Protocol for Use of Registry by Investigators

While the Illinois Women's Health Registry is a program developed and run by Northwestern University, we strongly encourage usage from investigators at all statewide institutions

1) Investigators who wish to obtain a pool of women for a study will apply by submitting an application with inclusion and exclusion criteria (this is based on the survey questions themselves), a copy of their IRB approved protocol, and grant application (if applicable).

2) The Registry Coordinator will review each application to determine that the proposed study has current IRB approval, has sufficient protections for subject confidentiality and safety, the appropriateness of using the Registry as a research or recruitment tool.

3) Once an investigator meets all Registry application processes, the Registry Coordinator will request a chart string in order to submit a database query[1], which will result in the number of women that match the selected criteria. A study specific letter will be sent to women who meet the basic criteria of the given study, informing them of their selection as a potential study subject. If there are no objections from a woman after a two week opt-out period, her contact information is released to the investigator (or study coordinator) who will follow up to discuss the study. (***Note: PIs and staff members of approved studies will not have direct access to the Registry database. Registry staff will perform database inquiries to determine who may be eligible based on the study's inclusion/exclusion criteria. Study investigators will only be given necessary contact information regarding participants***).

4) After the participant is contacted by an approved investigator, all procedures and confidentiality issues will fall under the investigator's approved research protocol.

5) Registry participants may or may not elect to become a subject in an approved research study. This will not affect their ability to remain in the Registry database and to be potentially selected for other research projects.

6) The Registry staff is working with IT staff to develop a method for flagging records of participants who agree to participate in research studies that they learned about through the Registry. This is important because inclusion in an on-going study may potentially make them ineligible for another investigator's protocol. Since we have not yet developed the software to coordinate this process efficiently, we ask that study coordinators diligently provide us with **monthly updates** on their enrollment progress. This way we can keep track of who has enrolled in specific studies vs. who is available to be contacted for another study.

7) In some cases investigators who have gone through the Registry approval procedures as described above, will have a research project that involves population and statistical research using the information from the Registry database. For these types of statistical-based studies, Registry staff will provide investigators with de- identified data. Such data will not include any identifying information (for instance name or address) and not require any notification of the Registry members. The informed consent process does inform the participant that their de-identified data may be used for such purposes.

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[1] All queries are performed through EDW, which charges to run database queries of the Registry. Our staffing services are provided free of charge, but database queries can cost $160 to $460, depending on the complexity of the query. Therefore, a chartstring is required for this cost.