Reviewer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Proposal Number: \_\_\_\_\_\_\_\_\_\_\_

**Model IRB Proposal Evaluation Worksheet**

Please review the proposals to which you and your group have been assigned. Complete this worksheet for each of the proposals you are reviewing. Include as much feedback as possible on this form so that you can use it in later discussion with your Model IRB Committee. You will submit this worksheet along with the final evaluation worksheet produced by your model committee.

**Evaluation Summary** (complete this section **after** filling out the table below)

Please answer questions one and two based on **your** **own** evaluation of the proposal. After you meet with your Model IRB Committee, you will decide as a group the final IRB action on the proposals you are reviewing and together you will complete a separate worksheet which will be given to the author of the proposal.

1. *Recommended Action* (circle one):

Approve Approve with Revisions Table Disapprove

1. *Comments:*

**Evaluation Instructions**

Evaluate the research proposal in each of the following “proposal element” categories. Select “Yes” if the proposal element is included and “No” if the proposal element is not included. In the “Specific Feedback/Comments” column, include specific recommendations or areas of concern.

|  |  |  |
| --- | --- | --- |
| **PROPOSAL ELEMENT** | **EVALUATION** | **SPECIFIC FEEDBACK/COMMENTS** |
| *Basic Elements* | | |
| Has the Principal Investigator (PI) included a research ethics training certificate with their proposal? | Yes No |  |
| Has the PI included a consent form with their proposal? | Yes No |  |
| **PROPOSAL ELEMENT** | **EVALUATION** | **SPECIFIC FEEDBACK/COMMENTS** |
| Does the study seem feasible, given the PI’s resources? | Yes No |  |
| Are the objectives of the study clearly communicated in the lay summary? | Yes No |  |
| *PI and Participants* | | |
| Has the Principal Investigator (PI) clearly described their relationship with study participants? | Yes No |  |
| Has the PI indicated that they are a superior to study participants? | Yes No |  |
| Has the PI indicated that there is a risk of coercion in this study? | Yes No |  |
| Do *you* perceive any potential for coercion in the relationship between the PI and the study participants? | Yes No |  |
| If there is any risk of coercion in this study, has the PI described how that risk will be minimized? | Yes No |  |
| Has the PI specified how many participants will be in the study (i.e. sample size)? | Yes No |  |

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| --- | --- | --- |
| **PROPOSAL ELEMENT** | **EVALUATION** | **SPECIFIC FEEDBACK/COMMENTS** |
| Is the sample size justified and reasonable? | Yes No |  |
| Could participant privacy be compromised because of the proposed sample size? | Yes No |  |
| Are any study participants members of vulnerable populations? | Yes No |  |
| If any study participants are members of vulnerable populations, are steps taken to protect them? | Yes No |  |
| *Methods* *and Procedures* | | |
| Did the PI describe where and how they would recruit participants? | Yes No |  |
| Is the location and timing of participant recruitment appropriate? | Yes No |  |
| Did the PI include any necessary site permission letters? | Yes No |  |
| Did the PI justify any exclusion of potential participants? | Yes No |  |

|  |  |  |
| --- | --- | --- |
| **PROPOSAL ELEMENT** | **EVALUATION** | **SPECIFIC FEEDBACK/COMMENTS** |
| Did the PI clearly describe their method of data collection and include a copy of their research instrument(s)? | Yes No |  |
| Is the information being collected appropriate to the research question? | Yes No |  |
| Does the PI propose to collect extraneous information (i.e. additional information that is not directly related to the research question)? | Yes No |  |
| If the PI is collecting extraneous information, do they justify the collection of this information? | Yes No |  |
| *Risks and Benefits* | | |
| Are measures are taken to protect the privacy of research participants? | Yes No |  |
| Are measures are taken to protect the confidentiality of data during and after the research? | Yes No |  |
| Are risks and benefits to potential participants adequately described? | Yes No |  |
| Are the broader impacts (i.e. benefit to society) of this research adequately described? | Yes No |  |
| **PROPOSAL ELEMENT** | **EVALUATION** | **SPECIFIC FEEDBACK/COMMENTS** |
| Do *you* think that this research could pose any possible risks to any stakeholders in this research? | Yes No |  |
| Are all risks are minimized to the greatest extent possible? | Yes No |  |
| Are the risks of this research reasonable relative to its benefits? | Yes No |  |
| *Consent* | | |
| Are all consent and assent items written in clear and understandable language? | Yes No |  |
| Is an information sheet for participants included? | Yes No |  |
| Are risks and benefits associated with participation clearly and thoroughly described in the consent form and information sheet? | Yes No |  |
| Do the consent form and information sheet include a description of how the data and results of this study will be used? | Yes No |  |
| Do the consent form and information sheet include contact information for the PI and the IRB? | Yes No |  |