European Research Council
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EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)
Unit B1 – Ethics Review and Expert Management

Dear Mr. francesco RICCI,
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, 101069250_IMMUNO-MONITORING-null in subject line).

With kind regards,

Victor LOSADA GONZALEZ
Acting Head of Unit

EUROPEAN RESEARCH COUNCIL EXECUTIVE AGENCY (ERCEA)

Unit B1 – Ethics Review and Expert Management

Ethics Summary Report

Grant 101069250 - IMMUNO-MONITORING

Proposal Title	ELECTROCHEMICAL DNA-BASED SENSORS FOR IMMUNOTHERAPY MONITORING
Applicant	Mr. francesco RICCI
Panel	
Call	ERC-2022-POC1

Abstract

During the initial part of the ERC-Consolidator Grant PRO-TOOLKITS we have successfully demonstrated a novel approach for antibodies detection. The platform uses antigen-conjugated synthetic DNA strand to achieve the rapid and inexpensive detection of target antibodies. Our platform offers several advantages (low-cost, single-step, rapid) in comparison of other methods for antibody detection and is so versatile that can be used also for the detection of Bispecific Antibodies (BsAb). On the basis of interactions with pharmaceutical companies and following a market analysis we have found that there is a growing need for similar approaches that can allow to monitor the efficacy of immunotherapies. This is especially true for immunotherapies using BsAb as there are no standard analytical methods for these targets. Given these considerations, the goal of this project is to evaluate the commercial potential of our innovative platform for immunotherapy efficacy monitoring with particular focus on the detection and characterization of BsAb. During the project we will 1) Fully characterize the DNA-based antibody sensor for the detection of a model BsAb (Anti EGFR/Anti HER2 BsAb) in terms of analytical performances (i.e. sensitivity, specificity, stability etc.) with direct comparison with other used techniques; 2) Prepare a Manufacturing Plan for producing/testing the Ab-switch; 3) Establish an IP strategy for patent filing and maintenance; 4) Determine a business and commercialization planning.

Ethics Issues

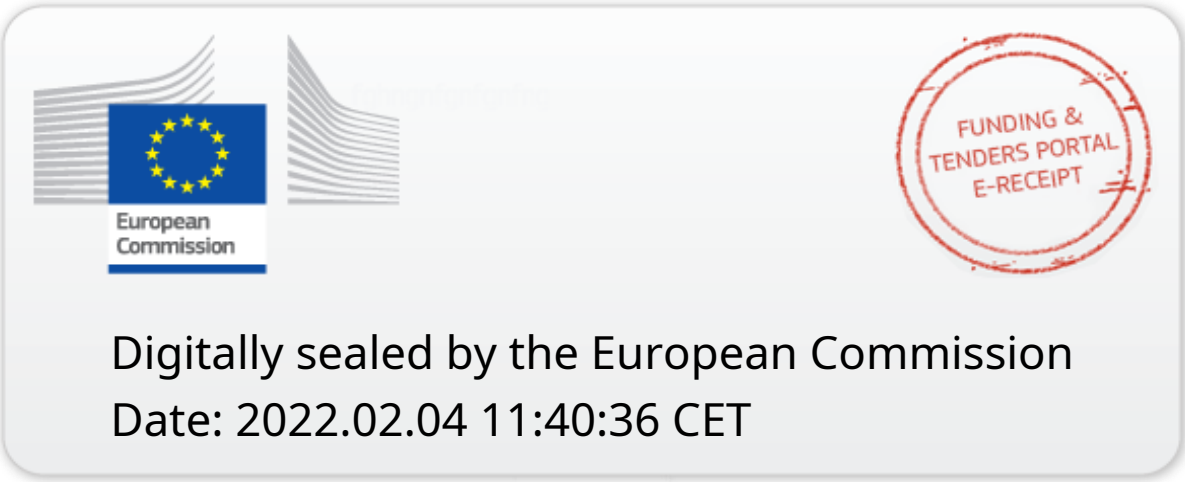
On the basis of the proposal's methodology and the ethics self-assessment provided, the ethics review identified the following ethics issues:

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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