DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Biologics Evaluation and Research

Publication Clearance Request

Use for the review of any FDA related Article or Speech*, see CBER SOPP 8122

Upon completion of the clearance form, the electronic version of the form, article, speech or presentation should be immediately forwarded to your Office's Program Manager and to Research Central, researchcentral@fda.hhs.gov

Date Submitted *(mm/dd/yyyy)*	Request Submitted by
07/17/2023	John Dennis

Title
Evaluation of Digital Biomarkers in Nonclinical Research: Barriers to Information-Sharing

Authors/Affiliations *(list all, including the submitting author)*
John Dennis / CBER OM Division of Veterinary Services

COMPLETE THE SECTION RELEVANT TO THE PUBLICATION SUBMITTED

Article

The article to be submitted for publication in

Speech/Presentation/Abstract

Meeting Name
11th Annual FDA Annual Scientific Computing Days Virtual Poster Presentation

Meeting Date *(mm/dd/yyyy)*	Location *(City, State, or Country)*
09/13/2023	Silver Spring, MD

Book Chapter/Book

Publisher and Editor(s)

Name of Book

Electronic Public Collaborative Project *(including wikis/blogs)*

Name of Organizing Party	Website

*FDA-Related Article or Speech is defined as any article, poster, abstract, book, book chapter, published writing, or speech, including presentations, by slides or in other media format, written or presented by a CBER author, either as sole author or as co-author, that: (1) relies on or discusses FDA data or information that was available to the author due to her or his FDA position, (2) discusses products or matter within FDA's jurisdiction, (3) discusses or analyzes an FDA program, policy, regulation. Action or initiative, or (4) could reasonably be perceived to reflect FDA's approach to issues within its jurisdiction. Speeches do not include interviews given to the media. Such interviews are already subject to Agency and/or center or office policies on media inquiries.

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This article will be submitted with a signed FDA Publishing Agreement Cover Sheet. If a peer-reviewed article, it will be submitted to PubMed Central upon acceptance for publication, unless the journal deposits the final published article directly in PMC.

☒ Yes ☐ No

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Could this publication be readily misused to pose a biologic threat to public health and/or national security?

☐ Yes ☐ No ☒ Not Applicable

If yes, please explain.

Data Management Plan (DMP)

Has a Data Management Plan been implemented for the research covered in this publication?

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Technology Transfer

Was this work performed in collaboration with a CRADA partner?

☐ Yes ☒ No

If yes, has the CRADA partner reviewed/approved the publication?

☐ Yes ☐ No

Does the work have potential commercial impact or is it patentable?

☒ Yes ☐ No

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1. Is the FDA-Related Article or Speech the product of a Non-Assigned/Outside Activity?

   ☐ Yes ☒ No

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   ☐ Yes ☐ No

   If yes, is the following FDA SMG 2126.3 Section 6.B.11 Disclaimer included in the publication?

   ☒ Yes ☐ No

"This [article/speech/presentation/book chapter] reflects the views of the author and should not be construed to represent FDA's views or policies."

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The FDA employee's direct supervisor is responsible for reviewing FDA-related articles or speeches that are the product of a Non-Assigned/Outside activity to identify: (1) nonpublic information and (2) potential major concerns regarding the accuracy of the information or the manner in which the information is presented. Signing below indicates you review of the article/speech for submission. The supervisor must provide in writing any changes the supervisor notes that are necessary to protect nonpublic information. These comments may also include suggested revisions for the employee's consideration with respect to the accuracy and the presentation of the information.

Supervisor Signature	Date *(mm/dd/yyyy)*

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"[My comments/My contributions] are an informal communication and represent my own best judgement. These comments do not bind or obligate FDA."

Review

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A. Subject Matter Expert Review *(Subject Matter Experts must be FDA staff, to include at least one member of CBER staff.)*

Reviewer 1: Clearance Recommended

☒ Yes ☐ No

Name
Luisa Gregori

Signature	Date *(mm/dd/yyyy)*
Luisa Gregori -S Digitally signed by Luisa Gregori -S Date: 2023.07.19 10:30:10 -04'00'	07/19/2023

Reviewer 2: Clearance Recommended

☒ Yes ☐ No

Name
Mark Walderhaug

Signature	Date *(mm/dd/yyyy)*
Mark O. Walderhaug -S Digitally signed by Mark O. Walderhaug -S Date: 2023.07.19 14:14:59 -04'00'	07/19/2023

B. Division Review

Require use of Informal Communication Disclaimer	Clearance Recommended
☐ Yes ☐ No	☐ Yes ☐ No

Name

Signature	Date *(mm/dd/yyyy)*

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C. Office Review

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Action *(check box below)*:

☐ Clearance Approved

☐ Clearance Not Approved

☐ Review Requested by Center Director

☐ Review is requested by another FDA Center

If clearance is not approved or additional review is requested, please explain in Section D.

Name

Signature	Date *(mm/dd/yyyy)*

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D. Optional Section for Comments

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Center Director review requested by

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Decision

Require use of Informal Communication Disclaimer

☐ Yes ☒ No

☐ Clearance for Submission

☐ May contain *significant* Cross-Center policy implications

☐ Submit to Center(s):

☐ Not Cleared

Comments

Cleared pending recommended revisions.

Center Director or Designee Signature	Date *(mm/dd/yyyy)*
Karen L. Elkins -S Digitally signed by Karen L. Elkins -S Date: 2023.07.20 17:45:04 -04'00'	07/20/2023

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