HARVARD
Human Research Protection Program

Exemption Request Form

Instructions: Use this form to request an exemption from IRB approval. Select the appropriate exemption category(ies) in section B, and indicate how the project explicity corresponds to the exemption category(ies) in section C.
Please Note: Use of this form requires prior consultation to confirm eligibility. To do so, contact a QA/QI Specialist or discuss with your department-assigned IRB Review Specialist.

The IRB uses "WORKSHEET: Exemption Determination (HRP-312)" to determine whether an activity is research. This worksheet can be found on the IRB Web site and may be used to guide the information you provide in your description below.

A. ELIGIBILITY REQUIREMENTS. Check yes or no. If the response is "yes" to any of the following, the research is **not** eligible for an exemption determination.	
Confirmation of Consultation	☒ IRB; Name of IRB Review Specialist: **Keisha M. Turner**; Date: **3/31/2016** ☐ QIP; Name of QA/QI Specialist: ; Date:
☐ **Yes** ☒ **No**	The research is FDA regulated, e.g., drug, device, and/or biologics.
☐ **Yes** ☒ **No**	The research involves prisoners as participants.

B. EXEMPT CATEGORIES: 45 CFR 46.101(b)(1-6). Select the applicable exemption category(ies) relevant to the proposed research.	
☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Note:** If the research involves children, the activities must be limited to observation of public behavior when the investigator(s) do not participate in the activities being observed.
☐	3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☒	4. Research involving the collection or study of existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. ***Existing means "on the shelf" at the time the exemption request is submitted.**
☐	5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐	6. Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

C. STUDY ACTIVITIES: Briefly describe how the research fits the above exemption category(ies). Include the target population and/or describe how existing data/specimens will be accessed when applicable. For exemption clarifications, describe the changes here. Upload any related study documents into ESTR, e.g., consent script, survey questions, Data Use Agreements, etc.

Harvard Pilgrim Health Care (HPHC) has been conducting a multi-year study in which they collected strains of Streptococcus pneumoniae and associated epidemiologic data from study participants. The study is closing, and HPHC wishes to transfer the de-identified strains and limited associated data to HSPH.

Our goal is to preserve the de-identified strains and data for future analysis or experiment. Future analyses will include studies of associations of particular characteristics of the genome sequences of the strains or their biological properties with properties of the host epidemiologic data. Experimental uses may include in vitro or animal studies with the strains themselves, or use of the DNA from the isolates to create recombinant strains (with biosafety approval) We plan to share the isolates on request with colleagues requesting them for legitimate scientific research purposes, with the understanding that those colleagues are responsible for obtaining appropriate approvals to receive the isolates and put them to scientific use.

Under no circumstances will the identities of the study participants be disclosed to us, and we will never receive the code linking the de-identified samples to the participants.

The coded samples will not contain any information that could pose a risk of de-identification.

HPHC is in the process of reviewing the informed consents from all phases of the study. Their IRB will not approve release of any samples for which the consent does not cover our proposed use, transfer of the strains, or future use and broad sharing of the strains.

Once the study at HPHC is officially closed and their IRB approves the transfer of the strains a MTA will be negotiated between HSPH and HPHC.

1. The Code of Federal Regulations, Title 45 CFR Part 46, identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. These categories are not considered exempt from IRB review or oversight.

HARVARD Human Research Protection Program | Electronic Submission, Tracking, & Reporting

Date: Wednesday, May 25, 2016 11:36:03 AM

Print Close

View: SF: Basic Information HVD

Basic Information

1. * **Title of study:**
   Pneumococcal carriage and antigenic diversity

2. **Short title:** *80 Character limit. Note that the short title is the name that will appear in all workspaces. If this question is left blank, it will be automatically defaulted to the first 80 characters of the study title.*
   Pneumococcal carriage and antigenic diversity

3. **Brief description or abstract:**
   Harvard Pilgrim Health Care (HPHC) has been conducting a multi-year study in which they collected strains of Streptococcus pneumoniae and associated epidemiologic data from study participants. The study is closing, and HPHC wishes to transfer the de-identified strains and limited associated data to HSPH.
   Our goal is to preserve the de-identified strains and data for future analysis or experiment. Future analyses will include studies of associations of particular characteristics of the genome sequences of the strains or their biological properties with properties of the host epidemiologic data. Experimental uses may include in vitro or animal studies with the strains themselves, or use of the DNA from the isolates to create recombinant strains (with biosafety approval) We plan to share the isolates on request with colleagues requesting them for legitimate scientific research purposes, with the understanding that those colleagues are responsible for obtaining appropriate approvals to receive the isolates and put them to scientific use. We will submit a modification adding the HPHC IRB approval for transfer, future use and sharing of strains prior to conducting any research.

4. * **Principal investigator:**
   Marc Lipsitch

5. * **Does the investigator have a financial interest related to this research?**
   ○ Yes ◉ **No**

6. * **Study's Department:**
   Epidemiology

7. * **Are you requesting that an external IRB act as the IRB of record for this study?**
   ○ Yes ◉ **No**

8. * **Attach the Research Protocol or relevant Request Form (see documents below):**
   Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

	Document	Category	Date Modified	Document History
View	Lipsitch HRP-203 - EXEMPTION Request_1-21-2014.doc(0.01)	IRB Protocol	4/26/2016	History

Refer to the following templates and instructional documents, associated with the appropriate IRB:
HMS, HSDM, and HSPH (Studies in Longwood Medical Area only):

- For human research applications: HLMA Template Research Protocol
- For Exempt human research applications: HLMA HRP-203 - Exemption Request (IRB/QIP Consultation is required for access to this form)
- For requests for non-human research: HRP-215 - Not Human Research Request Form

FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only):

- For all Exempt and Non-Exempt human research applications: CUHS Template Research Protocol
- For requests for non-human research: HRP-215 - Not Human Research Request Form

View: SF: Funding Sources (not integrated with Grants) HVD

Funding Sources

- Include any pending/awarded funding sources or financial support for this study.
- Leave questions 1 and 2 blank to indicate that there is no funding for this study.
- Reminder: If the funding status changes following IRB determination, submit a modification to this study.

1. **If a grant proposal has been submitted to the sponsored programs office (SPA or OSP), if a proposal was created a proposal in GMAS, or if there is federal or other sponsored funding for the study, add here:**
   Project # GMAS Status Abbreviated GMAS Title PI Fund Sponsor GMAS Link
   There are no items to display

2. **If there is financial support for this project from a non-sponsored source such as a department, gift or Harvard program, add here:**
   Funding Source Unlisted Funding Source Sponsor's Funding ID
   There are no items to display

View: SF: Study Team Members HVD

Study Team Members

Study Team Members Include:

1. Individuals who:
   a. Have contact with human subjects;
   b. Have access to data that is identifiable (including data that is indirectly identifiable using a coding system or key); OR
   c. Are responsible for the design, conduct, or reporting of the research
2. At the University Area, the Faculty Sponsor for studies conducted with a non-faculty PI

- Do not list the PI on this page.
- Each of the individuals named as study team members must complete human subjects training (refer to your IRB website to learn about training requirements).
- Include non-Harvard collaborators who meet these criteria only in the absence of their local IRB review.

1. **List study team members with an HUID:**

For instructions to obtain an HUID for individuals who must be listed here, please visit your IRB website.

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
Maria Georgieva	Other Study Team Member	no	no	georgiev@hsph.harvard.edu	
Lisa Kagedan	Other Study Team Member	no	no	lkagedan@hsph.harvard.edu	
Claudette Thompson	Other Study Team Member	no	no	cthompso@hsph.harvard.edu	6174323269

2. **List study team members without an HUID (by attaching the Non-Harvard Study Personnel Form) and/or attach other relevant documents:**
Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

Name	Description
There are no items to display	

Suggested Attachments:
- Financial Interest Disclosure Form
- Non-Harvard Study Personnel Form
- Training Information
- Individual Investigator Agreement (IIA) For non-Harvard Investigators who are not covered under a local IRB. For more information about this form, please see your IRB website.

View: SF: Study Scope HVD

Study Scope

1. * **Are there external sites where the investigator will conduct or oversee the research?**
   ○ Yes ◉ **No**

2. * **Does the study involve the use of a DRUG in one or more persons other than use of an approved drug in the course of medical practice?**
   ○ Yes ◉ **No**

3. * **Does the study involve:**
   - The use of a DEVICE in one or more persons that evaluates the safety or effectiveness of that device, or
   - Data regarding the use of a device on human specimens?

   ○ Yes ◉ **No**

View: SF: Recruitment Materials Hvd

Consent Forms and Recruitment Materials

1. **Consent, Assent, Permission, and HIPAA Authorization Forms:**
   Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

Document	Category	Date Modified	Document History
There are no items to display			

2. **Recruitment Materials:**
   Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

Document	Category	Date Modified	Document History
There are no items to display			

   Refer to the following templates and instructional documents, associated with the appropriate IRB:
   HMS, HSDM, and HSPH (Studies in Longwood Medical Area only):

   - HLMA Adult Consent Form Template
   - HLMA Parental or Guardian Permission Template
   - HLMA Child Assent Form Template
   - HLMA Adult Surrogate Consent Form Template
   - HLMA Consent form template for study conducted at HIPAA-covered entities
   - HLMA Short Form Consent

   FAS, GSE, HKS, HBS, SEAS, HLS, GSD, HDS, and Radcliffe Institute (Studies in University Area only):

   - CUHS Adult Consent Form Template
   - CUHS Child Assent Form Template
   - CUHS Parental or Guardian Permission Template
   - Additional templates for Exempt research and for specific types of non-Exempt research are posted on the CUHS website

View: SF: Supporting Documents Hvd

Supporting Documents

Attach supporting files, naming the file as you want them to appear in the approval letter:
Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

	Document	Category	Date Modified	Document History
View	HPHC SPARC strains.pdf(0.01)	Data Use Agreement or Other Agreements	5/4/2016	History

Suggested attachments (if not already attached to a previous section of the SmartForm):

- Ancillary Approvals/Permissions
- Data use agreements or other Agreements
- Debriefing Materials
- External Site Information
- Federal Department Requirements Checklists
- Financial Interest Disclosure Form
- Foreign Language Documents

- Funding Source Attachments
- Individual Investigator Agreement (IIA)
- IRB Authorization Agreement Request Form
- PI's Current CV (ICH-GCP E6 Only)
- Radiation Safety Form
- Sponsor Protocol including DHHS-approved protocol
- Study Instruments/Tools
- Translation Attestation Form