CRIS Access for IRB Exempt Retrospective Chart Review

**Instructions:** All investigators, who wish to complete a retrospective chart review using NIH records for research purposes, are expected to first contact the Office of Biomedical Translational Research Informatics (BTRS) team (BTRISSupport@nih.gov) to determine whether it would be possible to conduct the study using de-identified data in BTRIS or if the BTRIS staff can help obtain and de-identify data for the study team. For example, at times, the BTRIS staff are able to obtain identifiable biospecimens or data for the researchers and either anonymize it, or de-identify it and/or act as an honest broker (and retain a code key linking to identifier). If you have sought feedback from the BTRIS team and learned that it is not possible to effectively or efficiently conduct your study without access to CRIS, you may proceed.

Once you have received a formal determination letter from the NIH IRBO stating that your planned retrospective chart review project is exempt from IRB review and approval, please complete and sign this form. Do not list anyone on this form who will access CRIS for the project, unless he or she already has approved CRIS access. Please note that any research team member who plans to access CRIS and does not currently have access to CRIS, will need to complete the required steps to obtain access, prior to being included on this form or beginning any research activities for the project.

Once you have completed this form, you should email the signed copy (without the instructions page) and a copy of the exemption letter from the IRBO to the Health Information Management Department (HIMD): Marisa Owens, owensms@cc.nih.gov and Amanda Grove, groveak@cc.nih.gov and cc: Julie Eiserman, julie.eiserman@nih.gov.

Please note that no one can access CRIS for this project, including outside of the submitted start and end dates, without first formally notifying the HIMD. If you do not have a CRIS account please notify Marisa and Amanda for further instructions. Personnel All personnel accessing individual medical records without proper IRB approval and HIMD authorization are at risk of being audited.

If after you complete this form, you need to add new investigators to conducting chart reviews in CRIS; if the criteria of your eligible subject population changes; or if you must add or eliminate a protocol from the list of involved protocols for the project, you must amend your secondary research protocol and submit an amendment in iRIS. Once you have received a new determination, you must complete a new version of this form and submit it to the HIMD, following the same steps above.

If your end date for needed access to CRIS must be extended, you must revise just this form with the new date and submit the signed form with the original exemption letter to the HIMD.
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Project Number (on IRBO letter): ____________________________

Project Title: __________________________________________________________________________________________

NIH Principal Investigator Name: ______________________________

Determination Date (on IRBO letter): _______________________

Names of all NIH employees, staff, fellows, trainees, etc. who will access CRIS to complete the retrospective chart review:

_________________________________   _________________________________
_________________________________   _________________________________
_________________________________   _________________________________
_________________________________   _________________________________

Description of patients whose records will be accessed, i.e. the eligibility criteria required in order for a patient to be included:

Protocols numbers and associated PI names, if only certain protocols will be accessed for this project:

Start Date for accessing CRIS: _________________________________

End Date for accessing CRIS: _________________________________