*Mental Health and Related Services Act 1998*

*Section 65*

|  | ***Complete person details or affix patient label in box below:*** |
| --- | --- |
| **Full name of person:** |  |       |  |
| **Also known as** |  |      **Patient Label** |  |
| **Date of Birth:** |  |    / /   |  |
| **HRN:** |  |       |  |
| **Sex:** |  | [ ]  Male [ ]  Female [ ]  Non-binary [ ]  Not specified |
|  |
| It is an offence to perform a clinical trial or experimental treatment on a person who is an involuntary patient or subject to a community management order unless:1. the trial or treatment is approved by an ethics committee nominated by the Chief Health Officer; and
2. either:
	1. the person, or a decision maker for the person, gives informed consent to the trial or treatment; or
	2. the Tribunal gives approval to the trial or treatment.

This form is to be used in the event that the patient or their decision maker does not or cannot give informed consent.**If the patient or their decision maker does give informed consent please use Form 25 - Clinical Trials or Experimental Treatment Informed Consent Form**. |
|  |
| ***Full name of person to be included in clinical trial and/or experimental treatment that has been approved by the ethics committee as nominated by the Chief Health Officer or delegate:***      |
| ***Person is currently admitted or residing at:***      |
| ***Details of the clinical trial or experimental treatment:***       |
| ***Title of the ethics committee that has reviewed and approved the clinical trial or experimental treatment:***     ***Approval details:***      |
| ***Rationale for the proposed participation in the clinical trial or experimental procedure:***      |
|  |  |
| ***Risks associated with the person participating in the clinical trial or experimental procedure and risks associated with the person not participating in the clinical trial or experimental procedure:***     ***How and when have the risks and benefits and possible outcomes or side effects been advised to the person on whom the procedure is being done:***       |
| ***Details of any second opinions:*** *(where applicable)*      |
| ***Steps taken to try to gain consent*** *(including supports provided such as use of interpreters, patient advocates, peer support workers, Community Visitor Program or other advocates)*      |
| ***What is the person’s objection and/or why are they are not able to provide consent:***      |
| ***Full name of person making request:***     ***Signature:***     ***Date:***   /   /    | ***Position of person making request or notification:***[ ]  Medical Practitioner[ ]  Authorised Psychiatric Practitioner (APP)[ ]  Designated Mental Health Practitioner (DMHP) |
| ***Name of Approved Treatment Facility, Agency or Medical Practice:***      |
|  |
| **Approval by the Tribunal**On behalf of the Tribunal,I approve [ ]  I do not approve [ ] the inclusion of the above mentioned patient in clinical trials and/or experiments that have been approved by the Ethics Committee as nominated by the Chief Health Officer or delegate. |
| ***Full name of President of the Tribunal:***      | ***Signature:***      | ***Date:***   /   /    |

**Form Requirements**

[ ]  Placed on clinical file

[ ]  Sent to Tribunal    /   /

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| --- | --- |
| **PGC ID:** HEALTHINTRA-1880-8875 | **TRM ID:** EDOC2018/165617 |
| **Version:** | Version: 9.0 | **DO NOT EDIT THIS** | **Approved Date:** <dd/mm/yyyy> | **Review Date:** <dd/mm/yyyy> |