



European Research Council
Executive Agency

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EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)

Unit B1 – Ethics Review and Expert Management

Dear principal investigator,

Dear representative of the host institution,

We have now finalised the ethics review process of your proposal. Please find attached the ethics summary report. It provides an analysis of the ethics issues involved in your proposal, and it may bring some particular concerns to your attention.

No further action is required from you before the signature of the Grant Agreement.

The responsibility for an ethically sound implementation of the project lies with the scientists and organisations that carry out the work. However, contractually, the responsibility lies with the Host Institution as signatory of the Grant Agreement. Collectively, the beneficiaries carry the responsibility to follow the ethical provisions laid out in, and deriving from, the Horizon Europe Framework Programme.

ERC grants have a long duration and offer considerable freedom to the Investigator(s) to (re) direct the research. Should the research develop in directions that raise additional ethics questions - not covered in this report – this should be brought to the attention of the ERCEA, either by means of an amendment, or informally by contacting the ERCEA Ethics Sector (ERC-ETHICS-MONITORING@ec.europa.eu, 101189340_ELIDIS in subject line).

With kind regards,

Raluca IONESCU
Head of Unit

EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)

Unit B1 – Ethics Review and Expert Management

Ethics Summary Report

Grant 101189340 - ELIDIS

Proposal Title	Enzyme-Linked DNA Displacement (ELIDIS) Assay as an innovative immunoassay platform
Applicant Name	francesco RICCI
Panel	
Call	ERC-2024-POC

Abstract

Since its introduction more than 50 years ago, ELISA (Enzyme-Linked Immunosorbent Assay) remains one of the most widely used technologies for research, drug discovery and diagnosis. The reasons for this extraordinary longevity are manifold: ELISA combines the high specificity of antibody-antigen interactions with the high sensitivity of enzyme amplification. However, ELISA also has disadvantages: multiple washing steps and reagents are required and a specialized instrument is needed, which is not always available in all laboratories. An innovative immunoassay technology that can overcome the limitations of ELISA while retaining all of its best features would therefore represent a turning point in the global immunoassay market (> \$35 billion in 2023). Under the ERC Consolidator Grant PRO-TOOLKITS, we have developed a novel immunoassay, which we have named Enzyme-Linked DNA Displacement (ELIDIS), which has all the characteristics to meet this need and become an alternative to ELISA. In short, ELIDIS involves 2 steps and is based on the use of enzyme-conjugated DNA strands and disposable electrodes. ELIDIS retains the advantageous properties of ELISA (high sensitivity and specificity) but, unlike ELISA, is easier to perform, does not require enzyme-labeled antibodies and, more importantly, can be performed using portable electronic devices such as a laptop or smartphone without the need for additional instruments. With these considerations in mind, in this PoC project we will validate the ELIDIS assay as a candidate to replace ELISA in any biotech and biopharma laboratory. To achieve the above goal, we will: 1) Validate the ELIDIS assay for the detection of two model targets (Trastuzumab and EGFR); 2) Develop two prototype kits using disposable sensor arrays and a portable device (or an app/software). 3) Create a “manufacturing plan” for assay production; 4) Develop an IP strategy for patent filing/maintenance; 5) Create a plan for business/commercialization.

Ethics Issues

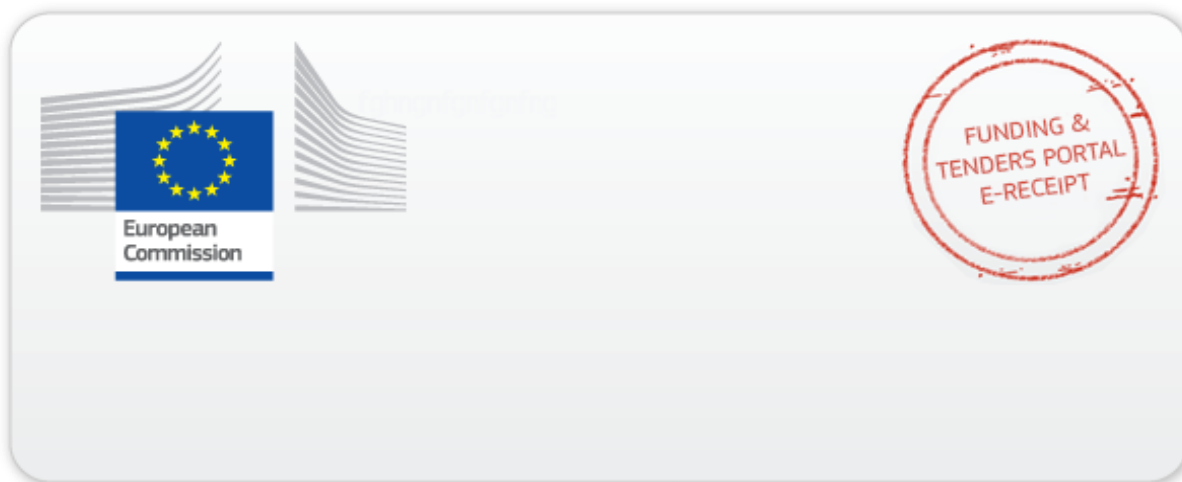
On the basis of the proposal’s methodology and the ethics self-assessment provided, the ethics review identified the following ethics issues:

No ethics issues were identified.

Ethics analysis

This section summarises and concludes the analysis performed during the ethics review.

No ethics issues were identified in this proposal. It is therefore cleared for granting.



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