

Publications: Per the Study VII MOU, all site PIs own their own data. However, to prevent scientific overlap and to facilitate manuscript tracking and dissemination, all site PIs and related investigators, should:

- a. Submit the Planned Data Use/Request for Data form to Dr. Webel. These initial manuscripts were discussed at the Ottawa 2017 meeting (See Appendix 1).
- b. Those proposing manuscripts have 12 months to write the manuscript and submit it for publication. If, after 12 months, the manuscript is not written and someone else would like to write the same manuscript (i.e. another member of the writing team), that person must submit an amended proposal form and will have 12 months to write the manuscript.
- c. All site PIs fulfill the authorship criteria and should be listed as co-authors, unless they have been consulted and other arrangements agreed to in writing.
- d. PI's can only have one paper in development at a time, once a manuscript is submitted they can move on to their next manuscript.
- e. If the site PI wants to add another non-site PI from their site who has contributed to the study effort and writing, the PI has the discretion to do so
- f. All co-authors on the manuscript must review and provide feedback on the final version of the manuscript, within two weeks of the primary author circulating it. Note: if a site PI is unable, for some reason, to review the manuscript within two weeks, that person must communicate this to the primary author. If not, that person may be removed as an author from the manuscript.

After the initial manuscripts are written, if students or other members of the research community are interested in analyzing the data for publication the following steps must be adhered to.

- a. A written protocol must be submitted to the study coordinating site PI Dr. Webel.
- b. The site PIs and Dr. Webel will determine the scientific validity of the protocol.
- c. If all site PI's agree to allow the analysis, the applicant must submit an IRB application to determine if the analysis adheres to contemporary ethical standards.
- d. After IRB approval or exemption, the PI will release a de-identified dataset in MS excel to the applicant (no identifying information including name, birth date, address or phone number will be included in the released data).
- e. In any resulting publications, the author must acknowledge the primary study, supporting grants, and all site principal investigators.