# RC Reviewer Worksheet

| Protocol Title: | | |
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| RC #: | Principal Investigator: | Reviewer: |

**This worksheet is a guide/help for reviewing projects. Its goal is to help guide your review of a study and remind you of what the IRB will eventually be asking of it.**

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| **Stakeholders:**<br>What OSH research stakeholders should be contacted regarding this project? | Comments: |
| **Writing:**<br>Do you have any comments/concerns regarding the writing in the documents? | Comments: |
| **Research Design / Methodology:**<br>Do you have any comments/concerns regarding the research design or methodology in the documents? | Comments: |
| **Hypothesis / Specific Aims:**<br>Do you have any comments/concerns regarding the hypothesis or specific aims in the documents? | Comments: |
| **Data Analysis / Statistics:**<br>Do you have any comments/concerns regarding the data analysis or statistic sections in the documents? | Comments: |
| **Data Collection:**<br>Do you have any comments/concerns regarding the proposed data collection in the documents? | Comments: |
| **Information or Document Request:**<br>Would you like to see any additional documents or added information regarding this project? | Comments: |
| **Consent:**<br>Do you have any comments/concerns regarding the consent form or process in the documents? | Comments: |
| **HIPAA / Private Health Information:**<br>Do you have any comments/concerns regarding the protection of health information in the documents? | Comments: |
| **Sample Selection:**<br>Do you have any comments/concerns regarding the sample selection or size in the documents? | Comments: |
| **Other:**<br>Do you have any comments/concerns regarding any other areas of the documents? | Comments: |

| **Issues Related To IRB Review** | |
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| **Risks are minimized:**<br>Risks are minimized by using procedures that are consistent with sound research design and which do not expose subjects to unnecessary risk<br>Is the importance of the scientific question sufficient to merit inclusion of human subjects? | Comments: |

| **Risks are reasonable:** | Comments: |
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| Risks to subjects are **reasonable** in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result.<br>Consider physical, psychological, social, economic, and legal risks.<br>What is the risk level? Is there prospect of benefit to subjects?<br>Will the research achieve the objectives proposed? | |

| **Subject selection is equitable:** | Comments: |
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| • The purposes of the research<br>• The setting where it will conducted<br>• Vulnerable prospective participants / coercion<br>• The inclusion/exclusion criteria<br>• Recruitment & enrollment procedures<br>• The influence of payments to participant<br>Who will be enrolled? OSH patients? Decisionally impaired patients? Are these subjects appropriate for the protocol? What is the rationale for inclusion/exclusion? | |

| **Adequate Resources:** | Comments: |
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| Will the investigator have access to a population that will allow recruitment of the required number of subjects? Will the investigator have adequate numbers of qualified staff? Have available medical or psychological resources? Sufficient time to conduct and complete the research? | |

| **Informed consent process:** | Comments: |
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| Will the investigator obtain informed consent of the subject or their legally authorized representative? Will the circumstances of the consent process provide sufficient opportunity for the subject to consider whether or not to participate? Will the circumstances of the consent process minimize the possibility of coercion or undue influence? | |

| **Informed consent form:** | Comments: |
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| Does the informed consent document include the basic element of consent?<br>Is the consent document understandable to subjects? | |

| **Data monitoring:** | Comments: |
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| When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of subjects.<br>When appropriate does the protocol include a monitoring plan? | |

| **Privacy and Confidentiality:** | Comments: |
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| When appropriate, there are adequate provisions to protect subject privacy & maintain confidentiality of the data.<br>Does the protocol describe adequate provisions to protect the privacy interests of participant? Will personally identifiable research data be protected to the extent possible from access or use? | |

| **Vulnerable populations:** | Comments: |
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| When appropriate, there are additional safeguards in place when some or all subjects are likely to be vulnerable to coercion or undue influence.<br>Does the research involve OSH patients? Does the application adequately address Subpart C concerns and added protections? Does the research involve subjects who may be educationally or economically disadvantaged, or decisionally-impaired? | |