

## Questions for Determining Applicability of NIH CoC Policy

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1. **Was the research** begun or ongoing on after December 13, 2016? ☐ YES ☐ NO

If the answer is NO (i.e. the research was completed prior to 12/13/2016), the policy does not apply. If the answer is YES, answer the following questions.

1. **Is the research conducted or funded by NIH?** ☐ YES ☐ NO
2. **Is the activity biomedical, behavioral, clinical, or other research?** ☐ YES ☐ NO

If the answer to either of these questions is NO, then the activity is not issued a CoC and the policy does not apply. If the answer to both is YES, answer the following questions:

1. **Does the research involve human subjects as defines by 45 CFR 46?** ☐ YES ☐ NO
2. **Are you collecting or using biospecimens that are identifiable to an individual as part of the research?** ☐ YES ☐ NO
3. **I collecting or using biospecimens s part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?** ☐ YES ☐ NO
4. **Does the research involve the generation of individual level, human genomic data?**  
☐ YES ☐ NO

If the answer to any one of these questions is YES, then a CoC is automatically issued and the policy applies.