UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-320 WORKSHEET:** Scientific or Scholarly Review		
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The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet, or equivalent, to determine whether the research has scientific or scholarly validity. IRB members conducting scientific or scholarly review are to use this worksheet, or equivalent, but do not need to complete or retain it. Consultants providing scientific or scholarly review may complete this worksheet, or equivalent, and provide it to Office of IRB Administration (OIA) staff.

	1 Overall Scientific and Scholarly Validity (Check if **"Yes."** All must be checked)
☐	Does the protocol accurately describe the research in a clear, detailed protocol in terms of? • Objectives • Background • Setting • Procedures • Data and safety monitoring plan • Risks • Potential benefits • Alternatives to participation
☐	Have the risks of the study been appropriately minimized to protect subjects and still answer the study's hypothesis?
☐	Does the study include sufficient procedures to assess subject safety (e.g. lab tests, imaging, clinical/psychological questionnaires, etc.)?
☐	If carried out as proposed, is the study likely to provide an answer to its overall hypothesis and thus at least provide benefit to society, if not to the subjects?
☐	Are the stated benefits, whether to society or individual subjects, realistic?
	2 Additional Risk/Benefit Considerations for Clinical Trials (Check if **"Yes"** or **"N/A."** All must be checked if the research is a clinical trial.)
☐	Is there sufficient information regarding the investigational product to determine whether the risk/benefit ratio is appropriate to justify the study? NOTE: In Phase 1 (first in human) studies, this may be limited to pre-clinical data.
☐	The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
☐	There is adequate expertise from the study personnel to safely conduct the study (e.g. a study of a medical device or treatment includes a physician with expertise in condition of study).

Comment on the above: