

Title:	Development and Management of HOVON Policies	
Version:	01	
Effective date:	01-MAR-2015	
<i>Author name</i>	<i>Signature</i>	<i>Date</i>
P. Westveer		27-Jan-2015
<i>Approver name</i>	<i>Signature</i>	<i>Date</i>
J. Cornelissen		30-01-15

Definition and scope

HOVON policies are formal documents that describe the standards that need to be adhered to in the execution of activities by or on behalf of HOVON.

In general the policies need to be adhered to by the HOVON board, the HOVON working groups and the Principal Investigators of trials sponsored by HOVON.

The scope and affected persons or organizations of a specific policy may be defined otherwise or in more detail in the policy document itself.

Policies may be accompanied by supporting documents such as guidelines and templates, that are developed and managed the same as policy documents.

Management and compliance

It is the responsibility of the HOVON board to establish policies on relevant subjects. The HOVON board is responsible for the content of the policies.

The HOVON board may delegate the task of document management to the HOVON Data Center or to the HOVON management bureau: recording the policies in formal documents, version control of the policy documents, filing of the policy documents and publishing the policy documents.

Each policy has a title, version number, version date and effective date. A policy is effective from its effective date until the effective date of a new version, or until the policy is withdrawn.

It is the responsibility of the HOVON board to ensure compliance to the policies, i.e. to maintain oversight and take corrective actions if necessary.

Policy development

The HOVON board or HOVON executive board decides if it is necessary to develop a new policy or change an existing policy. The HOVON executive board informs the delegated author (HOVON Data Center or HOVON management bureau) that a new policy or new policy version needs to be recorded, and provides to the author the requirements for the policy content.

The author creates a draft of the policy document. This draft is reviewed by the executive board. Once the draft is accepted by the executive board, the draft is sent by the author to the members of the full HOVON board for review.

Within two weeks (unless specified otherwise) HOVON board members can comment on the draft or request that the policy is discussed at a board meeting. The executive board decides how these comments and requests are followed up.

Once the draft is reviewed and (if applicable) discussed by the HOVON board, the author draws up a final version of the policy document. This final version needs to be approved by the HOVON executive board.

Formal approval is recorded on the policy document by a signature and date from the author and from a member of the HOVON executive board.

Publication

After approval a copy of the policy document is sent by the author to the full HOVON board and the working group chairpersons. Specific policies may also be sent to other stakeholders, as indicated by the HOVON executive board.

The author ensures that a copy of the policy document is published on the HOVON website. Policy documents on the website are open to the public, unless the HOVON executive board indicates that a specific policy needs to be accessible only after logging in with a HOVON account. The website contains only the most recent version of each policy.