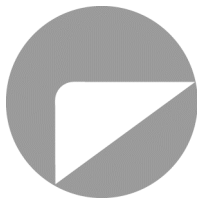


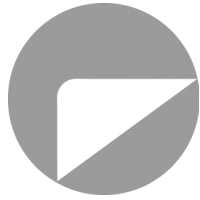
## SYNOPSIS (SUMMARY)

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<b>Project Title:</b>	Swiss registry on autoimmune hepatitis
<b>Project Plan Version and Date:</b>	Version 1.2,7.8.2016
<b>Risk categorisation:</b>	Risk category A
<b>Type of Research:</b>	Research project in which biological material is sampled and health-related personal data is further used and collected. Coded data are used.
<b>Project design:</b>	retrospective and prospective registry with biobank.
<b>Background and Rationale:</b>	Autoimmune hepatitis is a rare inflammatory liver disease of unknown origin, affecting both children and adults. No standard second-line treatment schedules for difficult to treat patients exist. No data about the disease epidemiology, treatment schedules, response to treatment and overall outcomes exist from Switzerland.
<b>Objectives:</b>	To collect high quality prospective data on a rare disease in order to elucidate epidemiology, natural history, response to treatment and outcome. In addition, a biobank allows addressing specific scientific issues on a variety of open questions. The registry will provide a platform for carrying out scientific research projects on AIH. In addition, the registry will allow collaborations with reference networks on AIH abroad.
<b>Inclusion / Exclusion criteria:</b>	Inclusion criterion is diagnosis of AIH (1), either type I or type II. Only patients living in Switzerland are enrolled.
<b>Measurements and procedures:</b>	Enrolment visit and one follow-up visit at least once a year are planned. An additional follow-up visit at 6 months post-diagnosis is planned for newly diagnosed patients. Whole blood is collected for biobanking once a year. Optionally, if available and collected during normal clinical procedures, liver fragments are obtained.
<b>Number of Participants:</b>	Number of subjects projected for the entire study (all sites combined): 500 (corresponding to 1/3 of the estimated global AIH population residing in Switzerland, assuming a disease prevalence of 20:100,000)
<b>Project Duration, schedule:</b>	The project will start by 1.1.2017. Estimated duration for the main investigational plan: at least 5 years.
<b>Project Centres:</b>	Multi-centre project, including 6 centres throughout Switzerland.



## FONDAZIONE EPATOCENTRO TICINO

<b>Risk-Benefit statement:</b>	This project has no risk for participants; biosamples will only be collected concurrently with planned blood collection/liver biopsy for clinical purposes.
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**SCHEDULE OF ASSESSMENTS (FLOW OF RESEARCH PROJECT)**

Project Periods	Screening				
Visit	1	2	3	4	.....
Time (month)	0	12	24	48	.....
Participant Information and Informed Consent	x				
Legal representative Information and Informed Consent for participants aged < 14	x				
Demographics	x				
Medical History	x	x	x	x	x
Inclusion Criteria	x				
Physical examination	x	x	x	x	x
Vital signs	x	x	x	x	x
Treatment history	x	x	x	x	x
Biochemistry	x	x	x	x	x
Liver autoantibodies	x	x	x	x	x
Immunoglobulin G	x	x	x	x	x
Sampling of biological material	x	x	x	x	x

For newly diagnosed subjects, an additional visit 6 months after diagnosis is planned.  
 For subjects aged 14-18, a consent form using a simple lay wording