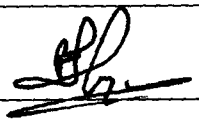
Title:	**ICF version control**	
Version:	02	
Effective date:	01-APR-2013	
Author name	*Signature*	*Date*
P. Westveer		07-MAR-2013
Approver name	*Signature*	*Date*
P.C. Huijgens		07-03-2013

The Patient Information Letter and Informed Consent Form (one document from here on referred to as ICF) is part of the essential trial documents. According to GCP the ICF document has to be approved by the Ethics Committee (EC).

To be able to check if patients have signed the correct EC approved ICF(s), the site and the sponsor need to know which versions were approved and used during specific periods. A clear method of version control is therefore needed.

ICF study template

At the start of the trial an ICF study template must be available in each applicable language (depending on which countries are participating in the trial). This ICF study template must comply with the requirements of GCP and applicable national laws.

The ICF study template should not contain any site specific information (names, addresses).

The ICF study template should not contain information regarding treatment or procedures that is not specified in the protocol and therefore may vary between sites.

HOVON will provide for each trial an ICF study template in Dutch.

HOVON will ensure that the ICF study template is approved by the EC before the start of the trial.

For international trials HOVON will provide an English translation of the ICF study template. HOVON will make arrangements with coordinating investigators or co-sponsors to ensure that ICF study templates in local languages and in compliance with national regulations are developed and approved by the EC before start of the trial in each country.

The ICF study template should contain clear version information in the footer:

- name of the protocol the ICF belongs to
- reference to the document as “ICF study template” and applicable country
- version number of the ICF study template
- version date of the ICF study template
- space to record the site name, site specific version number and site specific version date of the site specific ICF based on the ICF study template

Site specific ICF

Each participating site should create a site specific ICF using the ICF study template provided by HOVON (or the national coordinating investigator or co-sponsor)

The trial manager for HOVON will instruct the sites in the procedure for creating a site specific ICF from the ICF study template.

Sites should adapt the ICF study template for the following items:

- site specific information in the designated space (site name, contact telephone numbers, name of investigator, etc.)
- site specific version information in the footer

These items will be clearly marked in the ICF study template.

If the site wishes to print the ICF on paper with their logo, it is allowed to adapt the margins and page breaks of the ICF document.

No other changes should be made by the site.

If the site detects an error or omission in the text of the ICF study template, the site should contact the trial manager for HOVON.

ICF study template amendment

The sponsor (i.e. HOVON) decides whether an ICF amendment is necessary.

HOVON will ensure that a new version of the ICF study template is available in all applicable countries.

HOVON will ensure that the new version of the ICF study template is approved by the EC in all applicable countries.

Each site receives the approved new version of the ICF study template. The site creates a new version of its site specific ICF from the study template according to the procedure outlined above.

The trial manager for HOVON will instruct sites on the procedure to obtain re-consent for patients that were included with the previous version of the ICF.

Compliance review

GCP requires that HOVON as sponsor files a copy of each ICF version used in the trial and a copy of the EC approval of each ICF version. Therefore the investigator is obliged to send a copy of each version of the site specific ICF to the trial manager for HOVON.

HOVON may review a site specific ICF for compliance to GCP, applicable laws and regulations and the content of this policy.