

Hôpitaux Universitaires de Genève
Département des Spécialités de Médecine
Service de Gastroentérologie et d'Hépatologie

1
2
3 **Swiss Hepatitis C Cohort Study**
4 **Information for participants**
5

6 Dear Madam / Sir :
7

8 The hepatitis C virus may cause a persisting inflammation of the liver. This disease requires a
9 specialized management, and regular controls over the following years. We invite you to
10 participate into a cohort study (i.e. a registry) that could lead us to better understand of the
11 spread of this disease in Switzerland, its modalities of transmission, its mechanisms and its
12 natural course or upon antiviral treatment. These data may help us to fight this disease in a
13 more effective way.
14

15 Your consent is voluntary and may be revoked at any time. Moreover, your decision will not
16 affect your medical treatment. Please take as much time as you need to communicate us your
17 decision.
18

19 To help you make your decision, the main information is summarised in this leaflet.
20

21 **Aims of the study**

22 The primary aim of this study is to follow on a regular basis and with standardised tools a
23 great number of patients who are representative of the whole population of patients infected
24 with the hepatitis C virus in Switzerland, in order to better understand and treat this disease.
25 At the same time we will collect and freeze blood samples to perform further analysis.
26

27 **General information regarding this clinical study**

28 Every participant to the Swiss hepatitis C cohort study and all study physicians are informed of
29 its progress. This is a study conducted in several Swiss institutions simultaneously (multi-
30 center study) and will bring together about 7,000 patients in our country.

31 The participation in the study entails:

- 32 1) The collection – once a year – of some data concerning your health status and medical
33 history;
34 2) The collection – once a year – of approximately 20 ml of blood.

35 The blood samples will be stored in a biobank for further analysis, which may help improve our
36 knowledge about the disease and possible treatments.

37 If, during the course of the normal management of your disease, there is a medical indication
38 to perform a liver biopsy, we reserve the right to store some fragments of your liver tissue for
39 further analyses.
40

41 **Course of the study for the participants**

42 Data collection occurs once a year during a routine consultation at the agreed place and does
43 not require additional medical visits. In addition, during these visits, an additional blood sample
44 is taken (approximately 20 ml of blood).

45
46 When the participant receives an antiviral therapy, additional time points are foreseen at
47 baseline pre-treatment, week 2, week 4, week 12 or week 24 if applicable, otherwise at end of
48 treatment and 12 weeks after the end of treatment. At the time of these treatment-related
49 visits, an additional blood sample is taken for the study (approximately 6 ml of blood).

50

51 **Obligations of participants**

52 As a participant into the study you are expected :

- 53
- 54 • To attend the routine annual visits. Unless otherwise stated by you, we reserve the right
55 to seek to contact you in case of absence to one of these visits, in order to have news
56 about your health. This research may include various means such as contacting the
municipality of your last known address
 - 57 • To tell your doctor-investigator of the evolution of the disease and report any new
58 symptoms, any new problem and any change in your status
 - 59 • To inform your doctor-investigator of any treatment or concomitant therapy, prescribed
60 by another physician; to also inform about all medicines you may be taking, even in case
61 of, for example, medicines you bought yourself and for which you do not need a
62 prescription, including herbal teas, natural products, or alternative medicine drugs
63 (homeopathy and so on).

64 It is possible that your physician-investigator withdraws you from the study for a valid reason,
65 for example in case the study is terminated.

66

67 **Benefits for the participants**

68 By participating in this clinical trial, you should not expect a direct benefit. The results of
69 research projects are generally published and may help to improve the treatment of future
70 patients.

71

72 **Risks and constraints for the participants**

73 To participate in this cohort study does not present any specific risk. The only drawback is an
74 additional blood test once a year.

75

76 **Discoveries made during the study**

77 In many cases, the results of research are not relevant for the individual patient. However, if a
78 study does yield results which are directly relevant to your health, and preventive or
79 therapeutic measures would be possible, you have a right to be informed of this. If you wish to
80 exercise this right to receive information, you must indicate this on the consent form.

81

82 **Voluntary participation**

83 Your participation in this study is voluntary. Refraining from taking part in this study will have
84 no impact on your future medical care. The same applies to the revocation of your initial
85 consent. Therefore, you can quit the study at any time. You are not required to justify your

86 revocation of consent or the possible withdrawal. However, unless otherwise stated by you,
87 hitherto collected data and samples will continue to be used.

88

89 **Your consent**

90 If you give your consent, your biological material, genetic data and health-related data can be
91 made accessible to biomedical research. This means that your biological material and health-
92 related data can be passed on to researchers or to another institution for research purposes,
93 under the conditions specified below.

94 As long as it is not revoked, your consent applies to all future projects approved by ethical
95 committees. Accordingly, you will not be informed each time your biological material and
96 health-related data are used in research projects or passed on to another institution.

97

98 **Health-related data**

99 The term “health-related data” covers all the data in the patient record – e.g. data on possible
100 risk factors and the results of clinical, imaging or laboratory (chemical) tests and genetic
101 analyses obtained by the physician investigating your condition. It also covers data concerning
102 the course of disease and the response to treatment.

103

104 **Protection of biological material and of health-related data**

105 The institution undertakes to store your biological material securely. Access to your biological
106 material and health-related data is clearly regulated. Only authorised and clearly defined
107 persons at the institution have access to the uncoded personal data and to the coding key.
108 It may be that some samples and information about your health are anonymized irreversibly.

109

110 **Coding and anonymisation**

111 Coding means that all the details that could identify you (e.g. name, date of birth, etc.) are
112 replaced by a code, so that it is not possible for data to be linked to your person by anyone
113 who does not know the code. Within the HUG, the data can also be accessed in uncoded
114 form by authorised and clearly defined persons. The coding key always remains in the HUG.
115 Some encoded data may be anonymised by permanently deleting the code or decoding key.
116 After this irreversible anonymisation, nobody can know that these data and this material are
117 yours, and this is the reason why any request for destruction of anonymised samples can not
118 be taken into consideration.

119

120 **Use of biological material and health-related data**

121 All research projects involving the use of your biological material and/or health-related data
122 have to be approved in advance by the responsible ethics committee. The HUG can only pass
123 on the biological material and health-related data to researchers in coded form. The
124 researchers may work at institutions such as hospitals, universities or industrial companies
125 either in Switzerland or abroad. However, the country in question must have legal
126 requirements for data protection which are at least equivalent to those applicable in
127 Switzerland.

128

129 **Costs and compensations for the participants**

130 Data collection occurs once a year during a routine consultation as part of the normal
131 management of your disease. Thus, your participation to the study does not generate any
132 extra costs for you or for your health insurance. No compensation is provided for the
133 participation in this study.

134
135 **Participants to the study cannot claim any rights on the commercial exploitation of**
136 **biological material or health-related data**

137 The results of research projects may also contribute to the development of commercial
138 products, such as new drugs. But research involving biological material and health-related
139 data is just a small component in this process. This means that you have no claims with
140 regard to commercial exploitation or patents associated with your biological material and
141 health-related data.

142
143 **Legal aspects**

144 This study is conducted in accordance with the Swiss law and internationally recognized
145 guidelines. It has been approved by the Ethics Committee on Research on humans at the
146 HUG. This study is funded by the Swiss National Science Foundation (NSF), the Swiss
147 Hepatitis C Cohort Study Foundation and other profit and nonprofit parties.

148
149 **Contact person(s)**

150 You can always contact us to obtain information on your personal data. If you have questions
151 or want to know more about it, you can at any time refer to the following contact person:

152
153 **Prof. Francesco Negro**

154 Principal Investigator of the study
155 Services de Gastroentérologie et d'hépatologie, Hôpitaux Universitaires de Genève, rue
156 Gabrielle-Perret-Gentil 4, 1211 Genève,
157 Email : Francesco.Negro@hcuge.ch Tél. 022-3729355

158
159 In case of an emergency, please contact the specialist on call (7/7, 24/24) at the Service de
160 Gastroentérologie et d'hépatologie.

161 Services de Gastroentérologie et d'hépatologie, Hôpitaux Universitaires de Genève, rue
162 Gabrielle-Perret-Gentil 4, 1211 Genève.

163 Phone : 079 55 34520 (day) ou 074 055 02 87 (night)

164
165
166
167
168
169
170
171
172
173

174 **Written declaration of consent to participate to this study**

175 ▪ Please read carefully this form

Number of the study:	00-28
Name of the study :	Swiss Hepatitis C Cohort Study
Promoter :	Prof. Francesco Negro Hôpitaux Universitaires de Genève Département de Médecine Interne Division de Gastroentérologie et d'Hépatologie
Principal Investigator	Prof. Francesco Negro
Place where the study is carried out :	Hôpitaux Universitaires de Genève (HUG) Genève
Other clinicians :	
Participant (surname / first name) :	<input type="checkbox"/> female <input type="checkbox"/> male
Date of birth :	

- 176
- 177 ▪ I declare that I have been informed by the undersigned physician, orally and in writing,
- 178 about the goals and course of the Swiss Hepatitis C Cohort Study;
- 179 ▪ I declare having read and understood the written information to patients that was given to
- 180 me, dated 15/04/2015 and that I have received a copy of my written consent;
- 181 ▪ I received satisfactory answers to the questions I posed in connection with my participation
- 182 in the study;
- 183 ▪ I take part in this study voluntarily. I can, at any time and without having to justify myself,
- 184 revoke my consent to participate in the study, without this having an adverse impact on the
- 185 rest of my medical care;
- 186 ▪ I had enough time to make my decision;
- 187 ▪ I accept the content of the information sheet given to me on the above study;
- 188 ▪ I know that my personal data will be transmitted only in coded or anonymised form to
- 189 external institutions for research purposes. I agree that the competent specialists of the
- 190 representatives of the study, the authorities and the Cantonal Ethics Commission may
- 191 consult my raw data (not encoded and non-anonymous) to conduct examinations and
- 192 inspections, provided, however, that their confidentiality is strictly guaranteed;
- 193 ▪ I have been sufficiently informed of the reuse of biological material and health-related data
- 194 for biomedical research. I agree that (i) the biological material that was taken from me as
- 195 part of the study (blood) or in case of procedures performed for diagnostic purposes or in
- 196 view of a treatment (liver biopsy), and (ii) the data about my illness be reused as part of
- 197 biomedical research;
- 198 ▪ I know that, as a donor, I have the right to be informed of results which are directly
- 199 relevant to my health. I am aware that I will only be informed if I have indicated – by
- 200 checking the box on this consent forms (see below) – that I wish to exercise my right to
- 201 receive information.
- 202

I wish to be informed about the results regarding directly my health (as long as it is possible to contact me and to communicate to me such information).

203

Place / date	Signature of the participant or of his/her legal representative
--------------	---

204 **Certification of the doctor-investigator** : I am herewith certifying that I have explained to the
205 participant the nature, size and scope of the study. I declare to fulfil all the obligations to this
206 study in accordance with the law. If at any given time during the study I came to know new
207 elements that may influence the consent of the participant to take part in the study, I agree to
208 inform him/her immediately.

Place / date	Signature of the investigator
--------------	-------------------------------

209