8 DOH works cooperatively with other State agencies that provide services to individuals with disabilities, informing them when mutual providers experience significant or numerous Serious Reportable Incidents.

6.9 Any employee under investigation for Serious Reportable Incidents by DOH or another State agency is not permitted to provide service to any HCBS/TBI or NHTD waiver participant.

7.0 **Serious Incident Review Committee**

7.1 The primary purpose of the standing committee shall include the review of all recordable, serious reportable incidents and allegations of abuse to:

- A) Ascertain that recordable, serious reportable incidents and allegations of abuse were reported, managed by the Serious Incident Review Committee and documented consistent with the provision of The Department of Health and with Head Injury Association policies and procedures. The SIRC will further make recommendations to the Executive Director to correct, improve, or eliminate inconsistencies.
- B) Ascertain that necessary and appropriate corrective, preventative action has been taken to protect participants from further harm and to safeguard against the recurrence of similar reportable incidents or alleged client abuse and to make recommendations to the Executive Director to correct, improve, or eliminate inconsistencies.
- C) Identify trends in recordable, serious reportable incidents or allegations of abuse by type, individual name, site, employee involvement, time, date, circumstance, etc. and to recommend appropriate corrective or preventative Executive Director to safeguard against such recurring situations or reportable incidents and allegations of abuse.
- D) Ascertain and ensure the adequacy of the agency's/program's reporting and review practices, including the monitoring of the implementation of approved recommendations for corrective and preventative action.

7.2 The Serious Incident Review Committee will meet no less frequently than on a quarterly basis and always within one month of the report of a serious reportable incident or allegation of abuse, or sooner should the circumstances so warrant. The incident will be presented to the SIRC which will be notification an investigation has been initiated and that committee involvement is required.

7.3 The SIRC will ensure documentation of reports of recordable, serious reportable incidents and allegation of abuse have been reviewed by the committee and that results and recommendations have been conveyed to appropriate agency executives and others with a need to know.

7.4 The SIRC will monitor actions taken on any and all recommendations made and advise the

Executive Director when there is a problem.

7.5 The SIRC will report annually to the Board of Directors, Executive Director and the RRDS concerning the committee's general monitoring functions, general identified trends in reportable incidents, serious reportable incidents, allegation of abuse and corrective, preventive and/or disciplinary action pertaining to identified trends.

7.6 The Serious Incident Review Committee is responsible for maintaining overall statistical information that reflect single events and that, when an event involves more than one person, records are retrievable by event in addition to being retrievable by a person's name.

#### 8.0 **Organization and Membership of the Serious Incident Review Committee**

- A. The Committee is organized on an agency-wide basis.
- B. The Committee will contain at least five staff members and all must be present any time the committee convenes. Participation of a cross section of staff, including professional staff, direct care staff and at least one member of the administrative staff will be part of the committee.
- C. The Executive Director of the agency shall not serve as a member of the Committee, but may be consulted by the Committee in its deliberations.
- D. The staff person assigned to conduct an investigation can be part of the Committee, but may not serve on the Committee at the same time he/she is involved in an active investigation for the agency.

#### 8.1 **Responsibilities of the Serious Incident Review Committee**

This Committee is responsible for reviewing the investigation of every Serious Reportable Incident. The Committee will evaluate whether the investigation has been thorough, complete and objective and appropriately reported, investigated and documented.

The committee will determine if the conclusions and recommendations of the investigator comply with best clinical practices and are in compliance with the standards and guidelines of the HCBS/TBI or NHTD waiver.

- A. Review all Serious Reportable Incidents and Recordable Incidents to assure that incidents are appropriately reported, investigated and documented.
- B. Ascertain that necessary and appropriate corrective, preventive, and/or disciplinary action has been taken in accordance with the Committee's recommendations. If other actions are taken, the Committee must document the original recommendations and explain why these recommendations were revised.

- C. Develop recommendations for changes in provider policy and procedure to prevent or minimize the occurrence of similar situations. These recommendations must be presented to the appropriate administrative staff.
- D. Identify trends in Serious Reportable Incidents (by type, client, site, employee, involvement, time, date, circumstance, etc.), and recommend appropriate corrective and preventive policies and procedures.
- E. Head Injury Association will submit quarterly reports to the RRDC by the end of the month following the end of each quarter that includes all SRI's and the number of recordable incidents that have occurred. Even if there have been no SRI investigations during the quarter, a report will be submitted.
- F. Head Injury Association will submit an annual report to the RRDC by January 31 of each year for the prior year to the HCBS/TBI or NHTD waiver staff regarding reportable incidents and allegations of HCBS/TBI or NHTD waiver providers and corrective, preventive and/or disciplinary action pertaining to identified trends. This report will
  - o Include all corrective, preventive and/or disciplinary actions taken pertaining to identified trends.
  - o Reflect the activities of the SIRC in the investigation process, investigation outcomes, and remediation activities.
  - o Include the name and position of each of the members of the SIRC, documentation of any changes in the membership during the reporting period and the dates of the SIRC meetings.
  - o Be submitted to the RRDC in each waiver provider's region in which it is authorized to provide waiver services by January 31 of each year for the prior year.

The RRDC reviews the quarterly and annual reports for regional trend analysis, makes recommendations for interventions and subsequently forwards the report with its analysis and outcomes to DOH waiver staff for further review. DOH waiver staff may also request reports at any time.

## 8.2 **Documentation of Serious Incident Review Committee Activity**

- A. The chairperson shall ensure that minutes are kept for all meetings and collected in one location in a manner that ensures confidentiality. For each SRI reviewed, minutes must include:
  - o The SRI number assigned by the RRDC
  - o Waiver participant's name and CIN
  - o A brief summary of the situation that caused the report (including date and type of incident)
  - o Committee findings and recommendations
  - o Actions taken on the part of the agency/program as a result of the recommendations
- B. Minutes addressing the review of Serious Reportable Incidents shall state the identification number of the incident (provided by the RRDS), the waiver participant's name and CIN number, a brief summary of the situation that caused the report to be

generated (including date and type of incident), Committee findings and recommendations, and actions taken on the part of the agency/program as a result of such recommendations.

- C. DOH may request to review minutes at any time.
- D. All information regarding Serious Reportable Incident reports, including but not limited to the information collected to complete the investigation and the investigation report and minutes of the standing Serious Incident Review Committee, must be maintained separately from the participant's records. This includes the RRDC SRI close-out letter that is sent to the SC.