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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21CH; Docket No. CDC-2021-0005]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Serological Assay Development: *Brucella* spp. Rough Strains. This proposed collection will involve specimen collection and relevant clinical information from individuals exposed to rough strains of *Brucella* spp., or cases of brucellosis due to infection with rough strains of *Brucella* spp..

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0005 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed

collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Serological Assay Development: *Brucella* spp. Rough Strains - New
- National Center for Emerging and Zoonotic Infectious Diseases
(NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Brucellosis is a zoonotic disease caused by *Brucella* spp., which are Gram-negative, intracellular bacterial pathogens. Annually, 500,000 human cases of brucellosis occur worldwide. Though isolation of the organism can help identify the causative species of infection, this method is not always possible due to laboratory biosafety capacity requirements and specimen availability. In some of these instances, serological methods are helpful for diagnosis. Serial serological methods are also useful for monitoring individuals who have had known exposures to smooth *Brucella* spp. for seroconversion, which can help detect potential infection and reduce time to diagnosis and treatment.

The proposed data collection will help to understand the frequency of exposures to rough strain *Brucella* spp. in the United States, identify specific antigens associated with rough strain *Brucella* infections, develop high-sensitivity and high-specificity serological diagnostic assays based on recognition of these antigens, and to better understand the human humoral immune response to rough *Brucella* strains. Data collected will be used to create a bank of specimens to help develop additional

tools for safer and more timely diagnosis of brucellosis caused by rough strains of Brucella spp.

CDC will collect specimens and medical/surveillance record abstractions from individuals exposed to rough strains of Brucella spp., and individuals with confirmed diagnosis of brucellosis as a result of infection from rough strains of Brucella spp.

CDC requests approval for three years. The estimated annualized burden hours are 55. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patient (specimen collection)	N/A	10	1	5	50
Health department	Clinical/exposure information	10	1	0.5	5
Total					55

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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