Instructions:

Researcher:

- You are only permitted to modify the yellow highlighted portions.
- Prefill the items highlighted YELLOW.
- Once you're finished, delete these instructions

The approver will complete the items in grey, remove the highlighting, sign and send to you.

Date:	Today's Date
То:	PI: Name of PI
	Names of Collaborators
From:	NAME OF APPROVING PI
Study PI	Name of PI
Anticipated end date of project:	Expected end date of grant, project etc.
Study Title:	Project Title
IRB Number	Project IRB Number
Approval Date	Date Signed
Expiration of Approval	Date Expires

Dear PI Name,

The DEPARTMENT approved your research project on date signed. The expiration date of this approval is date expires at Midnight. If this research is to continue beyond that date, it is your responsibility to submit a Continuing Review application as needed with CMS and the IRB. Research activities must be reviewed and re-approved on or before midnight of the expiration date. The approval period may be less than one year if so determined by CMS or the IRB.

Proposed changes to approved research must be reviewed and approved prospectively by both CMS and the IRB. No changes may be initiated without prior approval by the CMS and the IRB, except where necessary to eliminate apparent immediate hazards to subjects (eg, a security risk). Any suspected security issues or other risks to participants should be reported to PHS, the appropriate office at your institution (Privacy, IRB) and CMS immediately.

Investigator Responsibilities:

To ensure transparency and reproducibility, you must make derivative datasets, code used to construct cohorts and research findings available to other vetted researchers for replication studies or to build upon existing work. Standards for CMS citation information and cell size suppression policies will be provided on the PHS Data Portal. All investigators must abide by these terms for publication including allowing PHS at least 30 days to review any publication to address errors, citation and disclosure of confidential information.

Best of luck to you on your research,

Signature

NAME OF APPROVER