

US Department of Health and Human Services

Third Party Websites and Applications Privacy Impact Assessment

Date Signed:

May 31, 2022

OPDIV:

NIH

Name:

NIH BrainBaseline

TPWA Unique Identifier:

T-6166889-769574

Is this a new TPWA?

Yes

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?

No

If SORN is not yet published, identify plans to put one in place.

null

Will the use of a third-party Website or application create an information collection subject to OMB clearance under the Paperwork Reduction Act (PRA)?

No

Indicate the OMB approval number expiration date (or describe the plans to obtain OMB clearance).

Expiration Date: 1/1/01, 12:00 AM

Describe the plans to obtain OMB clearance.

Explanation: null

Does the third-party Website or application contain Federal Records?

No

Describe the specific purpose for the OPDIV use of the third-party Website or application:

Digital Artefact's BrainBaseline is a digital cognitive assessment platform used in a broad range of studies, from exploratory research to FDA-registered clinical studies. The data to be collected is configured to be study specific.

Participant eligibility is determined by the study team through a screening process done by the Principal Investigator (PI) and their clinical team at NIH. BrainBaseline will provide the study team with participant codes and the study team will help participants navigate the online tests.

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?

Yes

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:

Specific NIH clinical trials have procured the use of BrainBaseline for clinical assessment and measurement of patients enrolled in NIH Clinical Trials. Assessments are study specific and accessed through specific, de-identified access codes.

Does the third-party Website or application have appropriate branding to distinguish the OPDIV activities from those of nongovernmental actors?

Yes

How does the public navigate to the third party Website or application from the OPDIV?

Other...

Please describe how the public navigate to the thirdparty website or application:

N/A Study Participants are given a link and de-identified access code to participate.

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 anongovernmental Website?

No

Has the OPDIV Privacy Policy been updated to describe the use of a third-party Website or application?

Yes

Provide a hyperlink to the OPDIV Privacy Policy:

<https://www.nih.gov/web-policies-notice>

Is an OPDIV Privacy Notice posted on the third-part website or application?

No

Is PII collected by the OPDIV from the third-party Website or application?

No

Will the third-party Website or application make PII available to the OPDIV?

No

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:

Personally identifiable information (PII) is not collected, maintained and/or stored.

Brainbaseline allows for patient-reported and/or survey instrument reporting scaled or open-ended questions specific to the study. This information may include demographics, lifestyle, mood, medication adherence, and cognitive function. BrainBaseline enables qualified participants self-administration of fully-digitized, cognitive tests.

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:

Information gathered by BrainBaseline is de-identified. PII is not shared with study teams.

If PII is shared, how are the risks of sharing PII mitigated?

N/A

Will the PII from the third-party website or application be maintained by the OPDIV?

No

Describe how PII that is used or maintained will be secured:

N/A

PII is not collected, maintained and/or shared. However, participants sign an informed consent form before joining the study.

What other privacy risks exist and how will they be mitigated?

The NIH clinical trials maintain their own consent forms which participants must sign before entering the study. BrainBaseline abides by any restrictions or regulations contained in the informed consent document.