**INCLUSION OF INDIVIDUALS ACROSS**

**THE LIFESPAN TEMPLATE**

SF424 (R&R) – Version F

Last revised 6/10/20

**Content Instructions**

* For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., [children](https://grants.nih.gov/grants/glossary.htm#Child) or [older adults](https://grants.nih.gov/grants/glossary.htm#OlderAdult)) should be justified in this section. In addition, address the following points:
  + Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the [NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html) for additional information about circumstances that may justify the exclusion of individuals based on age.
  + Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.
* When children are involved in research, the policies under HHS' [45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd) apply and must be addressed in the Protection of Human Subjects attachment.
* Existing Datasets or Resources. If you will use an [existing dataset](https://grants.nih.gov/grants/glossary.htm#Existingdataset), resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study. For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH [FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources](https://grants.nih.gov/faqs#/inclusion-basic-on-sex-gender-and-race-ethnicity.htm).

**Review Criteria and/or Questions to Consider**

* If individuals will be excluded from the study based on age, has an acceptable justification for their exclusion been provided?
* If use of an existing data set is proposed, is its use justified in the proposed scientific context despite limitations placed on participant age?

**Suggested outline**

We have provided a suggested outline on the third page of this document. If you would like, you can enter your text directly below each subsection header. This document is already formatted appropriately (0.5 inch margins, Arial font, 11 point text). Just delete the first two pages and you are on your way to a complete draft!

**INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN**

***Scientific/Ethical Rationale for Age Range of Participants:***

***Expertise and Experience Working with Included Age Groups:***