Participation in Decision-making and Consent

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How Consent Obtained

- Human Rights Regulations (12 VAC 35-115)
- Health Care Decisions Act (§ 54.1-2981 et seq.)
- Judicial Authorization (§§ 37.2-1100 through -1109)
- Guardianship (§§ 64.2-2000 through -2029)
- Two Physician/Dentist Rule (§ 54.1-2970)
Participation in Decision-Making 12 VAC 35-115-70

- Rights & Duties
- Consent
- Informed Consent
- Capacity
- Surrogate Decision-Making
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Each individual has a right to participate meaningfully in decisions regarding all aspects of services affecting him. This includes the right to:
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Consent or not consent to receive or participate in services.
  - ISP and discharge plan shall incorporate the individual’s preferences consistent with his condition and need for service and the provider’s ability to address them;
  - Services record shall include evidence that the individual has participated in the development of his ISP and discharge plan, in changes to these plans, and in all other significant aspects of his treatment and services; and
  - Services record shall include the signature or other indication of the individual’s or his authorized representative’s consent.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Give or not give informed consent to receive or participate in treatment or services that pose a risk of harm greater than ordinarily encountered in daily life and to participate in human research except research that is exempt under § 37.2-162.17 of the Code of Virginia.

- Informed consent is always required for surgical procedures, electroconvulsive treatment, or use of psychotropic medications.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- To be informed, consent for any treatment or service must be based on disclosure of and understanding by the individual or his authorized representative of the following information:
  1. An explanation of the treatment, service, or research and its purpose;
  2. When proposing human research, the provider shall describe the research and its purpose, explain how the results of the research will be disseminated and how the identity of the individual will be protected, and explain any compensation or medical care that is available if an injury occurs;
Participation in Decision-making and Consent. 12 VAC 35-115-70

3. Description of adverse consequences and risks associated with the research, treatment, or service;

4. Description of benefits that may be expected from the research, treatment, or service;

5. Description of alternative procedures that might be considered, along with their side effects, risks, and benefits;

6. Notification that the individual is free to refuse or withdraw his consent and to discontinue participation in any treatment, service, or research requiring his consent at any time without fear or reprisal against or prejudice to him; and
Participation in Decision-making and Consent. 12 VAC 35-115-70

7. Description of the ways in which the individual or his authorized representative can raise concerns and ask questions about the research, treatment, or service to which consent is given.

- Evidence of informed consent shall be documented in an individual’s services record and indicated by the signature of the individual or his authorized representative on a form or the ISP.
Informed consent for electroconvulsive treatment requires the following additional components:

(1) Informed consent shall be in writing, documented on a form that shall become part of the individual’s services record. This form shall:

(a) Specify the maximum number of treatments to be administered during the series;

(b) Indicate that the individual has been given the opportunity to view an instructional video presentation about the treatment procedures and their potential side effects; and

(c) Be witnessed in writing by a person not involved in the individual’s treatment who attests that the individual has been counseled and informed about the treatment procedures and potential side effects of the procedures.
Participation in Decision-making and Consent. 12 VAC 35-115-70

(2) Separate consent, documented on a new consent form, shall be obtained for any treatments exceeding the maximum number of treatments indicated on the initial consent form.

(3) Providers shall inform the individual or his authorized representative that the individual may obtain a second opinion before receiving ECT and the individual is free to refuse or withdraw his consent and to discontinue participation at any time without fear of reprisal against or prejudice to him. The provider shall document such notification in the individual’s services record.
Participation in Decision-making and Consent. 12 VAC 35-115-70

(4) Before initiating ECT for any individual under age 18 years, two qualified child psychiatrists must concur with the treatment. The psychiatrists must be trained or experienced in treating children or adolescents and not directly involved in treating the individual. Both must examine the individual, consult with the prescribing psychiatrist, and document their concurrence with the treatment in the individual’s services record.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Have an authorized representative make decisions for him in cases where the individual has been determined to lack capacity to consent or authorize the disclosure of information.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- If an individual who has an authorized representative who is not his legal guardian objects to the disclosure of specific information or a specific proposed treatment or service, the director or his designee shall immediately notify the human rights advocate and authorized representative. A petition for LHRC review of the objection may be filed under 12 VAC 35-115-200.

- If the authorized representative objects or refuses to consent to a specific proposed treatment or service for which consent is necessary, the provider shall not institute the proposed treatment, except in an emergency in accordance with this section or as otherwise permitted by law.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Be accompanied, except during forensic evaluations, by a person or persons whom the individual trusts to support and represent him when he participates in services planning, assessments, evaluations, including discussions and evaluations of the individual’s capacity to consent, and discharge planning.

- Request admission to or discharge from any service at any time.
Participation in Decision-making and Consent. 12 VAC 35-115-70

The provider's duties:

- Providers shall respect, protect, and help develop each individual's ability to participate meaningfully in decisions regarding all aspects of services affecting him. This shall be done by involving the individual, to the extent permitted by his capacity, in decision making regarding all aspects of services.

- Providers shall ask the individual to express his preferences about decisions regarding all aspects of services that affect him and shall honor these preferences to the extent possible.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Providers shall give each individual the opportunity, and any help he needs, to participate meaningfully in the preparation of his services plan, discharge plan, and changes to these plans, and all other aspects of services he receives. Providers shall document these opportunities in the individual's services record.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Providers shall obtain and document in the individual's services record the individual's or his authorized representative's consent for any treatment before it begins.
Participation in Decision-making and Consent. 12 VAC 35-115-70

For **minors** in the legal custody of a natural or adoptive parent:
- Provider shall obtain this consent from at least one parent.
- Consent of a parent not needed if a court has ordered or consented to treatment or services pursuant to § 16.1-241 D, 16.1-275, or 54.1-2969 B of the Code of Virginia, or a local department of social services with custody of the minor has provided consent.
- Reasonable efforts must be made, however, to notify the parent or legal custodian promptly following the treatment or services.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Additionally, a competent minor may independently consent to treatment for sexually transmitted or contagious diseases, family planning or pregnancy, or outpatient services or treatment for mental illness, emotional disturbance, or substance use disorders pursuant to § 54.1-2969 E of the Code of Virginia.
Participation in Decision-making and Consent. 12 VAC 35-115-70

**Emergencies:**

- Providers may initiate, administer, or undertake a proposed treatment without the consent of the individual or the individual’s authorized representative in an emergency. All emergency treatment or services and the facts and circumstances justifying the emergency shall be documented in the individual’s services record within 24 hours of the treatment or services.
  
a. Providers shall immediately notify the authorized representative of the provision of treatment without consent during an emergency.
Participation in Decision-making and Consent. 12 VAC 35-115-70

b. Providers shall continue emergency treatment without consent beyond 24 hours only following a review of the individual’s condition and if a new order is issued by a professional who is authorized by law and the provider to order treatment.

c. Providers shall notify the human rights advocate if emergency treatment without consent continues beyond 24 hours.

d. Providers shall develop and integrate treatment strategies into the ISP to address and prevent future emergencies to the extent possible following provision of emergency treatment without consent.
Participation in Decision-making and Consent. 12 VAC 35-115-70

Providers shall obtain and document in the individual's services record the consent of the individual or his authorized representative to continue any treatment initiated in an emergency that lasts longer than 24 hours after the emergency began.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Providers may provide treatment in accordance with a court order or in accordance with other provisions of law that authorize such treatment or services including the Health Care Decisions Act (§ 54.1-2981 et seq. of the Code of Virginia).
- Provisions of these regulations are not intended to be exclusive of other provisions of law but are cumulative.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Providers shall respond to an individual's request for discharge and shall make sure that the individual is not subject to punishment, reprisal, or reduction in services because he makes a request.
- However, if an individual leaves a service against medical advice, any subsequent billing of the individual by his private third party payer shall not constitute punishment or reprisal on the part of the provider.
Participation in Decision-making and Consent. 12 VAC 35-115-70

**Discharge of Voluntary admissions:**
- Individuals admitted under § 37.2-805 of the Code of Virginia to state hospitals operated by the department who notify the director of their intent to leave shall be discharged when appropriate, but no later than eight hours after notification, unless another provision of law authorizes the director to retain the individual for a longer period.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- Minors admitted under § 16.1-338 or 16.1-339 of the Code of Virginia shall be released to the parent's or legal guardian's custody within 48 hours of the consenting parent's or legal guardian's notification of withdrawal of consent, unless a petition for continued hospitalization pursuant to § 16.1-340 or 16.1-345 of the Code of Virginia is filed.
Participation in Decision-making and Consent. 12 VAC 35-115-70

Discharge of Involuntary admissions:

- When a minor involuntarily admitted under § 16.1-345 of the Code of Virginia no longer meets the commitment criteria, the director shall take appropriate steps to arrange the minor's discharge.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- When an individual involuntarily admitted under § 37.2-817 has been receiving services for more than 30 days and makes a written request for discharge, director shall determine whether the individual continues to meet the criteria for involuntary admission.

- If the director denies the request for discharge, he shall notify the individual in writing of the reasons for denial and of the individual's right to seek relief in the courts. The request and reasons for denial shall be included in the individual's services record.

- Anytime the individual meets any of the criteria for discharge set out in § 37.2-837 or 37.2-838 of the Code of Virginia, the director shall take all necessary steps to arrange the individual's discharge.
Participation in Decision-making and Consent. 12 VAC 35-115-70

- If at any time it is determined that an individual involuntarily admitted under Chapter 11 (§ 19.2-167 et seq.) or Chapter 11.1 (§ 19.2-182.2 et seq.) of Title 19.2 of the Code of Virginia no longer meets the criteria under which the individual was admitted and retained, the director or commissioner, as appropriate, shall seek judicial authorization to discharge or transfer the individual. Further, pursuant to § 19.2-182.6 of the Code of Virginia, the commissioner shall petition the committing court for conditional or unconditional release at any time he believes the acquittedee no longer needs hospitalization.
Participation in Decision-making and Consent. 12 VAC 35-115-70

Discharge of Certified admissions:

- If an individual certified for admission to a state training center or his authorized representative requests discharge, the director or his designee shall contact the individual’s community services board to finalize and implement the discharge plan.
Substitute Decision Making
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

- If the capacity of an individual to consent to treatment, services, or research or authorize the disclosure of information is in doubt, the provider shall obtain an evaluation from a professional who is qualified by expertise, training, education, or credentials and conducted by or under the supervision of a licensed professional not directly involved with the individual to determine whether the individual has capacity to consent or to authorize the disclosure of information.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

1. Capacity evaluations shall be obtained for all individuals who may lack capacity, even if they request that an authorized representative be designated or agree to submit to a recommended course of treatment.

2. In conducting this evaluation, the professional may seek comments from representatives accompanying the individual pursuant to 12 VAC-35-115-70 A 4 about the individual’s capacity to consent or to authorize disclosure.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

3. Providers shall determine the need for an evaluation of an individual’s capacity to consent or authorize disclosure of information and the need for a substitute decision maker whenever the individual’s condition warrants, the individual requests such a review, at least every six months, and at discharge, except for individuals receiving acute inpatient services.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

a. If the individual’s record indicates that the individual is not expected to obtain or regain capacity, the provider shall document annually that it has reviewed the individual’s capacity to make decisions and whether there has been any change in that capacity.

b. Providers of acute inpatient services shall determine the need for an evaluation of an individual’s capacity to consent or authorize disclosure of information whenever the individual’s condition warrants or at least at every treatment team meeting. Results of such reviews shall be documented in the treatment team notes and communicated to the individual and his authorized representative.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

- **Capacity evaluations** shall be conducted in accordance with accepted standards of professional practice and shall indicate the specific type of decision for which the individual’s capacity is being evaluated (e.g., medical) and shall indicate what specific type of decision the individual has or does not have the capacity to make. Capacity evaluations shall address the type of supports that might be used to increase the individual’s decision-making capabilities.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

- If the individual or his family objects to the results of the licensed professional's determination, the provider shall immediately inform the human rights advocate.
  
a. If the individual or family member wishes to obtain an independent evaluation of the individual's capacity, he may do so at his own expense and within reasonable timeframes consistent with his circumstances. If the individual or family member cannot pay for an independent evaluation, the individual may request that the LHRC consider the need for an independent evaluation pursuant to 12 VAC 35-115-200 B.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

- The provider shall take no action for which consent or authorization is required, except in an emergency, pending the results of the independent evaluation. The provider shall take no steps to designate an authorized representative until the independent evaluation is complete.
Determination of capacity to give consent or authorization. 12 VAC 35-115-145

b. If the independent evaluation is consistent with the provider’s evaluation, the provider’s evaluation is binding, and the provider shall implement it accordingly.

c. If the independent evaluation is not consistent with the provider’s evaluation, the matter shall be referred to the LHRC for review and decision under 12 VAC 35-115-200.
Authorized Representatives
Authorized Representatives.
12 VAC 35-115-146

- When it is determined in accordance with 12 VAC-35-115-145 that an individual lacks the capacity to consent or authorize the disclosure of information, the provider shall recognize and obtain consent or authorization for those decisions for which the individual lacks capacity from the following if available:
  1. An attorney-in-fact who is currently empowered to consent or authorize the disclosure under the terms of a durable power of attorney;
  2. A health care agent appointed by the individual under an advance directive or power of attorney in accordance with the laws of Virginia; or
3. A legal guardian of the individual, or if the individual is a minor, a parent with legal custody of the minor or other person authorized to consent to treatment pursuant to § 54.1-2969 A of the Code of Virginia.

- If an attorney-in-fact, health care agent or legal guardian is not available, the director shall designate a substitute decision maker as authorized representative in the following order of priority:
The individual’s family member. In designating a family member, the director shall honor the individual’s preference unless doing so is clinically contraindicated.

a. If the director does not appoint the family member chosen by the individual, the individual shall be told of the reasons for the decision and information about how to request LHRC review according to 12 VAC 35-115-200.
Authorized Representatives.
12 VAC 35-115-146

b. If the individual does not have a preference or if the director does not honor the individual’s preference in accordance with these regulations, the director shall select the best qualified person, if available, according to the following order of priority unless, from all information available to the director, another person in a lower priority is clearly better qualified.

(1) A spouse;
(2) An adult child;
(3) A parent;
(4) An adult brother or sister; or
(5) Any other relative of the individual.
Authorized Representatives.
12 VAC 35-115-146

Next friend of the individual. If no other person specified above is available and willing to serve as authorized representative, a provider may designate a next friend of the individual, after a review and finding by the LHRC that the proposed next friend has, for a period of six months within two years prior to the designation either:

a. Shared a residence with the individual; or
b. Had regular contact or communication with the individual and provided significant emotional, personal, financial, spiritual, psychological, or other support and assistance to the individual.
In addition to the conditions set forth above, the individual must have no objection to the proposed next friend being designated as the authorized representative.

The person designated as next friend also shall:

a. Personally appear before the LHRC, unless the LHRC has waived the personal appearance; and

b. Agree to accept these responsibilities and act in the individual’s best interest and in accordance with the individual’s preferences, if known.
The LHRC shall have the discretion to waive a personal appearance by the proposed next friend and to allow that person to appear before it by telephone, video, or other electronic means of communication as the LHRC may deem appropriate under the circumstances. Waiving the personal appearance of the proposed next friend should be done in very limited circumstances.

If, after designation of a next friend, an appropriate family member becomes available to serve as authorized representative, the director shall replace the next friend with the family member.
Authorized Representatives.  
12 VAC 35-115-146

- No director, employee, or agent of a provider may serve as an authorized representative for any individual receiving services delivered by that provider unless the authorized representative is a relative or the legal guardian.

- When a provider, or the director, an employee, or agent of the provider is also the individual’s guardian, the provider shall assure that the individual’s preferences are included in the services plan and that the individual can make complaints about any aspect of the services he receives.
Authorized Representatives.
12 VAC 35-115-146

The provider shall document the recognition or designation of an authorized representative in the individual’s services record, including evidence of consultation with the individual about his preference, copies of applicable legal documents such as the durable power of attorney, advance directive, or guardianship order, names and contact information for family members, and, when there is more than one potential family member available for designation as authorized representative, the rationale for the designation of the particular family member as the authorized representative.
Authorized Representatives.

12 VAC 35-115-146

- If a provider documents that the individual lacks capacity to consent and no person is available or willing to act as an authorized representative, the provider shall:
  1. Attempt to identify a suitable person who would be willing to serve as guardian and ask the court to appoint that person to provide consent or authorization; or
  2. Ask a court to authorize treatment (See § 37.2-1101 of the Code of Virginia).

- Court orders authorizing treatment shall not be viewed as substituting or eliminating the need for an authorized representative.
Authorized Representatives.
12 VAC 35-115-146

- Providers shall review the need for court-ordered treatment and determine the availability of and seek an authorized representative whenever the individual’s condition warrants, the individual requests such a review, or at least every six months except for individuals receiving acute inpatient treatment.
- Providers of acute inpatient services shall review the need for court-ordered treatment and determine the availability of and seek an authorized representative whenever the individual’s condition warrants or at least at every treatment team meeting. All such reviews shall be documented in the individual’s services record and communicated to the individual.
Authorized Representatives.
12 VAC 35-115-146

- When the provider recognizes or designates an authorized representative, the provider shall notify the court that its order is no longer needed and shall immediately suspend its use of the court order.
Authorized Representatives.
12 VAC 35-115-146

- Conditions for removal of an authorized representative. Whenever an individual has regained capacity to consent as indicated by a capacity evaluation or clinical determination, the director shall immediately remove any authorized representative designated pursuant to the above, notify the individual and the authorized representative, and ensure that the services record reflects that the individual is capable of making his own decisions.
Whenever an individual with an authorized representative who is his legal guardian has regained his capacity to give informed consent, the director may use the applicable statutory provisions to remove the authorized representative. (See § 37.2-1012 of the Code of Virginia.) If powers of attorney and health care agents’ powers do not cease of their own accord when a clinician has determined that the individual is no longer incapacitated, the director shall seek the consent of the individual and remove the person as authorized representative.
The director shall remove the family or next friend authorized representative if the authorized representative becomes unavailable, unwilling, or unqualified to serve.

The individual or the advocate may request the LHRC to review the director’s decision to remove an authorized representative under the procedures set out at 12 VAC-35-115-180, and the LHRC may reinstate the authorized representative if it determines that the director’s action was unjustified.
Authorized Representatives.
12 VAC 35-115-146

- Prior to any removal under this authority, the director shall notify the individual of the decision to remove the authorized representative, of his right to request that the LHRC review the decision, and of the reasons for the removal decision. This information shall be placed in the individual’s services record.
- If the individual requests, the director shall provide him with a written statement of the facts and circumstances upon which the director relied in deciding to remove the authorized representative.
Authorized Representatives.  
12 VAC 35-115-146

The director may otherwise seek to replace an authorized representative who is an attorney-in-fact currently authorized to consent under the terms of a durable power of attorney, a health care agent appointed by an individual under an advance directive, a legal guardian of the individual, or, if the individual is a minor, a parent with legal custody of the individual, only by a court order under applicable statutory authority.
Special procedures for LHRC reviews involving consent and authorization
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- The individual, his authorized representative, or anyone acting on the individual’s behalf may request in writing that the LHRC review the following situations and issue a decision:
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

1. If an individual objects at any time to the appointment of a specific person as authorized representative or any decision for which consent or authorization is required and has been given by his authorized representative, other than a legal guardian, he may ask the LHRC to decide whether his capacity was properly evaluated, the authorized representative was properly appointed, or his authorized representative’s decision was made based on the individual’s basic values and any preferences previously expressed by the individual to the extent that they are known, and if unknown or unclear in the individual’s best interests.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- The provider shall take no action for which consent or authorization is required if the individual objects, except in an emergency or as otherwise permitted by law, pending the LHRC review.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If the LHRC determines that the individual’s capacity was properly evaluated, the authorized representative is properly designated, or the authorized representative’s decision was made based on the individual’s basic values and any preferences previously expressed by the individual to the extent that they are known, or if unknown or unclear in the individual’s best interests, then the provider may proceed according to the decision of the authorized representative.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If the LHRC determines that the individual’s capacity was not properly evaluated or the authorized representative was not properly designated, then the provider shall take no action for which consent is required except in an emergency or as otherwise required or permitted by law, until the capacity review and authorized representative designation is properly done.
Special procedures for LHRC reviews involving consent and authorization 12 VAC 35-115-200

- If the LHRC determines that the authorized representative’s decision was not made based on the individual’s basic values and any preference previously expressed by the individual to the extent known, and if unknown or unclear, in the individual’s best interests, then the provider shall take steps to remove the authorized representative pursuant to 12 VAC 35-115-146.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If an individual or his family member has obtained an independent evaluation of the individual's capacity to consent to treatment or services or to participate in human research or authorize the disclosure of information under 12 VAC 35-115-80, and the opinion of that evaluator conflicts with the opinion of the provider's evaluator, the LHRC may be requested to decide which evaluation will control.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If the LHRC agrees that the individual lacks the capacity to consent to treatment or services or authorize disclosure of information, the director may begin or continue treatment or research or disclose information, but only with the appropriate consent or authorization of the authorized representative. The LHRC shall advise the individual of his right to appeal this determination to the SHRC under 12 VAC 35-115-210.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If the LHRC does not agree that the individual lacks the capacity to consent to treatment or services or authorize disclosure of information, the director shall not begin any treatment or research, or disclose information without the individual’s consent or authorization, or shall take immediate steps to discontinue any actions begun without the consent or authorization of the individual. The director may appeal to the SHRC under 12 VAC 35-115-210 but may not take any further action until the SHRC issues its opinion.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- If a director makes a decision that affects an individual and the individual believes that the decision requires his personal consent or authorization or that of his authorized representative, he may object and ask the LHRC to decide whether consent or authorization is required.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- Regardless of the individual’s capacity to consent to treatment or services or authorize disclosure of information, if the LHRC determines that a decision made by a director requires consent or authorization that was not obtained, the director shall immediately stop such action unless and until such consent or authorization is obtained. The director may appeal to the SHRC under 12 VAC 35-115-210 but may not take any further action until the SHRC issues its opinion.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- Before making such a decision, the LHRC shall review the action proposed by the director, any determination of lack of capacity, the opinion of the independent evaluator if applicable, and the individual’s or his authorized representative’s reasons for objecting to that determination.

- To facilitate its review, the LHRC may ask that a physician or licensed clinical psychologist not employed by the provider evaluate the individual at the provider’s expense and give an opinion about his capacity to consent to treatment or authorize disclosure of information.
Special procedures for LHRC reviews involving consent and authorization
12 VAC 35-115-200

- The LHRC shall notify all parties and the human rights advocate of the decision within 10 working days of the initial request.
For Further Information

- Check the Department web site
- Frequently Asked Questions (FAQ)