IARPA-RFI-17-02

Synopsis

Request for Information (RFI): Detection of Genome Editing

The Intelligence Advanced Research Projects Activity (IARPA) is seeking information on potential tools and methods to detect organisms that have been modified using genome editing techniques. This request for information (RFI) is issued solely for information gathering and planning purposes; this RFI does not constitute a formal solicitation for proposals. The following sections of this announcement contain details of the scope of technical efforts of interest, along with instructions for the submission of responses.

Background & Scope

Recent breakthroughs in genome editing, including CRISPR-Cas9, are enabling significant advancements in the life sciences. Beneficial impacts are expected to be wide-ranging, from creating novel medical treatments to the development of crops that are more nutritious and able to grow in harsh environments. In addition, "gene drive" technology may provide opportunities to prevent diseases in crops, remove invasive species, or stop the spread of malaria and other vector-borne diseases. While genome editing technology will enable new biological breakthroughs, the unintentional or deliberate misuse of genome editing tools may have adverse economic, health, and national security implications. IARPA is interested in tools and methods that can be used to detect evidence of genome editing in biological organisms, including viruses. The fundamental components of many genome editing tools are found in nature, so detection requires an ability to distinguish engineered organisms from naturally-occurring background. Detection capabilities will help guard against unintended outcomes of genome editing, and expedite appropriate mitigation responses to unapproved release of edited organisms.

Within this topic, areas of interest include:

- research aimed at identifying direct or indirect signatures of genome editing in biological organisms;
- applications associated with edited microorganisms, plants and animals, especially those of economic importance (crops, livestock, pollinators) or those that serve as infectious disease reservoirs (insects);
- research efforts, including those in genomics, proteomics and metabolomics, that can better distinguish organisms that are engineered from those that occur naturally;
- scalable and/or high-throughput approaches for detection of organisms, that, if altered, have health or economic implications (including ecological and agricultural);
- methods to estimate the longitudinal stability of modifications once moved from a laboratory setting to the environment, and factors that determine if a modification is entirely lost or if markers of the modification still exist;
- methods for predicting or anticipating environmental effects resulting from a release of an engineered organism; and
- determination of provenance of genome editing tools and techniques.

Responses to this RFI should answer any or all of the following questions:

1. What computational and laboratory-based tools or methods are currently available for detection of genome editing? How accurate, with regard to sensitivity and specificity, are these methods and how do they compare to each other? What are the limitations of these approaches and do they vary depending upon species? What other types of methods could be developed or repurposed that have the potential to detect edited organisms?
2. Are there methods or approaches for detection that are agnostic to the type of genome editing technology used to make the modification(s)?
3. What tools can be developed that integrate data from new and/or existing databases for analysis of genetically altered organisms?
4. What are the timeframes (realized or estimated), from sample receipt to interpreted result, associated with the proposed detection methods? What technological advances will be required to shorten the time from sample receipt to interpreted result?
5. What data-driven modelling approaches, if any, can be developed or leveraged to assist with detection of edited organisms?
6. What opportunities currently exist or can be developed for the persistent detection of organisms that have been modified using genome editing techniques? Are there existing mechanisms in use by government, academia, or industry that can be leveraged as a detection capability (for example, can existing screening measures for mosquito-borne diseases also be used to investigate incongruent signatures or phenotypic variants)? If so, what are they, how can they be implemented and what are the associated challenges?
7. Describe the potential for screening organisms with intentionally edited genomes in the context of discerning such organisms from the naturally occurring background and how the results of such screening could be verified by independent methods. Roughly, what sample sizes or number of samples would be required for such approaches to yield statistically significant results? What is required to scale the capability to larger test/target populations?
8. What are appropriate training, test and evaluation datasets (i.e., "ground truth" data) as well as quantitative metrics to measure the efficacy of genome editing detection tools? How would sensitivity and specificity be evaluated? Are there existing test cases for which data and analyses are available or could be generated? What contained test beds or synthetic environments can be leveraged for testing, evaluation and/or validation purposes? What scalable test beds can be used? What are applicable and permitted edited systems that can be used to evaluate the efficacy of genome editing tools in natural environments?

Preparation Instructions to Respondents
IARPA requests that respondents submit ideas related to this topic for use by the Government in formulating a potential program. IARPA requests that submittals briefly and clearly describe the potential approach or concept, outline critical technical issues/obstacles, describe how the approach may address those issues/obstacles and comment on the expected performance and robustness of the proposed approach. If appropriate, respondents may also choose to provide a non-proprietary rough order of magnitude (ROM) estimate regarding what such approaches might require in terms of funding and other resources for one or more years. This announcement contains all of the information required to submit a response. No additional forms, kits, or other materials are needed.

IARPA appreciates responses from all capable and qualified sources from within and outside of the US. Because IARPA is interested in an integrated approach, responses from teams with complementary areas of expertise are encouraged.

Responses have the following formatting requirements:
1. A one page cover sheet that identifies the title, organization(s), respondent's technical and administrative points of contact - including names, addresses, phone and fax numbers, and email addresses of all co-authors, and clearly indicating its association with RFI-17-02;
2. A substantive, focused, one-half page executive summary;
3. A description (limited to 5 pages in minimum 12 point Times New Roman font, appropriate for single-sided, single-spaced 8.5 by 11 inch paper, with 1-inch margins) of the technical challenges and suggested approach(es);
4. A list of citations (any significant claims or reports of success must be accompanied by citations);
5. Optionally, a single overview briefing chart graphically depicting the key ideas.

Submission Instructions to Respondents
Responses to this RFI are due no later than 4:00 p.m., Eastern Time, on 3 March, 2017. All submissions must be electronically submitted to dni-iarpa-rfi-17-02@iarpa.gov as a PDF document. Inquiries to this RFI must be submitted to dni-iarpa-rfi-17-02@iarpa.gov. Do not send questions with proprietary content. No telephone inquiries will be accepted.

Disclaimers and Important Notes
This is an RFI issued solely for information and planning purposes and does not constitute a solicitation. Respondents are advised that IARPA is under no obligation to acknowledge receipt of the information received, or provide feedback to respondents with respect to any information submitted under this RFI.

Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Respondents are solely responsible for all expenses associated with responding to this RFI. IARPA will not provide reimbursement for costs incurred in responding to this RFI. It is the respondent's responsibility to ensure that the submitted material has been approved for public release by the information owner.

The Government does not intend to award a contract on the basis of this RFI or to otherwise pay for the information solicited, nor is the Government obligated to issue a solicitation based on responses received. Neither proprietary nor classified concepts or information should be included in the submittal. Input on technical aspects of the responses may be solicited by IARPA from non-Government consultants/experts who are bound by appropriate non-disclosure requirements.

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