

WORKSHEET: Quality Activity Determination

NUMBER	DATE	PAGE
12.205 (HRP-334)	5/1/2024	1 of 1

The purpose of this worksheet is to provide support for making Quality Activity determinations when there is uncertainty regarding whether the quality activity contains Human Research requiring IRB Review.

Directions: For a proposed project to be classified as containing only quality activities—which do not require IRB review—the answers to all of the questions in the WORKSHEET must be 'TRUE' for each activity proposed in the project. If one or more answers is 'FALSE or NOT SURE', the project requires IRB review.

<i>True</i>	<i>False or Not Sure</i>	
<input type="checkbox"/>	<input type="checkbox"/>	The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained.
<input type="checkbox"/>	<input type="checkbox"/>	No activity proposed provides less than standard of care, services or instruction to participants.
<input type="checkbox"/>	<input type="checkbox"/>	No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice.
<input type="checkbox"/>	<input type="checkbox"/>	The proposed activity does not: (1) include a 'control group' in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization.
<input type="checkbox"/>	<input type="checkbox"/>	The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications).
<input type="checkbox"/>	<input type="checkbox"/>	The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge.
<input type="checkbox"/>	<input type="checkbox"/>	The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity.
<input type="checkbox"/>	<input type="checkbox"/>	The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable.
<input type="checkbox"/>	<input type="checkbox"/>	Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed.
<input type="checkbox"/>	<input type="checkbox"/>	The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it.

Visit [Identifying Human Subject Research | Rutgers Research](#) to view the steps recommended for researchers to follow to assess whether their quality project includes activities requiring IRB review and approval.