

**New for investigators: Survey/Questionnaire Cover Letter Template**

The IRB may waive the requirement to obtain a signed consent document for some or all of the subjects if certain conditions are met. For example, your research may meet the conditions for this waiver if you are conducting a mail survey, telephone survey, internet research, or international research where recruitment of subjects would be inhibited based on cultural beliefs. In order for the IRB to consider approval for waiving this requirement, the IRB requests that you mark the appropriate selection on "Form A", complete "Form F" and submit it with your application. ORI has developed a **Cover Letter Template** guide for use with survey or questionnaire studies that have or are applying for a waiver of the requirement to **document** informed consent. See [IRB Forms Page](#)

<b>Form F</b>	<b>Request for Waiver of Documentation of Informed Consent Process</b> [WORD] [RTF] Revised 8/4/06  <b>Cover Letter Template</b> (survey/questionnaire research) [WORD] [RTF] Revised 4/2/09	<b>Form F Instructions</b> <a href="#">[HTML]</a>
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Even if a waiver from the requirement to obtain a signed consent document applies to your research, you may still need to provide information to individuals about the research so they have the knowledge and opportunity to consider whether or not to participate. The **Cover Letter Template** serves as a guide and ensures that required consent elements are included.

**DSMP vs. DSMB ... What's the difference???**

Clinical research investigators develop **data and safety monitoring plans (DSMP)** as a mechanism for assuring the safety of human subjects, the validity of research data and the appropriate termination of studies. The IRB requires review and approval of DSMPs for greater than minimal risk research, clinical research, or NIH funded/FDA regulated clinical investigations.

A sponsor or investigator may include as part of the plan, a **Data and Safety Monitoring Board (DSMB)**. Required for investigator-initiated clinical protocols and associated with most large multi-site clinical trials, a DSMB is an impartial, independent group developed according to specific guidelines to review the progress and results of a clinical research trial. Unique to the DSMB, is the ability to view un-blinded data for the entire trial to consider the overall picture including primary and secondary analysis relative to safety. Based on this assessment, the DSMB may recommend continuation of a study or early termination due to positive efficacy or unfavorable benefit-to-risk ratio. If a DSMP or DSMB applies to the research, the investigator indicates and describes on the initial IRB application ("Form A" and "Form B"). If the protocol includes a DSMP or DSMB, the investigator submits the DSMP/DSMB summary reports at continuation review time if available, and as a Modification Request at any other time they are provide to the investigator by the board or sponsor. See [ORI Resources on Data and Safety Monitoring](#) for more information.

**GINA**

OHRP has posted on its website a finalized guidance document entitled, "[Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and IRBs](#)". The document reviews protections provided by the Genetic Information Nondiscrimination Act of 2008 (GINA) and requirements for obtaining informed consent in genetic research. Among the risks typically associated with genetic research, investigators and IRBs have identified the potential adverse impact on insurability or employability if genetic information about the subject obtained as part of the research was disclosed to, or sought by, insurers or employers. When the provisions of GINA take effect, the risk of such harms will be decreased with respect to health coverage and most employment. Even though the provisions of GINA do not take place until later this year, investigators and IRBs need to be aware that GINA has implications for how risks are described for genetic research conducted prior to these effective dates. Regardless of when genetic information was obtained, GINA restricts the use of such information.

**New from CITI**

In addition to initial and continuing human research protection training, ORI has subscribed to the following optional training courses available at [www.citiprogram.org](http://www.citiprogram.org). ORI will not track completion of the optional courses so if you choose to complete one, be sure and print documentation for your records.

- HIPAA**
- Biomedical Responsible Conduct in Research (RCR)**
- Social and Behavioral Responsible Conduct in Research (RCR)**
- Good Clinical Practice (GCP)**
- Buenas Prácticas Clínicas en Español**

[CITI Registration Instructions](#)

