## 3.1 Protection of Human Subjects - Exemption Justification (Exemption 4 Only)



***Guidelines***

1. *Required for Exemption 4 studies. See* [*NIH’s Infopath Questionnaire*](https://humansubjects.nih.gov/questionnaire) *for guidance.*
2. ***Format:***
	1. *No page limit*
	2. *Margins min 0.5”*
	3. *NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype*
3. ***Content:***
	1. *Justify why the research meets the criteria for the exemption(s) that you have claimed and is exempt from regulatory requirements in 45 CFR 46. Reasons for Exemption 4 can include:*
		1. *Study involves the collection or study of existing data, documents, records, or specimens but sources are publicly available*
		2. *Information is recorded by the investigator and/or collaborators in a manner that subjects cannot be subsequently identified directly or through identifiers that are linked to the subjects*
		3. *Investigator and/or collaborators will not retain or access any identifiers*
	2. *Do not merely repeat the criteria or definitions for Exemption 4 themselves*
4. *When form is complete:*
	1. *Remove this box*
	2. *Save file as “3.1 Protection of Human Subjects Exemption 4 Justification”*