Published in final edited form as:

Virtual Mentor. ; 14(8): 653–656. doi:10.1001/virtualmentor.2012.14.8.pfor2-1208.

Certificates of Confidentiality and the Personalized Medicine Research Project

Wendy Foth [research coordinator],

Center for Human Genetics at the Marshfield Clinic Research Foundation, Marshfield, Wisconsin

Carol Waudby [research coordinator], and

Center for Human Genetics at the Marshfield Clinic Research Foundation, Marshfield, Wisconsin

Murray H. Brilliant, PhD [Director]

Center for Human Genetics at the Marshfield Clinic Research Foundation and is the PI for the Personalized Medicine Research Project, Marshfield, Wisconsin. Dr. Brilliant conducts research on complex Human Genetic Disorders

Participation in research studies is often limited by the fear that a participant's personal information cannot be kept private. One way researchers can address this is by obtaining a Certificate of Confidentiality for their study. This article briefly reviews what a Certificate of Confidentiality is, how to obtain one, and the Marshfield Clinic's experience in recruiting for the Personalized Medicine Research Project.

Certificate of Confidentiality (CoC)

Protecting privacy and confidentiality of participants is paramount in the recruitment for research studies. In developing research studies, every effort to protect the information that participants have allowed us to collect needs to be thoroughly planned, developed, and implemented. How this protection will be accomplished also needs to be conveyed to the research participants. One of the resources available for maintaining privacy and confidentiality is a Certificate of Confidentiality (CoC), Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)).

Intent of CoC

Issued by a limited number of Department of Health and Human Services (DHHS) agencies, a CoC allows researchers to "refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level" (<http://grants1.nih.gov/grants/policy/coc/index.htm>). With this additional level of protection in place, it helps researchers maintain the privacy and confidentiality of participants and helps promote participation in the research study by assuring specific legal aspects of confidentiality.

Qualifications for a CoC

1. This study will collect sensitive personally identifiable information; and/or
2. This study will maintain consent forms with identifiable information other than names (e.g., social security numbers, addresses, etc.).
3. This study cannot be conducted anonymously—that is, the research itself relies on personally identifiable data to gather data.
4. The study subject matter falls within the research mission of the NIH and its Institutes, Centers, and Offices.

5. Data is maintained within the United States.

Obtaining a CoC

To obtain a CoC, the first step is to determine the appropriate person to contact about the application and questions. This is determined by who is supporting the research. The CoC Kiosk, located at <http://grants.nih.gov/grants/policy/coc/>, has a flow chart to help establish this first step.

Some DHHS Institutes/Centers have an on-line application process and others require a letter of application detailing the research project, how privacy and confidentiality will be maintained, and the reasons a CoC would be appropriate and necessary to possess for the research.

Researcher's Responsibilities

There are certain responsibilities that are acquired once a CoC has been obtained. The study subjects must be informed that a CoC has been obtained, and they must be told what protections are offered under the CoC, as well as the limitations of a CoC. Also, the institution obtaining the CoC must submit an amendment application for any significant changes; this would include changes in personnel holding a major role in conducting the study, changes to the aim of the study, and changes in drugs being administered. An amendment application should be submitted 3 months prior to the changes being activated.

Marshfield Clinic's Personalized Medicine Research Project

The Personalized Medicine Research Project (PMRP) is a large cohort of residents of Central and Northern Wisconsin [1]. This database, which includes genetic, medical, and environmental information, is maintained by the Marshfield Clinic Research Foundation [2]. The main goals of the project are to better understand the role of genetics, environment, and behavior in the development of disease and response to medications and how to use this information to enhance personalized patient care. A CoC was applied for and issued as an additional layer of protection for participants' privacy. It was felt that this additional layer of protection had the potential to increase the willingness of participants to enroll. Increased enrollment would help strengthen the scientific value of the studies utilizing PMRP's bio-bank by obtaining a more accurate representation of the population, thus allowing for more powerful associations with genetics, phenotypes, and the environment.

Informed Consent for PMRP

At an enrolling appointment, the informed consent is thoroughly reviewed with the participant [3]. This is completed through a one-to-one consenting process or via a computer generated consenting process (kiosk) that has been developed. The PMRP participants are informed of the CoC using the following language in our current informed consent processes:

"We have a Certificate of Confidentiality from the National Institutes of Health. This helps us to protect your privacy. With the Certificate, researchers will not be forced to give out information that could identify you in any federal, state, or local court matter."

We have also incorporated CoC information into the Frequently Asked Questions (FAQ) literature that is available for people to review on our website (http://www.marshfieldclinic.org/chg/pages/default.aspx?page=chg_pers_med_res_prj), as part of

the computer consent or in print. The website links to our current CoC document, as does the computer assisted consent. The language reads as follows:

“To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.”

Ultimately, the level of trust and confidence an individual has in the facility/institution undertaking the research will be the best indicator of participation. It is still important and necessary to explain what measures are in place to protect their privacy and confidentiality. Having layers of protection—internal, external, and governmental—is a way of showing how seriously maintaining the security of the information that they allow us to obtain when participating in the research is taken. Having government involvement may or may not help participation. Some participants will have confidence in the government involvement, some will be neutral, and some may even distrust the involvement. Some people opt not to participate due to concerns of privacy, especially related to insurance, and no amount of security measures will be enough for them. This is understandable, as there is never a 100% guarantee of protection of privacy and confidentiality under any security system that can be put into place.

Acknowledgments

Research presented in this paper is supported by grant 1UL1RR025011 from the Clinical and Translational Science Award (CTSA) program of the National Center for Research Resources, and NHGRI grant No. 1U01HG006389-01 IRIS: Incorporating Research into Saving Sight, National Institutes of Health. The authors thank Marie Fleisner of the Marshfield Clinic Research Foundation for editorial assistance in the preparation of this article.

References

1. McCarty CA, Wilke RA, Giampietro PF, Wesbrook SD, Caldwell MD. Marshfield Clinic Personalized Medicine Research Project (PMRP): design, methods and recruitment for a large population-based biobank. *Personalized Medicine*. 2005; 2:49–79.
2. Strobush L, Berg R, Cross D, Foth W, Kitchner T, Coleman L, McCarty CA. Dietary intake in the Personalized Medicine Research Project: a resource for studies of gene-diet interaction. *Nutr J*. 2011 Jan 28;10:13. [PubMed: 21276236]
3. McCarty CA, Nair A, Austin DM, Giampietro PF. Informed consent and subject motivation to participate in a large, population-based genomics study: the Marshfield Clinic Personalized Medicine Research Project. *Community Genet*. 2007; 10(1):2–9. [PubMed: 17167244]