## No to Use of Human Subjects (but using Data and/or Specimens) Justification



***Guidelines***

1. *Required for studies that utilize human data and/or specimens but do not meet the definition of human subject studies*
2. ***Format:***
	1. *No page limit*
	2. *Margins min. 0.5”*
	3. *NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype*
3. ***Content:***
	1. *Provide information on who is providing the data/biological specimens and their role in the proposed research*
	2. *Describe the identifiers that will be associated with the human specimens and data*
	3. *Provide a list of who has access to subjects’ identities*
	4. *Provide information about the manner in which the privacy of research participants and confidentiality of data will be protected*
4. *When form is complete:*
	1. *Remove this box*
	2. *Save file as “No to Use of Human Subjects Justification”*

***Note:*** *Skip the rest of the PHS Human Subjects and Clinical Trials Information Form*