FONDAZIONE EPATOCENTRO TICINO

SYNOPSIS (SUMMARY)

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Project Title:	Swiss registry on autoimmune hepatitis
Project Plan Version and Date:	Version 1.2,7.8.2016
Risk categorisation:	Risk category A
Type of Research:	Research project in which biological material is sampled and health-related personal data is further used and collected. Coded data are used.
Project design:	retrospective and prospective registry with biobank.
Background and Rationale:	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.
Objectives:	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.
Inclusion / Exclusion criteria:	Inclusion criterion is diagnosis of AIH (1), either type I or type II. Only patients living in Switzerland are enrolled.
Measurements and procedures:	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.
Number of Participants:	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)
Project Duration, schedule:	The project will start by 1.1.2017. Estimated duration for the main investigational plan: at least 5 years.
Project Centres:	Multi-centre project, including 6 centres throughout Switzerland.

Risk-Benefit statement:	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