ID	Acronym	Coordinator	Does the research involve…?								periodic ethics verification needed	Requirements to be addressed before grant agreement/before signature deadline: 31st January 2020	Documents to be kept on file										Data Protection Officer appointed	Data Protection/Management Plan obtained	confirmation full compliance with national and EU law	ethics contact point established	ethics report drafted annually	external Ethics Advisor appointed by EJPRD	AREB evaluation of the statements	Feedback provided to AREB comments new deadline: end of May 2020
			hESCs	human participants	children	human samples	human foetal samples	animals	personal data	third countries																					
126	IDOLS-G	Udd		x	x	x	x	x	x			information on animal welfare measures and adherence to the Three Rs principle submitted to call secretariat: 30.01.2020	ethics approval	informed consent forms information sheets description of consent procedures	authorization /licenses for animal experiments			description minors' assent	documents for using/producing/collecting human samples (ethics approval, licences, accreditation)				x	x	x *	Peter Hackman (administrative) peter.hackman@helsinki.fi	x	x	Information on the adherence to the 3Rs guiding principles is provided. Information on how the animal welfare will be respected is included in the statement as well. They also listed the laws to be followed. -In the sentence "(n. 13/2018-UT, deadline 12/11/2024, in compliance with Decreto Legislativo 26/2014 and the EU regulation, directive 2010/63)," the "EU regulation" should be deleted (as there is no EU regulation on this matter but the directive), and "as implemented in the national law DECRETO LEGISLATIVO 4 marzo 2014, n. 26" should be added with reference to Directive 2010/63/EU -the research facilities should be licenced for animal experimentation: IGBMC and Unifi are declared to be authorised. It is not specified if UPC at the VUmc is authorised for animal experimentation.	**The sentence was changed and the document authorising the facilities provided. Last feedback received on June 20th: the ethical application has been updated and the submission process is ongoing (the old one is still in force). Feedback from the Ethics Committee is expected soon.**
135	EurDyscover	Volkmann		x		x		x	x	x		information on the animal welfare measures and adherence to the Three Rs principle submitted: 24.01.2020 to call secretariat	ethics approval	informed consent forms information sheets	authorization /licenses for animal experiments		if relevant - approval for transfer of data to third countries		documents for using/producing/collecting human samples (ethics approval, licences, accreditation)	import/export authorisation third countries			x	x	x	Chi Wang to (PI) ip_C@ukw.de>	x	x	The applicant has provided detailed information on the adherence to the 3Rs guiding principles (where applicable) and the justification for the non-adherence in some cases. The compliance with the European and national laws, including Directive 2010/63/EU, is expected as well.	**ETHICS REQUIREMENTS FULLY FULFILLED (no implementation required to the applicant)**
145	GENOMIT	Prokisch		x	x	x			x	x		Details on incidental findings and re-contact policy submitted to call secretariat: 03.03.2020	ethics approval	informed consent forms information sheets description of consent procedures			if relevant - approval for transfer of data to third countries		documents for using/producing/collecting human samples (ethics approval, licences, accreditation)	import/export authorisation third countries			x	x	x	Bozjana Büchner Bozjana.Buechner@med.uni-muenchen.de	x	x	The applicants addressed the Ethics Assessment, 5. recommendations: "Researchers should check stipulations on patient re-contact and/or consult the respective ethics committees on this topic." but they did not fully answered to the requirement to provide "Details on incidental findings and re-contact policy must be included in the grant agreement before signature". In particular, they well-provided the ICF issues on re-contacting in two countries involved in the registry and in five countries involved in the secondary use of samples. However, a clear policy on how to handle recontacting AND incidental findings in both the research activities is missing and applying in all the countries involved. Therefore the applicant should clarify where the registry will collect data (it seems that the registry will involve not only two countries but GENOMIT clinical networks of USA, UK, Germany/Austria/Switzerland, Italy and France). Notably, the plan of incidental findings should include not only information about recontacting or not the patient, but also how investigators will manage them, and if genetic counselling will be provided or not.	**ETHICS REQUIREMENTS FULLY FULFILLED (email message April 15th)**
187	LQTS-NEXT	Bezzina		x	x	x			x	x		Details on incidental findings policy submitted to call secretariat: 28.02.2020	ethics approval	informed consent forms information sheets description of consent procedures				description minors' assent	documents for using/producing/collecting human samples (ethics approval, licences, accreditation)				x	x	x *	Bezzina, Connie (coordinator) c.r.bezzina@amsterdamumc.nl>	x	x	The applicant provides an overview of the incidental findings handling in Milan and Nantes, but details for Muenster (Prof E. Schulze-Bahr) and Amsterdam (Prof. C. Bezzina) are lacking. With reference to the the Nantes site, the applicant should provide update on the French policy ruling incidental findings. Notably, the plan of incidental findings should include not only information about recontacting or not the patient, but also how investigators will manage them, and if genetic counselling will be provided or not.	**Last feedback received on June 29th. Information on all the sites were provided. Update on the Amsterdam site is expected soon.**
195	AspecT-NMO	Scheffold		x		x			x	x		Details on incidental findings and re-contact policy sumitted to call secretariat on 14.02.2020	ethics approval	informed consent forms information sheets					documents for using/producing/collecting human samples (ethics approval, licences, accreditation)				x	x	x	Alexander Scheffold (coordinator) Alexander.Scheffold@uksh.de	x	x	Information on the re-contact policy and on the incidental findings is included in the ICF. However, the option on the incidental findings is not specific "In the consent form, you can decide whether you want to be informed about such observations relevant to other diseases". Incidental findings may also be related to the disease under treatment. Besides the ICF, a plan of incidental findings should be put in place to explain if the patients will be recontacted or not, how investigators will manage them, and if genetic counselling will be provided or not.	**ETHICS REQUIREMENTS FULLY FULFILLED (email message May 2nd)**
208	TARID	Kekäläinen		x	x	x		x	x			confirmation: human samples are either legitimately available commercially or have been obtained following appropriate ethical approval submitted to call secretariat: 28.01.2020	ethics approval	informed consent forms information sheets		approval for transfer of human samples and data	if relevant - approval for transfer of data to third countries						x	x	x	Elisa Kekäläinen (coordinator) elisa.kekalainen@helsinki.fi	x	x	The applicants confirmed that all the human samples used in the project have been or will be obtained following appropriate ethical approval. With reference to the already collected samples, the applicants should confirm that the ethical approvals will be sought also for the secondary use or ethical approvals already obtained for this use is applicable for the purposes of this project.	**ETHICS REQUIREMENTS FULLY FULFILLED (email message April 20th)**
210	NSEuroNet	Tartaglia		x	x	x		x	x	x		description: source of any previously collected human biological samples or personal data and whether or not ethics approval has been obtained to cover their use in the present study submitted to call secretariat 13.02.2020	ethics approval	informed consent forms information sheets description of consent procedures	authorization /licenses for animal experiments	approval for transfer of human samples and data			documents for using/producing/collecting human samples (ethics approval, licences, accreditation)				x	x	x	Tartaglia Marco (coordinator) marco.tartaglia@opbg.net>	x	x	The question is not answered yet since the applicant replied that "All partners involved in the project with activities dealing with patient-derived specimens and clinical data and/or development of animal models already activated all procedures requested by their respective national funding agencies and institutional ethics boards." and "I will check that all partners have received the ethics approval to cover the use of previously collected patient-derived material/data in the frame of the activities planned in the present NSEuroNet project." With reference to the OPBG site, a new protocol including the use of previously collected material/data was submitted to the Ethics Committee and is currently under evaluation. A feedback from all the partners on the approvals is still required.	**Last feedback received on May 19th: the confirmation of the obtainment of the ethical approval from one of the sites (Otto-von-Guericke University Magdeburg) is still missing.**
234	Solve-RET	DE BAERE		x	x	x		x	x			a. description: procedures used for recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, risks and benefits for the participants etc.). Nature of material to be collected (e.g. human biological samples, sensitive or personal data etc.), specific procedures to ensure wellbeing of children involved and procedures for ensuring assent. submitted to call secretariat: 10.03.2020 b. confirmation: human samples used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval (also for personal data) submitted to call secretariat: 01.02.2020	ethics approval	informed consent forms information sheets	authorization /licenses for animal experiments	approval for transfer of human samples and data					source of any previously collected human biological samples or personal data and whether or not ethical approval has been obtained to cover their use in the present study		x *	x	x	Elfride De Baere (coordinator) Elfride.DeBaere@UGent.be>	x	x	a. A copy-paste text of section 9 "Ethical and legal issues" of the project is provided by the applicant to answer to the question, by only mentioning procedures in the section 9. It is not sufficient considering the request of the assessors to provide them with a description of procedures. b. The applicant states that "The consortium confirms that all the human samples used in this project have been obtained following appropriate ethical approval".With reference to the already collected samples and data, the applicants should amend section 3 of the ethics table and confirm that the ethical approvals will be sought also for the secondary use or ethical approvals already obtained for this use are applicable for the purposes of this project.	**Ethics requirements referred to point a) fully fulfilled. Information on ethical approvals obtained. Last feedback received on June 20th: the confirmation of the obtainment of the ethical approval from one of the sites (UNISTRA) is still missing.**
284	RiboEurope	Gleizes		x	x	x		x	x			Details on obtainment of ethics approval submitted to call secretariat: 17.02.2020		informed consent forms information sheets				description minors' assent	documents for using/producing/collecting human samples (ethics approval, licences, accreditation)		documents/certification of laboratory safety		x	x	x *	Arda Cetinkaya (PI) ardabiochem@yahoo.com	x	x	The applicant has not provided any detail on the ethics approval. The applicant mentions agreements between the consortium partners and national funding agencies and a grant agreement. These are not relevant with the ethics approval. In fact, the project foresees clinical studies with the prospective collection of biological samples and the secondary use of samples already collected. The applicant states that "Approvals are in place and study protocols, information for participants and consent forms have been approved by the appropriate Ethics Committee" but no document has been provided. In addition, the applicant states that "the non-interventional Clinical Research Ethics Board of the Hacettepe University (Approval Number: GO19/804) has already approved the participation of Turkish group in the RiboEurope project" and that "so no extra procedures are to be taken place due to this study: blood will be drawn as part of standard routine clinical diagnostic procedures and residual material stored in the biobanks of the consortium", but this project does not deal with non-interventional research given that blood withdraws are planned for research purposes (this is outside the clinical practice). Notably, the applicant itself states in the ethics issues table that: Does this research involve physical interventions on the study participants? YES - Does it involve invasive techniques?YES - Does it involve collection of biological samples?YES	**Last feedback received on June 5th: the confirmation of the approvals from some project partners is still missing.**

* requirements not specifically stated in the ethics review. Because those are very general requirements they were sent to all coordinators by e-mail.