

# Privacy Impact Assessment Form

v 1.47.4




Status

Form Number

Form Date

Question

Answer

|    |   |  |   |
|----|---|--|---|
| 1  | OPDIV:  |  |   |
| 2  | PIA Unique Identifier:  |  |   |
| 2a | Name:   | NIAID ClinRegs Country Experts Interest  |   |
| 3  | The subject of this PIA is which of the following?  | <input type="radio"/> General Support System (GSS)<br><input type="radio"/> Major Application<br><input type="radio"/> Minor Application (stand-alone)<br><input checked="" type="radio"/> Minor Application (child)<br><input type="radio"/> Electronic Information Collection<br><input type="radio"/> Unknown |   |
| 3a | Identify the Enterprise Performance Lifecycle Phase of the system.  | Implementation   | <input checked="" type="radio"/>  |
| 3b | Is this a FISMA-Reportable system?  | <input checked="" type="radio"/> Yes<br><input type="radio"/> No   | <input type="radio"/>   |
| 4  | Does the system include a Website or online application available to and for the use of the general public? | <input checked="" type="radio"/> Yes<br><input type="radio"/> No   | <input type="radio"/> Accept<br><input type="radio"/> Reject            |
| 5  | Identify the operator.  | <input type="radio"/> Agency<br><input type="radio"/> Contractor   |   |
| 6  | Point of Contact (POC):   | POC Title: Assistant Director for Special Projects<br>POC Name: Jonathan Kagan, Ph.D.<br>POC Organization: NIAID<br>POC Email: jkagan@niaid.nih.gov<br>POC Phone: 240-669-5221   | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 7  | Is this a new or existing system?   | <input type="radio"/> New<br><input checked="" type="radio"/> Existing   | <input type="radio"/>   |
| 8  | Does the system have Security Authorization (SA)?   | <input type="radio"/> Yes<br><input type="radio"/> No  | <input type="radio"/> Accept<br><input type="radio"/> Reject            |
| 8a | Date of Security Authorization  | Dec 31, 2018   |   |

|   |   |   |
|---|---|---|
| <p>11 Describe the purpose of the system.</p>   | <p>NIAID ClinRegs (clinregs.niaid.nih.gov) is a web-based resource providing country-specific clinical research regulatory information for the purpose of enhancing efficiency and quality in global clinical trials. To assure that ClinRegs is meeting its objectives, it is necessary to solicit feedback via the ClinRegs Country Experts Interest Form from users about the accuracy of content on the site and as to whether additional information should be included.</p> | <p><input checked="" type="radio"/> Accept<br/><input type="radio"/> Reject</p> |
| <p>12 Describe the type of information the system will collect, maintain (store), or share. (Subsequent organization questions will identify if this information about the specific data elements.)</p> | <p>The type of information NIAID ClinRegs will collect is email address, countries of expertise, and primary affiliation.</p>   | <p><input checked="" type="radio"/> Accept<br/><input type="radio"/> Reject</p> |
| <p>13 Provide an overview of the system and describe the resource information it will collect, maintain (store), or share, either permanently or temporarily.</p>                                       | <p>NIAID ClinRegs (clinregs.niaid.nih.gov) is a web-based providing country-specific clinical research regulatory information for the purpose of enhancing efficiency and</p>   | <p><input checked="" type="radio"/> Accept<br/><input type="radio"/> Reject</p> |
| <p>14 Does the system collect, maintain, use or share PII?</p>  | <p><input type="radio"/> Yes<br/><input checked="" type="radio"/> No</p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>39 Identify the publicly-available URL:</p>  | <p>clinregs.niaid.nih.gov <input checked="" type="radio"/></p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>40 Does the website have a posted privacy notice?</p>  | <p><input type="radio"/> Yes<br/><input checked="" type="radio"/> No</p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>40a Is the privacy policy available in a machine-readable format?</p>  | <p><input type="radio"/> Yes<br/><input checked="" type="radio"/> No</p>  | <p><input checked="" type="radio"/></p>   |
| <p>41 Does the website use web measurement and customization technology?</p>  | <p><input checked="" type="radio"/> Yes<br/><input type="radio"/> No</p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>42 Does the website have any information or pages directed at children under the age of thirteen?</p>  | <p><input checked="" type="radio"/> Yes<br/><input type="radio"/> No</p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>43 Does the website contain links to non- federal government websites external to HHS?</p>   | <p><input type="radio"/> Yes<br/><input checked="" type="radio"/> No</p>  | <p><input type="radio"/> Accept<br/><input checked="" type="radio"/> Reject</p> |
| <p>43a Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?</p>  | <p><input checked="" type="radio"/> Yes<br/><input type="radio"/> No</p>  |   |

**REVIEWER QUESTIONS:** The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

| Reviewer Questions  | Answer   |
|---|--|
| <p>1 Are the questions on the PIA answered correctly, accurately, and completely?</p>   | <p><input type="radio"/> Yes<br/><input type="radio"/> No</p> <p>Accept<br/>Reject</p> |
| <p>Reviewer Notes</p>   | <p><input checked="" type="radio"/></p>  |
| <p>2 Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?</p> | <p><input type="radio"/> Yes<br/><input type="radio"/> No</p> <p>Accept<br/>Reject</p> |
| <p>Reviewer Notes</p>   |  |

| Reviewer Questions |  | Answer  |   |
|--------------------|--|---|---|
| 3                  | Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors? | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 4                  | Does the PIA appropriately describe the PII quality and integrity of the data?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 5                  | Is this a candidate for PII minimization?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 6                  | Does the PIA accurately identify data retention procedures and records retention schedules?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 7                  | Are the individuals whose PII is in the system provided appropriate participation?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 8                  | Does the PIA raise any concerns about the security of the PII?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 9                  | Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 10                 | Is the PII appropriately limited for use internally and with third parties?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 11                 | Does the PIA demonstrate compliance with all Web privacy requirements?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 12                 | Were any changes made to the system because of the completion of this PIA?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |

|                  |   |
|------------------|---|
| General Comments | The NIAID ClinRegs Country Experts Interest is an electronic information collection form whose OMB Control number is 0925-0668 , with a expiration date of 04/2022. |
|------------------|---|

|   |  |  |  |
|---|--|--|--|
| OPDIV Senior Official for Privacy Signature |  | HHS Senior Agency Official for Privacy |  |
|---|--|--|--|

## Third-Party Website Assessment PIA Form

|        |             |           |           |           |
|--------|-------------|-----------|-----------|-----------|
|        |             |           |           |           |
| Status | Form Number | Read Only | Form Date | Read Only |

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| Question | Answer |
|----------|--------|
|----------|--------|

|          |                   |
|----------|-------------------|
| 1 OPDIV: | Read Only - OPDIV |
|----------|-------------------|

|                                 |                  |
|---------------------------------|------------------|
| 2 TPWA Unique Identifier (UID): | Read Only - TPWA |
|---------------------------------|------------------|

|              |                       |
|--------------|-----------------------|
| 3 TPWA Name: | UID                   |
|              | Read Only - TPWA Name |

|                       |   |
|-----------------------|---|
| 4 Is this a new TPWA? | <input type="radio"/> Yes <input checked="" type="radio"/> No |
|-----------------------|---|

|   |                                  |
|---|----------------------------------|
| 4a Please provide the reason for revision | <input checked="" type="radio"/> |
|---|----------------------------------|

|  |   |  |
|--|---|--|
| 5 Will the use of a third-party Website or application create a new or modify an existing HHS/OPDIV System of Records Notice (SORN) under the Privacy Act? | <input type="radio"/> Yes<br><input type="radio"/> No | <input type="radio"/> Accept<br><input type="radio"/> Reject |
|--|---|--|

|  |  |                                  |
|--|--|----------------------------------|
| 5a Indicate the SORN number (or identify plans to put one in place.) | SORN Number: <input style="width: 100%;" type="text"/> | <input checked="" type="radio"/> |
|  | If not published:                                      |                                  |

|   |   |  |
|---|---|--|
| 6 Will the use of a third-party Website or application create an information collection subject to OMB clearance under the Paperwork Reduction Act (PRA)? | <input type="radio"/> Yes<br><input type="radio"/> No | <input type="radio"/> Accept<br><input type="radio"/> Reject |
|---|---|--|

|  |  |                                  |
|--|--|----------------------------------|
| Indicate the OMB approval number and approval 6a number expiration date (or describe the plans to obtain OMB clearance.) | OMB Approval Number: <input style="width: 100%;" type="text"/> | <input checked="" type="radio"/> |
|  | Expiration Date  |                                  |
|  | Explanation  |                                  |

|  |   |  |
|--|---|--|
| 7 Does the third-party Website or application contain Federal Records? | <input type="radio"/> Yes<br><input type="radio"/> No | <input type="radio"/> Accept<br><input type="radio"/> Reject |
|--|---|--|

|     |   |   |  |
|-----|---|---|--|
| 8   | Point of Contact (POC):   | POC Title<br>POC Name<br>POC Organization<br>POC Email<br>POC Phone | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 9   | Describe the specific purpose for the OPDIV use of the third-party Website or application:  |   | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 10  | Have the third-party privacy policies been reviewed to evaluate any risks and to determine whether the Website or application is appropriate for OPDIV use?   | <input type="radio"/> Yes<br><input type="radio"/> No               | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 11  | Describe alternative means by which the public can obtain comparable information or services if they choose not to use the third-party Website or application:  |   | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 12  | Does the third-party Website or application have appropriate branding to distinguish the OPDIV activities from those of nongovernmental actors?   | <input type="radio"/> Yes<br><input type="radio"/> No               | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 13  | How does the public navigate to the third party Website or application from the OPIDIV?   |   | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 13a | Please describe how the public navigate to the third- party website or application:   |   |  |
| 13b | If the public navigate to the third-party website or application via an external hyperlink, is there an alert to notify the public that they are being directed to a nongovernmental Website?   | <input type="radio"/> Yes<br><input type="radio"/> No               |  |
| 14  | Has the OPDIV Privacy Policy been updated to describe the use of a third-party Website or application?  | <input type="radio"/> Yes<br><input type="radio"/> No               | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 14a | Provide a hyperlink to the OPDIV Privacy Policy:  |   |  |
| 15  | Is an OPDIV Privacy Notice posted on the third-party Website or application?  | <input type="radio"/> Yes<br><input type="radio"/> No               | <input type="radio"/> Accept<br><input type="radio"/> Reject |
| 15a | Confirm that the Privacy Notice contains all of the following elements: (i) An explanation that the Website or application is not government-owned or government-operated; (ii) An indication of whether and how the OPDIV will maintain, use, or share PII that becomes available; (iii) An explanation that by using the third-party Website or application to communicate with the OPDIV, individuals may be providing nongovernmental third-parties with access to PII; (iv) A link to the official OPDIV Website; and (v) A link to the OPDIV Privacy Policy |   | <input type="radio"/> Yes<br><input type="radio"/> No        |
| 15b | Is the OPDIV's Privacy Notice prominently displayed at all locations on the third-party Website or application where the public might   |   |  |

make PII available?

Yes

No

[Empty text box]



[Empty text box]

[Empty text box]

[Empty text box]



[Empty text box]



[Empty text box]



[Empty text box]



[Empty text box]



|     |   |   |   |
|-----|---|---|---|
| 16  | Is PII collected by the OPDIV from the third-party Website or application?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 17  | Will the third-party Website or application make PII available to the OPDIV?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 18  | Describe the PII that will be collected by the OPDIV from the third-party Website or application and/or the PII which the public could make available to the OPDIV through the use of the third-party Website or application and the intended or expected use of the PII: | <input type="text"/>                                  | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 19  | Describe the type of PII from the third-party Website or application that will be shared, with whom the PII will be shared, and the purpose of the information sharing:   | <input type="text"/>                                  | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 19a | If PII is shared, how are the risks of sharing PII mitigated?   | <input type="text"/>                                  |   |
| 20  | Will the PII from the third-party Website or application be maintained by the OPDIV?  | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 20a | If PII will be maintained, indicate how long the PII will be maintained:  | <input type="text"/>                                  |   |
| 21  | Describe how PII that is used or maintained will be secured:  | <input type="text"/>                                  | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| 22  | What other privacy risks exist and how will they be mitigated?  | <input type="text"/>                                  | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |

**REVIEWER QUESTIONS:** The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

| Reviewer Questions |  | Answer  |   |
|--------------------|--|---|---|
| 1                  | Are the responses accurate and complete?   | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 2                  | Is the TPWA compliant with all M-10-23 requirements, including appropriate branding and alerts?            | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |
| 3                  | Has the OPDIV posted an updated privacy notice on the TPWA and does it contain the five required elements? | <input type="radio"/> Yes<br><input type="radio"/> No | <input checked="" type="radio"/> Accept<br><input type="radio"/> Reject |
| Reviewer Notes     | <input type="text"/>   |   |   |



**REVIEWER QUESTIONS:** The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

4 Does the PIA clearly identify PII made available and/or collected by the TPWA?  Yes  Accept  
 No  Reject

Reviewer Notes

5 Is the handling of PII appropriate?  Yes  Accept  
 No  Reject

Reviewer Notes

General Comments

OPDIV Senior Official for Privacy Signature

HHS Senior Agency Official for Privacy