INSTRUCTIONS

I. COMMON ACTIVITIES THAT MAY REQUIRE AN OHSRP DETERMINATION

The NIH OHSRP makes determinations about whether or not NIH investigators' research activities are subject to IRB review. Below are some examples of activities that OHSRP commonly reviews.

Research Activities with <u>ONLY</u> Specimens or Data:

When NIH researchers are working ONLY with specimens or data and do not have the ability to identify the subjects from whom the specimens or data originated, ***IRB review is generally not required****. If NIH researchers have access to identifiers or subjects' identities may be readily ascertained,* ***IRB review is usually required****. OHSRP may determine that research involving data that is publicly available or existing data that is collected from records is* ***exempt from IRB review****, as long as it does not include recording any identifiable information or using codes linked to identifiable information. For more information about what constitutes individually identifiable information, please refer to SOP 5 Appendix 2 (link below).*

Research Activities with Surveys, Interviews or Focus Groups:

OHSRP may determine that survey, interview, or focus group research is ***exempt from IRB review****, provided that none of the potential responses could harm the subject if the information was released outside of the research context. When this type of research requires collection of sensitive data, an IRB* ***must review*** *the project.*

If you are uncertain of whether IRB review or OHSRP review is appropriate for your project, please consult with OHSRP before you complete a request for determination form. Also, if any of the questions on the form are unclear, please obtain clarification from OHSRP staff before you submit. A consult will save you time and ensure that you are on the correct path to begin your research project. ***You can reach OHSRP staff either by calling: 301-402-3444 or emailing: ohsr_nih_ddir@od.nih.gov.*** *For more information about activities that may require an OHSRP determination, please refer to:*

- SOP 5 - NIH Research Activities with Human Data/Specimens https://federation.nih.gov/ohsr/nih/ohrdocs/SOP_5_v1_9-16-13.pdf
- SOP 6 – Determinations Made by the Office of Human Subjects Research Protections (OHSRP) https://federation.nih.gov/ohsr/nih/ohrdocs/SOP_6_v1_9-17-13_508.pdf

II. SHOULD I STOP OR GO FORWARD WITH AN OHSRP SUBMISSION?

1. Have you already started or completed your research activity
   ☐ Yes *(**Stop here.** Please consult OHSRP.)*
   ☒ No

2. Is the proposed activity a component of a **protocol that is under NIH IRB review**, e.g. the results of this activity will be used in support of the protocol?
   ☐ Yes *(**Stop here.** You will likely need to amend the NIH protocol for the proposed activity. Please consult the IRB if you are unsure. Do not submit this request.)*
   ☒ No

3. Is this a research collaboration in which the NIH investigator has access to individually identifiable specimens/data (including coded specimens/data for which the investigator has the code key), and wants to send specimens/data that are either coded or anonymous to collaborators? *If the specimens/data are not individually identifiable, but the identity of the subjects may readily be ascertained by the investigator or associated with the information because of a small sample size or other reason, please answer "Yes" below.*

   ☐ Yes *(**Stop here.** You must obtain IRB approval of an amendment to the original protocol or IRB approval of a new protocol. Do not submit this request.)*
   ☒ No

4. Does this activity involve prisoners?
   ☐ Yes *(**Stop here.** Please consult the IRB. Do not submit this request.)*
   ☒ No

5. Please select the type of activity or materials involved in your project**.** *(Select all that apply.)*

   ☐ 5a. **Single Case Report** that does not contain any identifiable information about the participant; and no changes were made to the participant's care for the sake of reportability

   ☐ 5b. **Program Evaluation**, the results of which will only be shared with the relevant program or institution; and the participants have not been assigned to groups for comparison; and no comparison of a standard versus non-standard intervention is taking place

   ☐ 5c. **Quality Assurance/Quality Improvement activity with a clinical practice focus**, that does not introduce an untested clinical intervention or collect patient outcomes for the purposes of collecting scientific evidence about how well the intervention achieves its intended results, **in which the sole purpose is to**

improve internal practice and not to also conduct research to develop or contribute to generalizable knowledge

☒ 5d. **Quality Assurance/Quality Improvement activity with a non-clinical practice focus**, e.g. usability testing or evaluation of websites, workshops, conferences, tools, policies, etc., **in which the sole purpose is to improve a product or service and not to also conduct research to develop or contribute to generalizable knowledge**

☐ 5e. **Clinical Consulting**

☐ 5f. **Diagnostic Testing for Clinical Purposes** *(Other approvals may be needed if investigational tests are used. Please consult your IC FDA representative or the FDA.)*

☐ 5g. **Autopsy Materials, Specimens/Data from Deceased Persons** *(Please contact your privacy officer for further guidance.*)

☐ 5h. Specimens/data purchased from a **commercial repository** which will contain no identifying information

☐ 5i. **Derivatives** of materials (e.g. DNA, RNA, cell fragments or sub-parts, viruses or parasites) obtained from humans which will contain no identifying information

☐ 5j. **Established NIH Human Embryonic Stem Cell Lines that are available to qualified investigators and require no ethical review according to the registry**. The cell line must be listed here: http://grants.nih.gov/stem_cells/registry/current.htm and not be identifiable to the NIH researchers.

*If 5a. - 5j. is selected above, and your proposed project involves **ONLY** these activities: **STOP** answering questions here. No submission or determination is required from OHSRP or an IRB. However, other NIH policies or IC requirements apply. Please retain this documentation for your files.*

*If your proposed project involves **any of these activities above and other activities not listed here or involves none of these activities above**, please continue with the request for determination form.*

III. WHAT ADDITIONAL DOCUMENTATION MUST BE SUBMITTED TO OHSRP WITH THE REQUEST FOR DETERMINATION FORM?

There are three categories of research that require additional documentation to be submitted to OHSRP with the request for determination form. The categories are:

A. ***RECEIPT OF CODED SPECIMENS/DATA AT NIH FOR RESEARCH:*** *The NIH researcher is receiving coded specimens/data, and the person sending the specimens/data has the code key which links the specimens/data to individuals. In this case, the NIH investigator should submit a* ***de-identification agreement*** *or other equivalent agreement indicating that the party providing the coded specimens/data will not reveal the link to re-identify the subjects who provided the materials, e.g. an email confirmation between the sender and NIH investigator that is modified to reflect the nature of your arrangement as below. Please provide the agreement as a separate document, rather than simply revise the text below.*

De-identification Agreement

Sender of coded specimens/data:
I, [*Sender's Name*] of [*Sender's Institution*], holder of the code-key, cipher or identifiers for the shared [*specimens, data (specify)],* promise not to release the individually identifiable information about the subjects from whom the [*specimens, data (specify)]* derive, to [*Recipient's Name*] at [*Recipient's Institution*] per the provisions of U.S. Code 45 C.F.R. 46.

Recipient of coded specimens/data:
I, [*Recipient's Name*] of [*Recipient's Institution*], recipient of the [specimens, data (specify)], promise not to request individually identifiable information about the subjects from whom the [*specimens, data (specify)*] derive, from [*Sender's Name*] at [*Sender's Institution*] per the provisions of U.S. Code 45 C.F.R. 46.

B. ***PROJECTS INVOLVING AN "HONEST BROKER":*** *When an NIH investigator wants to conduct new research with existing individually identified specimens or data, IRB approval is required. However, if the investigator does not require identifiable information or the investigator would like to obtain specimens/data from an NIH collaborator, who is unable to de-identify the specimens or data prior to sharing them, the NIH investigator may choose to utilize the "honest broker" process to de-identify or re-code the specimens/data. For more information on the honest broker process, please see HRPP SOP 6 (see link above) or for questions, contact OHSRP.*

Submit the signed ***honest broker agreement and certification form*** *along with the request for determination form. The honest broker agreement and certification form can be found here:* https://federation.nih.gov/ohsr/nih/formtmp.php

C. ***SURVEYS; INTERVIEWS; FOCUS GROUPS; EDUCATIONAL RESEARCH OR TESTS; OBSERVATION OF PUBLIC BEHAVIOR; OR RESEARCH ON PUBLIC BENEFIT OR SERVICE PROGRAMS:*** *If your project involves any of these*

*research activities AND the NIH research team will be directly interacting with subjects or obtaining individually identifiable information about subjects, please submit the **instrument, focus group script or questions** along with the request for determination form.*

*If your project involves survey or interview procedures, observation of public behavior, or educational tests and qualifies as 'clinical research' as defined by the NIH (see question 29 below), the project **requires*** submission of a **Planned Enrollment Table** and collection and submission of **cumulative enrollment data annually**. The planned enrollment form can be found here:*
https://federation.nih.gov/ohsr/nih/formtmp.php

**For more information about the requirements for the Inclusion of Women and Minorities as Participants in Research see:*
http://grants.nih.gov/grants/funding/women_min/women_min.htm

All documentation should be submitted to OHSRP along with the request for determination form, in .pdf format, via email to ohsr_nih_ddir@od.nih.gov. Please write 'Request for Review' in the subject line of the e-mail.

PART I: GENERAL INFORMATION

This fillable form must be typed and submitted in pdf format, upon receipt of all required signatures. This form must be completed by NIH staff only.

1. Date of Request: / /

2. Is this a **new** request for determination or an **amendment** to a previously OHSRP-approved project? *(**Please note** if this is an amendment, we ask that you use your previously submitted request for determination form to answer the questions on this form.)*
   ☐ a. New project
   ☐ b. Amendment
   If an amendment, provide the determination number of the original approved project: OHSRP#:

3. Project Name:

4. Project Description *(Please describe the research activity that will be performed in lay terms, including its purpose. Explain the roles of the NIH investigator and collaborator(s) on the project; and what each party will contribute to the research. As you type, the box will increase to allow for additional text.)*:

5. Proposed Start Date: / /

   Proposed Completion Date ***(Required)***: / /

6. Requestor Details:
   Name: Institute/IC:
   Phone Number: ( ) -
   Email Address:

7. Are you the **Senior Investigator (SI)** for this project? *(i.e., the team lead. The term "SI" on this form does not refer to one's official NIH title. The SI must be an NIH FTE.)*
   ☐ Yes ☐ No

   7.1. If no, what is your role?
   ☐ a. Administrative Support
   ☐ b. Other investigator
   ☐ c. Other, *specify*:

8. **If not already included above**, provide SI details *(See instructions in Q. 7.):*
   Senior Investigator Name:

Institute/IC:
Phone Number: ( ) -
Email Address:

SI Signature *(Required)*: _____ **Date:** ___/___/_____

9. Supervisor Name:
*(**Please note** the supervisor cannot be a member of the research team for this specific project.)*

I (the supervisor) certify that the IC concurs that this project may proceed if it meets regulatory and NIH policy requirements.

Supervisor Signature *(Required)*: _____ **Date:** ___/___/____

10. Is there someone other than the **SI**, conducting this research *(e.g. a junior investigator, contractor, fellow, student, etc.)*?
☐ Yes ☐ No

10.1. If yes, provide the following information:

NIH Investigator Name: Institute/IC Name: Email Address:

11. Please provide the name(s) and email(s) of anyone else, who should receive a copy of the OHSRP determination:

Name:	Email Address:
Name:	Email Address:
Name:	Email Address:

12. What role(s) will the **NIH Investigator(s)** have on this research project? *(Select all that apply.)*
☐ a. Interacting directly with subjects to collect specimens/data
☐ b. Receiving specimens/data from a collaborator to conduct research
☐ c. Analyzing specimens/data
☐ d. Generating genomic data *(e.g. GWAS, WES/WGS; Additional NIH requirements may apply*: http://gds.nih.gov/03policy2.html *)*
☐ e. Running laboratory assays for research
☐ f. Sending specimens/data to a collaborator to conduct research
☐ g. Interacting directly or indirectly with subjects to recruit for or conduct surveys, interviews/focus groups, observation of public behavior, educational research or tests, or research on public benefit or service programs
☐ h. Consulting/advising the collaborator(s)
☐ i. Authoring publication(s)/manuscript(s) pertaining to this research
☐ j. Other, *specify*:

13. Will the SI be **collaborating on this research project with** any other person *(not on the NIH research team)* outside or inside the NIH?
☐ Yes ☐ No

13.1. If no, will the senior investigator **only be sending** specimens/data to someone not on the research team?
☐ Yes ☐ No (*If yes, please still add these individuals under Q.14 below.*)

14. Please include the details of each collaborator, his or her role, and when applicable, what will be sent or received. For any more than three collaborators, please provide the information requested below in the email request at the time of submission. *Provide the Federalwide Assurance (FWA)* number for each non-NIH collaborating institution (for more information contact OHSRP). Ask your collaborator for the FWA number or use this link to look it up:* http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc

A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support** to conduct non-exempt human subjects research. An FWA is an assurance of compliance with the U.S. Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46.*

a. Collaborator Name:
Institution/IC Name: FWA #:
City/State/Country:
Email Address:
Sending specimens/data: ☐ Receiving specimens/data: ☐ Both: ☐
Describe what will be sent/received:

b. Collaborator Name:
Institution/IC Name: FWA #:
City/State/Country:
Email Address:
Sending specimens/data: ☐ Receiving specimens/data: ☐ Both: ☐
Describe what will be sent/received:

c. Collaborator Name:
Institution/IC Name: FWA #:
City/State/Country:
Email Address:
Sending specimens/data: ☐ Receiving specimens/data: ☐ Both: ☐
Describe what will be sent/received:

15. For this project, will NIH be conducting a research activity with de-identified specimens or data **in support of FDA-regulated research** that is currently under IRB review at another institution?
☐ Yes ☐ No

15.1 If yes, has the **collaborator confirmed** that the planned research activity, which will occur at NIH, is included in the IRB/ethics committee-approved *protocol and consent form* at his/her institution?
☐ a. Yes, the NIH activity is IRB-approved at the collaborating institution
☐ b. No, the NIH activity has not yet been IRB-approved at the collaborating institution *(**Stop here.** Do not submit this request until your collaborator has confirmed **IRB approval** at his or her institution.)*

16. Does this activity include any of the following? *(Select all that apply.)*
☐ a. **NIH research team is interacting directly with subjects in person or has access to identifiers** to conduct survey, interview/focus group procedures, observation of public behavior, educational tests, educational research, or research on public benefit or service programs *(**If a. only, skip to question 25., otherwise continue.**)*
☐ b. Research with Specimens/Data
☐ c. NIH BTRIS Query
☐ d. Case Series
☐ e. Program Evaluation *(not meeting the definition in the Instructions, Part II, Q. 5b.)*
☐ f. QA/QI *(not meeting the definition in the Instructions Part II, Q. 5c. or 5d.)*
☐ g. Other, *specify*:

16.1. If e. or f. is selected above, does the activity involve **the NIH research team interacting directly with subjects in person or access to identifiers** to conduct survey, interview, or focus group procedures only?
☐ Yes ***(Skip to question 25.)***
☐ No ***(Continue.)***

PART II: RESEARCH WITH SPECIMENS AND DATA

17. Identify the types of specimens/data involved in this project. *(Select all that apply.)* ☐
a. Medical Records, *specify*:
☐ b. Specimens, *specify*:
☐ c. Data, *specify*:
☐ d. Imaging, *specify*:
☐ e. Pathological Waste/Results
☐ f. Autopsy Materials/Specimens/Data from deceased persons (*Please contact your privacy officer for further guidance.)*
☐ g. Audio Recording
☐ h. Video Recording/Conferencing

- ☐ i. Fetal Tissue Additional NIH requirements apply: https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/fetal-tissue-research
- ☐ j. iPSC lines *(Additional NIH requirements apply:* https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/guidelines-human-embryonic-induced-pluripotent-stem-cells
- ☐ k. hESC lines *(Additional NIH requirements apply:* https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/guidelines-human-embryonic-induced-pluripotent-stem-cells AND https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/areas-prohibited-research
- ☐ l. WES/WGS
- ☐ m. GWAS
- ☐ n. From a repository
  If an NIH Repository, *specify*:
- ☐ o. From a publicly available source (*meaning unrestricted access by anyone*), *specify*:
- ☐ p. Other, *specify*:

18. Do all the specimens/data or information already exist?
    - ☐ a. Yes
    - ☐ b. No
    - ☐ c. Some exist, and other specimens/data will be collected in the future

19. The specimens/data in this project were (or will be) originally collected for:
    - ☐ a. Clinical purposes only
    - ☐ b. Research purposes (*even if also collected for clinical purposes*)

20. Is there active IRB/ethics committee approval for the use of the specimens/data at your collaborator's site?
    ☐ Yes ☐ No

21. Can you identify the subjects, who are the source of the specimens or data, directly or through codes linked to individual identifiers? ☐ Yes ☐ No

22. Please select the response(s) that best describe(s) the specimens/data that will be shared/used for this activity. *(Please confirm this with your collaborator prior to submitting this form.)*

    - ☐ a. Specimens/data will not contain any identifiable information, and **cannot be linked to individual subjects by you or your collaborators**.

    - ☐ b. Specimens/data will be coded, however that **code cannot be used by either the sender or the receiver** to identify specific individuals.

☐ c. Specimens/data will be coded **so that the sender of the samples/data can link them to specific individuals,** but the receiver will not be able to do so.

☐ d. Specimens/data will contain **individually identifiable information**.

☐ e. Specimens/data currently contain identifiable information but data will be recorded in such a manner that subjects **cannot be identified directly, or through identifiers linked to subjects (e.g. a retrospective chart review), or an honest broker will be utilized for de-identification**.

23. If existing identifiable specimens/ data will be de-identified (including coded) before the research activity commences, please indicate who will conduct the de-identification:
☐ a. Collaborator(s)
☐ b. Senior investigator or a member of the research team at the NIH
☐ c. Honest broker *(For use only when identified specimens or data are coming from an NIH investigator; must be someone who will not be conducting the research) (The agreement can be found here:* https://federation.nih.gov/ohsr/nih/formtmp.php *(NIH Login required))*

24. Will recipient of specimens/data be returning results to the sender? *(Select all that apply)*
☐ a. Yes, coded results will be returned to the sender who can link them to individual subjects
☐ b. Yes, coded results will be returned, but neither the sender nor the recipient will have a link to the code key
☐ c. Only aggregate results will be returned (e.g. summary statistics, **not individual line-item data**)
☐ d. No, results will not be returned

24.1. If a.- c. is selected above **AND the sender is external to NIH**, is there IRB/ethics committee approval at his or her institution for the planned research activity to be conducted at NIH? ☐ Yes ☐ No

For all requests, other than those involving survey, interview/focus group procedures, observation of public behavior, educational research or tests, or research on public benefit or service programs, stop here. Otherwise, continue to Part III.

*Prior to submitting, review the instructions to insure that you include **the correct supportive documentation**. All documentation should be submitted in **.pdf format via email** to OHSRP to ohsr_nih_ddir@od.nih.gov. Please write **'Request for Review'** in the subject line of the e-mail.*

PART III: RESEARCH INVOLVING EDUCATIONAL RESEARCH OR TESTING, SURVEY OR INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR

25. Specify the nature of the data to be collected by: *(Select all that apply)*
    - ☐ a. Educational Research
    - ☐ b. Educational Testing
    - ☐ c. Survey or Interview/Focus Group Procedures
    - ☐ d. Observation of public behavior
    - ☐ e. Research on public benefit or service programs
    - ☐ f. Other, *specify:*

26. How will recruitment and data collection take place? *(Select all that apply)*
    - ☐ a. In-person at my collaborator's institution(s) or research site(s), *specify:*
    - ☐ b. In-person at an NIH site
    - ☐ c. In-person at another site(s), *specify:*
    - ☐ d. Online
    - ☐ e. Over the phone
    - ☐ f. Other, *specify:*

27. Who will be conducting the data collection? *(Select all that apply)*
    - ☐ a. NIH investigator or another member of the research team
    - ☐ b. Non-NIH collaborator
    - ☐ c. Off-site contractor, *specify* what company:
    - ☐ d. Online survey tool, specify:
    - ☐ e. Other, specify:

28. What is the age range of subjects involved in the research?
    - ☐ a. Children aged < 18 years
    - ☐ b. Adults aged ≥ 18 years

    28.1. If a. is selected above, and the project involves observation of public behavior, will the NIH investigator(s) participate in the activities being observed?
    ☐ Yes ☐ No

29. Does your project fall into any of the categories of 'clinical research' as defined by the NIH? (*See* http://grants.nih.gov/grants/glossary.htm#ClinicalResearch *for the full NIH definition of 'clinical research'.)*
    - ☐ a. Epidemiological and behavioral studies*
    - ☐ b. Outcomes research and health services research*
    - ☐ c. NONE OF THE ABOVE

If you a. or b. is selected above, please be sure to include the 'Planned Enrollment'** Table described in Part II of the instructions.*

*Prior to submitting, review the instructions to insure that you include **the correct supportive documentation**. All documentation should be submitted in **.pdf format via email** to OHSRP to ohsr_nih_ddir@od.nih.gov. Please write **'Request for Review'** in the subject line of the e-mail.*