

**The European HepCaRe project**

Hepatitis C Antiviral Therapy Registry

**Provider details**

Name:

Address:

Tel:

Email address:

**Recipient details**

The European Hepcare project

Name contact person:

Address:

Tel:

Email address:

This agreement governs the transfer of human personal data by the Provider to the Recipient for research purpose only. The Provider confirms that for the purposes of this DTA it is entitled to supply the data to the Recipient and assures anonymity of their patients.

**Data ownership and usage**

The Recipient will use data for purposes of the analyses set forth and within the limits set by the Research protocol only. The Recipient confirms that all work using the data will be carried out in compliance with all applicable laws, regulations, guidelines and approvals. The Provider may use the submitted data for research or other collaborations. Title to the data is and remains in the ownership of the Provider and the data are made available to the Recipient as a service to the research community. The Provider reserves the right to review or withdraw data from the Recipient at all times. Permission of the Provider will be requested for new analysis not described in protocol objectives.

**Data storage and access**

The Recipient will retain the Hepcare data in a secure network system (ESAR-HEPVIR database) at the Luxembourg institute of Health (LIH). The database manager and our study team (as defined further on) will have access to the data. The Recipient agrees not to give access to data, in whole or part, or any identifiable data derived from the data, to any third party without written consent from the Provider.

**Ethical approval**

The Provider is responsible for obtaining ethical approval if needed according to national guidelines.

**Acknowledgement**

The Recipient agrees to acknowledge a maximum of two researchers/clinicians per research group, in addition to researchers actively involved in the analysis, in the list of authors. Other participants will be included in the Study Committee list.

**Reports**

The Recipient shall provide a copy of any report of its results that derive from use of the data to the Provider in any format (e.g. paper journal, on-line report, meeting abstract). Notices required under this DTA will be in writing and will be delivered by email to the addresses set out above.

**Costs and payment arrangements**

The data shall be provided at no costs.

**Coordinating committee**

Annemarie Wensing MD, PhD

Carlo Federico Perno, MD, PhD Carole Devaux, MD,PhD

Charles Boucher, MD,PhD

Federico Garcia, MD,PhD Francesca Ceccherini-Silberstein, PhD

Joop Arends, MD,PhD

**Study coordination**

Antoinet van Kessel

Frederico Garcia, MD, PhD

Stephanie Popping, MD

Valeria Cento, MD, PhD

**Statistical analysis**

David van de Vijver, PhD

**Data management**

Laurence Guillorit

**SIGNATURE PAGE**

The Provider acknowledge and understands the terms to this agreement.

Name: …………………………………………

*Signature + date* ……………………………

The Recipient acknowledge and understands the terms to this agreement.

Name : …………………………………………

*Signature + date* ……………………………