**Protocol Title:**

**Principal Investigator:**

**Reviewer:**

**Date Assigned:**

**Date Completed:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| QUESTION | Yes (Y) | No (N) | NA | Comments |
| Is the **hypothesis clearly stated**? |  |  |  |  |
| Is the question or **hypothesis important** to the knowledge of the field? |  |  |  |  |
| Has an appropriate **literature search** been performed? (When risks to the subjects are high, an extensive search is essential) |  |  |  |  |
| Will **study design** address the question asked? |  |  |  |  |
| Are the **inclusion and exclusion criteria** clearly defined and are they appropriate?  Is there adequate discussion of **sample size** (convenience sample vs. power calculations)?  Is the study **feasible** (i.e., is it reasonable to achieve the results in the proposed timeframe, including the ability to recruit, retain, or follow subjects)? |  |  |  |  |
| Is there **chart review** in this protocol?  If so, is there justification for the specific data being collected? (not a fishing expedition) |  |  |  |  |
| Is there a **survey** in this protocol?  If so, is it a validated survey?  If it is not validated, are steps spelled out to explain how the survey was created? (multiple experts, cognitive interviewing, pilot testing etc.)  If the survey has questions about mental health, is there provision for a mental health provider to respond to results within 24 hours? |  |  |  |  |
| QUESTION | Yes (Y) | No (N) | NA | Comments |
| In the design of the study, are **all tests and measurements appropriate and necessary** to answer the research questions? |  |  |  |  |
| Are the individuals who are conducting the trial **properly qualified and trained** to perform the procedures included in the protocol? |  |  |  |  |
| Are the endpoints and criteria for evaluation clearly defined?  Is there a measurable outcome? |  |  |  |  |
| Does this protocol present minimal risk?  Is this an acceptable risk to patients? |  |  |  |  |

Overall Recommendations: (Approve, Revise or Reject?) (If reject – scientifically or ethically unfeasible?)

\_\_\_\_\_ Approve

\_\_\_\_\_ Revise

\_\_\_\_\_ Reject

Additional Comments: