The activity that falls under Exempt category 7 is obtaining broad consent to store or maintain identifiable data for secondary research. Given that this category only covers secondary research, you cannot only apply for this exempt category to be exempt because your study must have a primary research topic and primary research does not fall under this category. If your study does not also meet the criteria for one of the other exempt categories (except 4 or 8) then your study is not eligible to be reviewed at the exempt level. However, you may still be eligible to collect broad consent under this exempt category if you meet the criteria below. A limited IRB review will be conducted to determine if the criteria is met.

Contact the REC office if you have any questions.

Is broad consent or a waiver of documentation of consent appropriately documented? .111(a)(8)(ii)

Is there adequate provisions established to protect the privacy of subjects if the way in which the data is stored or maintained is changed? .111(a)(8)(iii)

Is the following information included in the consent form?

1. A general description of the types of research that may be conducted with the identifiable data
2. A description of the identifiable private data that might be used in research
3. Whether or not the data will be shared with people not on the research team
   1. If shared, who the data might be shared with
4. A description of how long the identifiable data might be kept and for how long it might be used for research
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable data, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies
6. Unless it is known that clinically relevant research results will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.
7. Information on whom to contact for answers to questions about the subject’s rights and about storage and use of the subject’s data, and whom to contact in the event of a research-related harm.

This study may be eligible to obtain broad consent .104(d)(7)