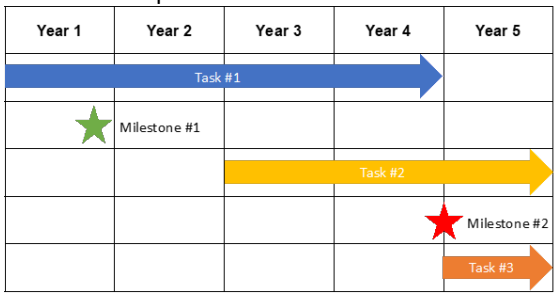
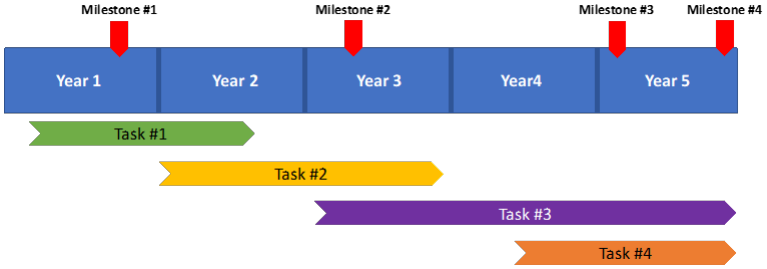
NIH Grant Applications/Human Subjects Template - Document Checklist for Human Subjects Research (Non-Clinical Trials)

Required content instructions in blue.
Special Instructions in grey and italicized.

Section 2.3a Inclusion of Individuals Across the Lifespan ☐ Age exclusions ☐ Rationale for the minimum and maximum age of study participants ☐ Scientific/ethical rationale for exclusions ☐ Expertise of investigators and appropriateness of facilities for specified ages ☐ How age distribution will contribute to meaningful analysis.	(1) Justify exclusion of any specific age or age range group (e.g. children or older adults). (2) Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. (3) Provide a scientific or ethical rationale for any exclusions. (4) Describe the expertise of the investigators and appropriateness of facilities for specified ages and how age distribution will contribute to meaningful analysis. *For research involving children: These policies must be addressed below in section 3.1* *If using existing datasets or resources: Provide reason for limiting inclusion of any group. In general, cost or location alone are not acceptable. More information*
Section 2.4 Inclusion of Women and Minorities ☐ Planned distribution of subjects by sex/gender, race, and ethnicity ☐ Rationale for selection in terms of the scientific objectives and proposed study design ☐ Proposed outreach programs for recruiting of these subjects ☐ Reason(s) for limiting inclusion of any group by sex/gender, race, and ethnicity ☐ [NIH-Defined Phase III Clinical Trials] Plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial	(1) Describe the planned distribution of subjects by sex/gender, race, and ethnicity. (2) Describe the rationale for selection in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study. (3) Describe proposed outreach programs for recruiting of these subjects. (4) Provide reasons for limiting inclusion of any group by sex/gender, race, and ethnicity. *If using existing datasets or resources: Provide reason for limiting inclusion of any group. In general, cost or location alone are not acceptable. More information* *NIH-Defined Phase III Clinical Trials: Address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. More information*
Section 2.5 Recruitment and Retention Plan (not required for exemption 4 studies) ☐ Description of how you will recruit and retain participants in your study (planned recruitment and strategies for retention)	(1) Describe how you will recruit and retain participants in your study. Address both planned recruitment activities and engagement strategies for retention. *If you selected Exemption 4: This section is not required.*
Section 2.7 Study Timeline (optional) ☐ Description or diagram of study timeline	(1) Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates. *If you selected Exemption 4: This section is not required.* (see next page for timeline examples)

	Timeline Example #1  Timeline Example #2: 
Section 3.1 Protection of Human Subjects (exempt studies)	(1) Justify why the research meets the criteria for the exemption(s) that you have claimed. (2) Explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves.
Section 3.1 Protection of Human Subjects (non-exempt studies) ☐ Risks to Human Subjects ☐ a). Human Subjects Involvement, Characteristics, and Design ☐ b). Study Procedures, Materials, and Potential Risks	**Risks to Human Subjects** a. ***Human Subjects Involvement, Characteristics, and Design*** (1) Describe the overall study design. (2) Describe the subject population(s), assignment procedures, and anticipated numbers for each study group. (3) List any collaborating sites, their role, and any collaborating investigators. b. ***Study Procedures, Materials, and Potential Risks*** (1) Describe all planned interventions/interactions involving study subjects, how research material (biospecimens, data, and/or records) will be obtained, and whether private identifiable information will be collected. (2) Describe all potential risks to subjects associated with each intervention. Risks include physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality, and others. (3) Discuss the risk level and likely impact to subjects. (4) Describe the risks and benefits of alternative treatments/procedures. Include rationale for proposed intervention versus alternative approaches. *Studies including previously collected biospecimens, data, or records: Describe the source, and linkers to identifying information, and who possess those linkers.*

(section 3.1 Protection of Human Subjects, cont.) ☐ Adequacy of Protection Against Risk ☐ a). Informed Consent and Assent ☐ b). Protections Against Risk ☐ c). Vulnerable Subjects	**Adequacy of Protection Against Risks** a. ***Informed Consent and Assent*** (1) Describe the informed consent process. Include a description of how consent will be sought and obtained, who will seek it, the nature of information provided, and documentation methods. (2) Describe how potential adult subjects' capacity to give consent will be determined and a plan for obtaining consent from a legally authorized representative. If seeking a waiver of informed consent, provide justification for the waiver. *For research involving Children: Describe the process for meeting HHS regulatory requirements for parental permission and child assent. More information* b. ***Protection Against Risk*** (1) Describe planned strategies for protecting against/minimizing risk, including managing and protecting the privacy and confidentiality for research data. (2) Discuss plans for enduring necessary medical or professional intervention in the event of adverse effects on subjects. (3) Describe plans for handling incidental findings from research imaging, screening tests, or paternity tests. c. ***Vulnerable Subjects*** (1) Explain the rationale for involving special vulnerable populations. *For studies involving pregnant women, fetuses, neonates, and children: Provide clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.* *For studies involving prisoners: Discuss the potential benefit to the research participants and others. Discuss why the risks are reasonable in relation to the anticipated benefits. More information (note: financial benefit should not be presented as a benefit)* *For studies that do not involve vulnerable populations: This section is not required.*
☐ Potential Benefits of Proposed Research to Research Participants and Others ☐ Potential benefits to participants and others ☐ Why risks are reasonable in relation to benefits	**Potential Benefits of the Proposed Research to Research Participants and Others** (1) Discuss the potential benefits of the research to participants and others. (2) Discuss why the risks are reasonable in relation to the anticipated benefits to the research participants and others. *Note: Financial compensation should not be listed as a benefit*

(section 3.1 Protection of Human Subjects, cont.) ☐ Importance of Knowledge to be Gained ☐ Importance of knowledge to be gained ☐ Why risks are reasonable in relation to importance of knowledge	**Importance of Knowledge to be Gained** (1) Discuss the importance of the knowledge to be gained as a result of the proposed study. (2) Discuss why the risks are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.
Section 4.3 Statistical Design and Power ☐ Number of expected enrolled subjects, effect size, power, and statistical methods	(1) Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in 4.2 Outcome Measures. (2) Show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage.