

Determination of Human Subjects Research Checklist

Checklist to determine the need of completion of New Protocol Form

		YES	NO	NOT SURE
Section A: Does your activity involve human subjects ?	Is the data being obtained about living individuals?			
	Is the data collected intervention or interaction with individuals?			
	Does the data contain identifiable private information ?			
If any question in Section A is "YES", go to Section B. If any question in Section A is "NOT SURE", go to Section B & C. If all questions in Section A are "NO", IRB review is not required.				
Section B: Is it Research ?	Is the activity a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge ?			
If any question in Section A is "YES" and Section B is "YES", submit a New Protocol Application form. If Section B is "NO", go to Section D If Section B is "NOT SURE", go to Section C.				
Section C: Is IRB review required?	Does the activity involve secondary data sets with identifiable private information?			
	Does the activity use identifiable specimens or cell lines from other institutions or are they commercially available?			
	Is the data collected for administrative purposes with the intention of publication?			
	Does the activity involve the use of publicly available data that contains sensitive, persona, or identifiable data?			
	Does the interview or survey focus on experiences, opinions, and sensitive information about people?			
	Is the activity a biography that is generalizable?			
	Is the activity an oral history that is generalizable?			
	Does the activity involve case histories of multiple individuals?			
	Is the activity a genetic study providing private information about live relatives?			
Is the activity a class related project that will lead to publication or poster presentations?				

If any question in Section C is "YES", submit a New Protocol Application form.
 If all questions in Section C are "NO" go to Section D. If any questions in Section C is "NOT SURE", contact OPRS.

	Does the activity intentionally focus on one or more specific populations listed below? If "YES", check the appropriate box(es).			
Section D: Is the focus on a specific population?	Children (age < 18 years) Neonates/Fetuses/In vitro Fertilization Persons Mentally disabled or cognitively impaired persons Adults with legal guardians Prisoners	Pregnant or lactating women group(s)—describe: Dillard Students—name subject pool, if applicable:		