

Goals / Definitions

Conduct Formative Human Factors study and make assessment to modify design as needed.

A study conducted on a combination product prototype user interface at one or more stages during the iterative product development process to assess user interaction with the product and identify potential user errors.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> Formative Human Factors Study completed 	<ul style="list-style-type: none"> a) Results from Human Factors Studies to optimize the device design b) Updated risk assessments based on the results of these studies and develop risk mitigation strategies as needed c) Modified interface design, Instructions for Use, and/or training to address the problems found d) Re-testing to assess whether mitigation strategies effectively reduced the known risks and did not introduce any new risks 	