**Abbreviated Participant Information Sheet/Consent Form**

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>A randomised phase III double-blind placebo-controlled study of regorafenib in refractory Advanced Gastro-oesophageal Cancer (AGOC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short Title</strong></td>
<td>INTEGRATE II</td>
</tr>
<tr>
<td><strong>Protocol Number</strong></td>
<td>AG0315OG / CTC0140</td>
</tr>
</tbody>
</table>
| **Study Sponsor** | Australasian Gastro-Intestinal Trials Group (AGITG)  
| **Study Coordinating Centre** | NHMRC Clinical Trials Centre |
| **Coordinating Principal Investigator/Principal Investigator** | Associate Professor Nick Pavlakis & Professor David Goldstein |
| **Associate Investigator(s)** | [Associate Investigator(s)] |
| **Location** | [Location] |

This is an addendum to the:  
INTEGRATE II Master Participant Information and Consent Form version 4.0, dated 24 Apr 18  
<Insert site name here> Participant Information and Consent Form version #, dd/mm/yyyy  
[Please update above line and insert version & date of site-specific PISCF that was previously signed by the participant].

This Abbreviated Participant Information and Consent Form is 4 pages long. Please make sure that you have all the pages.

You are currently participating in the above clinical research study which is testing the effects of a new drug, regorafenib, on participants with advanced gastro-oesophageal cancer (AGOC), which has progressed after standard anti-cancer therapy, and for which there are no other treatment options.
When you agreed to do so, we undertook to provide you with new information about the study as it became available.

This Abbreviated Participant Information contains new information about possible side effects of the study treatment. Its purpose is to explain to you as openly and clearly as possible all the changes to enable you to decide whether or not to continue to take part in the study.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the study changes with a relative or friend or your local health worker.

Once you understand what the changes to the study mean for your participation and if you agree to continue to take part in it, you will be asked to sign the Consent Form at the end of this document. By signing the Consent form, you indicate that you understand the new information and that you give your consent to continued participation in the research project.

You will be given a copy of the Abbreviated Participant Information and Consent form to keep as a record.

**UPDATED INFORMATION**

This is to advise you that new safety information has become available for the study treatment. The following risks were not included in the Participant Information and Consent form/s you have already signed:

**Common (Between 1 in 10 and 1 in 100)**
- Loss of body fluids (dehydration)

**Uncommon (Between 1 in 100 and 1 in 1000)**
- Severe inflammation of the pancreas

In addition, the following risk has been moved from uncommon to common:
- Altered sensations in hands and feet including tingling, numbness, weakness or pain

There are no other changes to the information that you have previously agreed to, however please ask your study doctor or a member of the study team if you wish to discuss any other aspect of the study.
CONSENT FORM

Title
A randomised phase III double-blind placebo-controlled study of regorafenib in refractory Advanced Gastro-Oesophageal Cancer (AGOC)

Short Title
INTEGRATE II

Protocol Number
CTC0140 / AG0315OG

Study Sponsor

Study Coordinating Centre
NHMRC Clinical Trials Centre

Coordinating Principal Investigator/Principal Investigator
Associate Professor Nick Pavlakis & Professor David Goldstein

Associate Investigator(s)
(if required by institution) [Associate Investigator(s)]

Location
(Where CPI/PI will recruit) [Location]

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand that I am agreeing to continue my participation in this research study. I understand that I can withdraw from the study at any time.

I understand the new information that has been provided to me.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to continue my participation in this study.

Name of Participant (please print) ____________________________________________

Signature ___________________________ Date ___________________________

INTEGRATE II
ABBREVIATED Master Participant Information and Consent Form, Version 5.0 7 Dec 18
<insert site name here> Participant Information and Consent Form, Version #, dd/mm/yyyy Page 3 of 4
Name of Study Doctor/Senior Researcher† (please print)  __________________________________________
Signature __________________________ Date __________________________

† A senior member of the research team must provide the explanation of, and information concerning, the research study.

Note: All parties signing the consent section must date their own signature. The patient must receive a copy of the signed consent form.