

**Notification of 45 CFR 46.118 Determination for a Project Lacking Immediate Plans for  
Involvement of Human Subjects, their Data, or their Specimens**

**Date:**

**Principal Investigator:**

**Grant or Protocol #:**

**Grant or Protocol Title:**

On <date>, it was determined that the above-referenced grant or protocol meets the requirements of 45 CFR 46.118. The study will involve research with human subjects for which the protocol is not yet fully developed.

One year from the date identified above, the Authorized Organizational Representative is required to either:

1. verify that the project continues to lack immediate plans for the involvement of human subjects, their data, or their specimens; or
2. provide documentation to the cognizant NSF Program Officer to demonstrate that IRB approval has been obtained.

**No work with human subjects, including recruitment, may be conducted under this protocol or grant until IRB approval has been obtained.**

Please contact <individual> with any questions.