



Ethics Review Procedure applied to LAW-TRAIN by the European Commission

For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. There is clear need to make a thorough ethical evaluation from the conceptual stage of the proposal not only to respect the legal framework but also to enhance the quality of the research. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. The process to assess and address the ethical dimension of activities funded under Horizon 2020 is called the Ethics Appraisal Procedure.

In addition to the scientific evaluation focusing on the scientific merit, the quality of the management and the potential impact, the Ethics Appraisal ensures that all research activities carried out under the Horizon 2020 Framework Programme are conducted in compliance with fundamental ethical principles.

All proposals above threshold and considered for funding undergo an Ethics Review carried out by independent ethics experts and/or qualified staff working in a panel. The Review starts with an Ethics Screening and if appropriate a further analysis called the Ethics Assessment is conducted. The Ethics Review can lead to ethics requirements that become contractual obligations.

The Ethics Review Procedure focusses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorizations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research.

The first phase of the Ethics Review Procedure, the Ethics Screening, is carried out during the scientific evaluation or soon after. The ethics experts and/or qualified staff first perform an Ethics Pre-Screening taking into account the Self-assessment. The objective of the pre-screening is to list the (potential) ethical issues but not to assess them.

When there is at least one confirmed ethical issues, the proposal is subject to a complete Ethics Screening that will mainly assess the ethical aspects of its objectives, methodology and potential impact. The ethics experts and/or qualified staff notably identify all proposals that require (ethical) approval at the national level (e.g. with regards to data protection, the conduct of clinical trials and animal welfare). Because of the complexity or the nature of the ethical issues they at stake (e.g. severe intervention on humans) the ethics experts and/or qualified staff may also recommend an Ethics Assessment rather than formulating directly requirements. Proposals involving the use of Human Embryonic Stems Cells (hESCs) automatically proceed to the second step, the Ethics Assessment.

For a limited number of proposals (e.g. severe intervention on humans, lack of appropriate ethics framework in the country where the research will be performed, etc.) the Ethics Screening can be followed by an Ethics Assessment prior to the signature of the grant agreement. The Ethics Assessment is an in-depth analysis of the ethical issues of the proposals, taking into account, when available the conclusions of the Ethics screening.

The above described Ethics Review Procedure has been applied to the project LAW-TRAIN. As a result, the project has obtained conditional ethics clearance subject to compliance with both Pre and Post Grant Agreement requirements. The Ethics Committee has also recommended an Ethics assessment to be performed along with the implementation of the activities.

The Ethics assessment took place on the 26th of October 2016. Following an in-depth analysis of the ethical issues of the projects, the panel concluded that the ethics issues have been correctly identified and addressed by the project participants. Furthermore, the experts have also concluded that the analysis of the document submitted initially and in response to the ethics requirements showed that the ethics issues have been addressed in a professional and comprehensive manner and that a very high level of attention to Ethics issues throughout the project, and embedded within the project life, has been demonstrated by the Consortium.

Furthermore, ethics aspects are constantly monitored during the implementation of the projects through the revision of relevant deliverables and also carefully analysed in cooperation with external independent experts during the technical review meetings linked to the end of the reporting periods. Additional actions to reinforce monitoring of ethics issues may be requested by the European Commission at any time during the project life.

Contractual obligations and related consequence of non-compliance with ethical principles are regulated by the Article 34 – Ethics of the Grant Agreement which states that if a beneficiary breaches any of its obligations under this Article, the grant may be reduced and the Agreement or participation of the beneficiary may be terminated.