

<p style="text-align: center;"><b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> FOOD AND DRUG ADMINISTRATION</p> <p style="text-align: center;"><b>STATEMENT OF INVESTIGATOR</b> <i>(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)</i> (See instructions on reverse side.)</p>	<p>Form Approved: OMB No. 0910-0014. Expiration Date: May 31, 2009. See OMB Statement on Reverse.</p>
	<p><b>NOTE:</b> No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).</p>
<p>1. NAME AND ADDRESS OF INVESTIGATOR</p>	
<p>2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.</p> <p style="text-align: center;"><input type="checkbox"/> CURRICULUM VITAE      <input type="checkbox"/> OTHER STATEMENT OF QUALIFICATIONS</p>	
<p>3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.</p>	
<p>4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.</p>	
<p>5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE</p>	
<p>6. NAMES OF THE SUBINVESTIGATORS (<i>e.g., research fellows, residents, associates</i>) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).</p>	
<p>7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL IN THE IND FOR THE STUDY TO BE CONDUCTED BY THE INVESTIGATOR.</p>	