1.a. If YES to Human Subjects

Your answers here in question “1.a. If YES to Human Subjects” will populate the corresponding

fields in the [F.500 – PHS Human Subjects and Clinical Trials Information form](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/fellowship-forms-g.pdf#%5B%7B%22num%22%3A147%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C94.5%2C730.5%2C0%5D).

Is the Project Exempt from Federal regulations? Yes/No

If the project is exempt from federal regulations, check “Yes” and check the appropriate exemption number.

Human subjects research should only be designated as exempt if all of the proposed research projects in an application meet the criteria for exemption.

If the project is not exempt from federal regulations, check “No.”

For more information, see the NIH’s [Exempt Human Subjects Research infographic](https://humansubjects.nih.gov/sites/hs/public_files/exemption_infographic_v6_hs_internet.pdf).

If yes, check appropriate exemption number 1, 2, 3, 4, 5, 6, 7, 8:

If you selected “Yes” to “Is the Project Exempt from Federal Regulations,” select the appropriate

exemption number.

The categories of research that qualify for exemption are defined in the Common Rule for the

Protection of Human Subjects. These regulations can be found at [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

Need help determining the appropriate exemption number? Refer to NIH's Research

Involving Human Subjects [Frequently Asked Questions](https://humansubjects.nih.gov/human-specimens-cell-lines-data).

The Office for Human Research Protections (OHRP) guidance states that appropriate use of

exemptions described in 45 CFR 46 should be determined by an authority independent from the

investigators (for more information, see [OHRP's Frequently Asked Questions](http://answers.hhs.gov/ohrp/categories/1564)). Institutions often

designate their Institutional Review Board (IRB) to make this determination. Because NIH does not

require IRB approval at the time of application, the exemptions designated often represent the

opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. See NIH Grants Policy Statement Section 4.1.15 for more information.

4. Human Fetal Tissue Section

Notes on public health surveillance activities: Projects involving public health surveillance activities described in 45 CFR 46.102(l)(2) must answer questions in Section 1.a. as if the exclusion does not apply. In rare circumstances, applicants may request NIH approval for use of the exclusion in accordance with Just-in-Time procedures.

If no, is the IRB review Pending? Yes/No

If IRB review is pending, check “Yes.”

Applicants should check “Yes” to the question “Is the IRB review Pending?” even if the IRB

review/approval process has not started by the time of submission.

If IRB review is not pending (e.g., if the review is complete), check “No.”

IRB Approval Date:

Enter the latest IRB approval date (if available). Leave blank if IRB approval is pending.

An IRB approval date is not required at the time of submission when IRB review is pending. This

may be requested later in the pre-award cycle as a Just-In-Time requirement. See the [NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm) for more information.

Human Subject Assurance Number:

Enter the approved Federalwide Assurance (FWA) number that the applicant has on file with

OHRP. Enter the 8-digit number. Do not enter “FWA” before the number.

Enter “None” if the applicant organization does not have an approved FWA on file with OHRP. In

this case, the applicant organization, by the signature in the Certification section on the [F.200 -](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/fellowship-forms-g.pdf%22%20%5Cl%20%22%5B%7B%22num%22%3A786%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C94.5%2C206.25%2C0%5D)

[SF424 (R&R) Form](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/fellowship-forms-g.pdf%22%20%5Cl%20%22%5B%7B%22num%22%3A786%2C%22gen%22%3A0%7D%2C%7B%22name%22%3A%22XYZ%22%7D%2C94.5%2C206.25%2C0%5D), is declaring that it will comply with [45 CFR 46](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/) and proceed to obtain a FWA

(see [Office for Human Research Protections website](http://www.hhs.gov/ohrp)). Do not enter the FWA number of any

collaborating institution.

Additional Instructions for Fellowship:

If research proposed in the fellowship application has been previously reviewed and

approved by an IRB and is covered by an approved FWA, provide the FWA number

and the latest IRB approval date for the proposed activities. The latest IRB approval

date must be within one year of the application due date.