

SAMPLE RESEARCH REGISTRY PROTOCOL (9.07)

Center for XX Disease Research Registry

Objective and Specific Aims:

The objective of this project is the development of a Center for XX Disease Research Registry for the purpose of:

1. performing retrospective research studies on XX disease; such research involving analyses of the medical record information of patients seen by the Center for XX Disease who agree to allow their medical record information to be recorded in the Research Registry.
2. permitting review of medical record information contained within the Registry to identify patients who may be eligible for participation in future research studies conducted by the Center for XX Disease.
3. obtaining the permission of Research Registry participants to be contacted to ascertain their interest in participating in future research studies being conducted by the Center for XX Disease for which it appears (i.e., based on medical information contained within the Research Registry) they may be eligible.

Background and Significance:

In accordance with Federal regulations and institutional policies, research or research procedures (e.g., potential research subject identification and recruitment) involving the use of identifiable medical record information (a.k.a., protected health information) requires the prior written informed consent (a.k.a., authorization) of the respective patients-subjects. Patients seen at the Center for XX Disease will be asked to provide their written informed consent (authorization) to allow their identifiable medical record information related to their XX disease to be placed in Center's Research Registry for the purpose of facilitating retrospective research studies directed at XX disease, and the identification and recruitment of potential, eligible subjects for participation in future research studies involving XX disease.

Research Design and Methods:

Participation in the Center for XX Disease Research Registry is limited to placement of the subjects' identifiable medical information related to their XX disease in a research database (i.e., the Research Registry) and the use of this information for retrospective research studies directed at XX disease, and/or for the identification and recruitment of potential, eligible subjects for participation in future research studies involving XX disease.

1. Patients seen by the Center for XX Disease will be asked to provide their written

informed consent to allow their past, current and future identifiable medical record information related to their XX disease to be placed in the Center for XX Disease Research Registry. The medical record information that will be placed in the Research Registry will be related directly to the patients'-participants' XX disease. However, since concurrent medical conditions and treatments (i.e., not related directly to XX disease) may impact substantially the patients'-participants' XX disease, it is likely that all of the patients'-participants' past, current and future identifiable medical record information will be placed in the Research Registry.

- a) Patients will be asked to provide their permission for the use of this information for retrospective research studies directed at XX disease; such research to be conducted by the Center for XX Disease investigators.
- b) Patients will be asked to provide their permission to allow Center for XX Disease investigators to review this information to determine if the patients-participants may be eligible for participation in future research studies being conducted by Center for XX Disease investigators.
- c) Patients will be asked to provide their permission to allow Center for XX Disease research staff to contact them (i.e., based on a determination of their potential eligibility) to ascertain their interest in participating in future research studies being conducted by Center for XX Disease investigators.

Interested Research Registry participants contacted for possible participation in future research studies being conducted by Center for XX Disease investigators will undergo a separate informed consent process for each such research study.

2. Participant medical information will be stored electronically within the Research Registry. The names, social security numbers, and medical record numbers of the Research Registry participants will be deleted from their stored medical information and replaced with a linkage code. Access to participant medical information contained within the Research Registry will be restricted to Center for XX Disease investigators.
 - a) Information linking the linkage codes to the participants' names, social security numbers and medical record numbers will be stored in a secure location separate from the medical information. Access to the information linking the linkage codes with participant names, social security numbers and medical record numbers will be granted only to Center for XX Disease investigators on a need-to-know basis as approved by the Principal Investigator of this Research Registry. Access to the information linking the linkage codes with participant identifiers shall be documented.
 - b) Participant medical record information will be stored in the Research Registry

for an indefinite period of time.

3. The Principal Investigator of the Research Registry must approve all retrospective research studies being conducted by Center for XX Disease investigators using medical information contained within the Research Registry. Such approvals shall be obtained prior to providing investigator access to the Research Registry information; shall be based upon considerations of scientific quality and validity; shall be granted only for research studies related to XX Diseases; and shall be documented. Access of Center of XX Disease investigators to the Research Registry for the purpose of performing retrospective research studies shall be documented.
4. Participant medical record information contained within the Research Registry may be provided to secondary research investigators (i.e., research investigators who are not affiliated with the Center for XX Disease). However, prior to its provision to any secondary investigator, the information shall be de-identified. The Center for XX Disease shall require secondary investigators to obtain IRB approval of an “exempt” research application prior its provision of de-identified information to the secondary investigator.
5. Participants will not be informed of the results of retrospective research studies involving the use of the use of their medical record information contained with the Research Registry.
6. Access of Center for XX Disease investigators to information contained within the Research Registry for the purpose of determining if the participants may be eligible for participation in a research study shall be granted only upon evidence of IRB approval of the research study for which access is being requested. Access of Center of XX Disease investigators to the Research Registry for the purpose of identifying potential subjects for participation in a research study shall be documented.

Human Subjects:

Individuals to be approached for participation in this Research Registry will include all adult (age \geq 18 years old) patients who are receiving or seeking medical care at the Center for XX Diseases Clinic. Note that Center for XX Diseases Clinic does not provide medical care to children; thus forming the basis for their exclusion as potential participants in the Research Registry. Due to the complexity of state and federal requirements governing the participation of prisoners in research, prisoners-patients shall not be approached for participation in the Research Registry. Since participation in the Research Registry does not involve a risk of physical harm, women of childbearing potential will not be queried as to pregnancy status or tested for pregnancy. There are no additional inclusion/exclusion criteria.

The racial, gender and ethnic characteristics of the individuals approached for participation in this Research Registry shall reflect the demographics of patients receiving or seeking medical

care at the Center for XX Diseases Clinic. We shall attempt to recruit participants in accordance with these demographics. No individuals shall be excluded from participation in the Research Registry based on race, ethnicity, gender or HIV status.

Recruitment Procedures:

All patients who are receiving or seeking medical care at the Center for XX Diseases Clinic will be invited to participate in the Research Registry. Potential participants will be approached by a member of the Clinic staff and will be asked to review a copy of the informed consent form prior to being seen by a Clinic physician (i.e., Research Registry investigator). The Clinic physicians (i.e., Research Registry investigators) will review the informed consent form with potential participants and address any questions or concerns prior to obtaining written informed consent for Research Registry participation. The Clinic physicians (i.e., Research Registry investigators) will also address any future questions or concerns of Research Registry participants.

Only the medical record information of patients who have provided directly their written informed consent for Research Registry participation will be placed in the Research Registry. The participation of patients who are mentally incapacitated (e.g., comatose, unresponsive) will not be sought (i.e., during the period in which they are mentally incapacitated).

Potential Risks of Research Registry Participation:

There are no risks of physical harm associated with participation in the Research Registry. Participation in the Research Registry does involve the potential risks of a breach of confidentiality of the medical record information and associated privacy of the participants. Such risks will be minimized by 1) removing direct participant identifiers (i.e., names, social security numbers, medical record numbers) from information stored in the Research Registry; 2) securing, in a separate location, and limiting access to information linking codes (i.e., linkage codes) assigned to the Registry information with direct participant identifiers; and 3) limiting access to information contained within the Research Registry to Center for XX Disease investigators.

The data and safety monitoring plan for the Research Registry will involve routine (i.e., quarterly) monitoring by the Principal Investigator of 1) the removal of direct identifiers from information contained within the Research Registry; 2) the documentation of investigator access to the Research Registry; 3) the security of the database linking the Research Registry linkage codes with participant identifiers and the documentation of investigator access to this database; and 4) any conditions that may negatively impact the confidentiality of information contained within the Research Registry. As specified previously, the Principal Investigator must provide approval for a Center of XX Disease investigator to access the research registry for retrospective research studies involving the use of Registry information. The Principal Investigator must also prior approve any access of Center for XX Disease investigators to the database linking the Registry information to participant direct identifiers. Access of Center for XX Disease investigators to the Research Registry for the purpose of identifying potential subjects for participation in a research study shall be granted only upon the provision of documentation that the IRB has approved the respective research study. At the time of annual renewal, a list of

studies conducted using the registry will be submitted to the IRB. In addition, any unauthorized access to medical record information contained within the research registry or to the database linking the Registry information to participant direct identifiers shall be reported to the IRB.

Potential Benefits of Research Registry Participation:

There are no direct benefits associated with participation in the Research Registry. The use of information contained within the Research Registry for retrospective research analyses may be of future benefit to patients with XX diseases. Participants in the Research Registry will be informed of future research studies involving XX diseases for which they may be eligible. Participation in a future research study involving XX disease, for which separate informed consent will be obtained, may offer direct benefit to Research Registry participants.

Costs and Payments:

All costs associated with the implementation and maintenance of the Research Registry shall be supported by the Center for XX Diseases. No costs will be incurred by Registry participants or their health care providers. Center for XX Disease patients will not be remunerated for their participation in the Research Registry.