OMB No. 0990-0263
Approved for use through XXXXXX

Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Federal Policy for the Protection of Human Subjects (the Common Rule), unless the activities are exempt from or approved in accordance with the Common Rule. The pre-2018 Common Rule (or "pre-2018 Requirements") was originally promulgated in 1991 and amended on June 23, 2005 (70 FR 36325). The 2018 Common Rule (or "2018 Requirements") was originally published on January 19, 2017 (82 FR 7149) and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497). The categories of exempt research are provided in section 101(b) of the pre-2018 Common Rule and section 104(d) of the 2018 Common Rule.

The pre-2018 Common Rule requires institutions to certify that each application or proposal for research covered by the regulations, and that does not quality for exemption, has been reviewed and approved by an institutional review board (IRB) (section 103(f)). The 2018 Common Rule requires institutions to certify that each proposed research study covered by the regulations, and that does not quality for exemption, has been reviewed and approved by an IRB (section 103(d)). Institutions must have an assurance of compliance that applies to the research to be conducted and must submit certification of IRB review and approval according to the pre-2018 or 2018 Requirements, as applicable, to the satisfaction of the Department or Agency head.

Purpose: The purpose of this form is to provide institutions engaged in research conducted or supported by departments and agencies that have adopted the Common Rule a simplified method of collecting information for IRB certification to satisfy the requirements of the Common Rule at section 103. This form also collects information for identification of assurance status, and if applicable, declaration of exempt status. These collections provide institutions a method of administrative tracking and record keeping for proposed research studies.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:	

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with the Department of Health and Human Services, covers this activity:

Assurance Identification No. _____, the expiration date _____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)* _____, covers this activity.

Assurance No. _____, the expiration date _____IRB Registration/Identification No. _____*(if applicable)*

If additional assurances apply, these can be described in the "Comments" section below.

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the pre-2018 Common Rule, section 101(b), paragraph _____.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under the 2018 Common Rule, section 104(d), paragraph _____

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7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.

by:
[ ] Full IRB Review on (date of IRB meeting) _____ or
[ ] Expedited Review on (date) _____

[ ] If applicable, provide the expiration date for the IRB approval _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

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8. Comments

<table>
<tr><td>9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.</td><td rowspan="2">10. Name and Address of Institution</td></tr>
<tr><td>11. Phone No. (with area code)
12. Email:</td></tr>
<tr><td>13. Name of Official</td><td>14. Title</td></tr>
<tr><td>15. Signature</td><td>16. Date</td></tr>
</table>

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