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## Section 6.10 -- Research Activities

REVISION DATE	CHANGE NUMBER	CHANGE
3/23/2011	1	<a href="#">Click Here To See Red Letter Version</a>
10/15/04	1	<p><b>POLICY:</b> Change from:</p> <p>Any request to conduct research in, or use records from, local or regional health departments from an agency or individual not employed or working on behalf of the Department of Health must be reviewed by the Health Services Research Review Committee of the Bureau of Health Services.</p> <p>To:</p> <p>Any request to <b>utilize records, patient specimens, or patients</b> to conduct research in, <del>or use records from,</del> local or regional <b>or the state</b> health departments <del>from an agency or individual not employed or working on behalf of the Department of Health</del> must be reviewed by <del>the Health Services Research Review Committee of the Bureau of Health Services.</del> <b>Institutional Review Board (IRB) of the Tennessee Department of Health (TDH). Policies outlined in 46CFR45, Protection of Human Subjects, will be followed in conducting all research. (1)</b></p> <p><b>CHANGE REASON:</b> The only change to this policy involves the deletion of the requirement that prior to being reviewed by the Tennessee Department of Health's Institutional Review Board (TDH IRB), a research project must first be reviewed by a three member committee of the Bureau of Health Services. The original purpose of this committee was to determine if it was necessary for a project to proceed to the TDH IRB, or whether it could be approved by the smaller committee as being exempt from TDH IRB review. Since all projects are now routinely routed to the Chair of the TDH IRB, who routinely makes this same determination, the review by the Bureau committee represents an unnecessary duplication of effort.</p>
10/15/04	2	<p><b>APPLICABILITY:</b> Change from:</p> <p>This policy applies to all offices under the auspices of the Bureau of Health Services.</p>

		<p>To:</p> <p>This policy applies to all offices under the auspices of the Bureau of Health Services. <b>Research should be distinguished from certain routine public health activity. The distinction is not always clear cut. CDC has identified three critical areas of public health practice for which confusion exists. These are public health surveillance, emergency responses, and program evaluation. The intent of the activity is a distinguishing feature. The intent of research is to contribute to generalizable knowledge. The intent of public health practice is to conduct programs to prevent disease and injury and improve the health of communities.(2)</b></p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	3	<p><b>PROCEDURE, 1st Paragraph:</b> Change from:</p> <p>If an agency or individual not employed or working on behalf of the Department of Health requests permission to conduct research in or use records from a local or regional health department, a written request should be directed to the Health Services Research Review Committee in the Bureau of Health Services. The Health Services Research Review Committee is made up of the Bureau of Health Services Medical Director, or designee, and representatives from the Department's Office of General Counsel and the Bureau of Health Services Assessment and Planning Section.</p> <p>To:</p> <p>If an agency or individual <del>not employed or working on behalf of the Department of Health</del> requests permission to conduct research in or use records from a <del>local or regional health department,</del> <b>the Tennessee Department of Health (local, regional or state)</b> a written request should be directed to the <del>Health Services Research Review Committee in the Bureau of Health Services.</del> <b>Chairperson of the Institutional Review Board of the Tennessee Department of Health.</b> The Health Services Research Review Committee is made up of the Bureau of Health Services Medical Director, or designee, and representatives from the Department's Office of General Counsel and the Bureau of Health Services Assessment and Planning Section.</p>

		<b>CHANGE REASON: Same as above</b>
10/15/04	4	<p><b>POLICY, 3rd paragraph, 4th sentence:</b> Change from:</p> <p>There must be written approval from the local health department or regional office participating in the research.</p> <p>To:</p> <p>There must be written approval from the local, health department or regional <b>or Tennessee Department of Health</b> office participating in the research.</p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	5	<p><b>POLICY: 4th paragraph:</b> Change from:</p> <p>The Health Services Research Review Committee will review the request and give final approval or denial. If appropriate, the committee may refer the request to the Department of Health's IRB which includes both provider and consumer representatives. The types of research that only require review by the Health Services Research Review Committee include:</p> <p>To:</p> <p><del>The Health Services Research Review Committee</del> <b>The Tennessee Department of Health Institutional Review Board</b> will review the request and give final approval or denial <b>or the Chairperson or designee IRB member may be able to exempt the study from IRB review.</b> <del>If appropriate, the committee may refer the request to the Department of Health's IRB which includes both provider and consumer representatives. The types of research that</del> <b>may qualify for exemption include</b> <del>only require review by the Health Services Research Review Committee include:</del></p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	6	<p><b>PROCEDURE, 5th paragraph, 1st sentence:</b> Change from:</p> <p>If the Health Services Research Review Committee identifies components of the proposed research which require approval by the IRB, the request will be forwarded to that committee. The types of research which require review by the IRB include:</p> <p>To:</p>

		<p>If the <b>Chairperson or designee Institutional Review Board Committee member</b> <del>Health Services Research Review Committee</del> identifies components of the proposed research which require approval by the IRB, the request will be forwarded to that committee. The types of research which require review by the IRB include:</p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	7	<p><b>PROCEDURE, 5th paragraph, bullet #1, sentence #1:</b> Change from:</p> <p>Research that involves obtaining information through intervention or interaction with the individual other than the types of intervention and interaction previously listed as requiring Health Services Research Review Committee approval only.</p> <p>To:</p> <p>Research that involves obtaining information through intervention or interaction with the individual other than the types of intervention and interaction previously listed as <b>qualifying for exemption</b> <del>requiring Health Services Research Review Committee approval only.</del></p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	8	<p><b>EXCEPTIONS, 1st paragraph:</b> Change from:</p> <p>Any records for which access is specifically allowed by Tennessee Law will not be covered by these guidelines. For example, confidential vital records information may be released to researchers without review by the Human Subjects Research Committee in accordance with the Vital Records statute and regulations.</p> <p>To:</p> <p>Any records for which access is specifically allowed by Tennessee Law will not be covered by these guidelines. For example, confidential vital records <del>information</del> <b>and other registries and databases</b> may be released to researchers without review by the <b>Institutional Review Board</b> <del>Human Subjects Research Committee</del> in accordance with the Vital Records statute, <del>and regulations</del> <b>and Institutional Review Board policies such as the policies of the Health Data Policy Committee.</b></p>

		<b>CHANGE REASON: Same as above</b>
10/15/04	9	<p><b>OFFICE OF PRIMARY RESPONSIBILITY, telephone #:</b> Change from:</p> <p>(615)741-7305</p> <p>To:</p> <p>(615)741-7305532-2431</p> <p><b>CHANGE REASON: Same as above</b></p>
10/15/04	10	<p><b>New section: References at end of document: Add:</b></p> <p>References:</p> <ol style="list-style-type: none"> <li>1. Office for Protection from Research Risks, National Institutes of Health. Protection of Human Subjects. CFR Title 45, Part 46. Bethesda: OPRR; Revised 1991, 1998.</li> <li>2. Snider, DE, Stroup, DF Defining Research When It Comes to Public Health. Public Health Reports 1997; 112:29-32.</li> </ol> <p><b>CHANGE REASON: Same as above</b></p>
12/29/1999	1	<b>PROCEDURE, 1st paragraph, 1st sentence:</b> Delete "the health department selected to participate in the research should forward"
12/29/1999	2	<b>PROCEDURE, 1st paragraph, 1st sentence:</b> Change "a written request to the Health Services Research Review Committee" to "a written request should be directed to the Health Services Research Review Committee"
12/29/1999	3	<b>PROCEDURE, after 1st paragraph:</b> Add new paragraph "The request to conduct research is to include a concise description of the study, including objectives, design, and methods. The study description must address informed consent and confidentiality. An informed consent form must be included with the proposal."
12/29/1999	4	<b>PROCEDURE, 3rd paragraph, after 3rd sentence:</b> Add new sentence "There must be written approval from the local health department or regional office participating in the research."
12/29/1999	5	<b>OFFICE OF PRIMARY RESPONSIBILITY:</b> Change "(615)532-6369" to "(615)741-7305"

