*Phoebe Putney does not allow investigators to determine if their activity requires IRB review and approval. This firm is designed to determine whether research is being conducted and constitutes human participants research. This form may be submitted to funding agencies when that agency requires documentation that IRB approval is not necessary****.***

1. **Principle Investigator.**

|  |  |
| --- | --- |
| Name of Person Submitting Form |  |
| Study Number |  |
| Study Title |  |
| Address |  |
| Telephone |  |
| Research ethics training source |  |
| Date research ethics training completed |  |
| Funding source/agency (if applicable) |  |
| If request is being submitted by a student, please  complete the following: | |
| Type of student research |  |
| Name of School/College |  |
| Department |  |
| Faculty Advisor Name |  |

1. **Proposal Summary.**

On a separate sheet, provide a narrative of the purpose and rationale of the project. Describe how data collection will occur and the type of information to be collected about the subjects. Indicate whether data will be identified, de-identified, or coded. If coded, explain whether the code will be accessible to the investigators? Do you intend to publish or present your results?

1. **Signatures.**

I will conduct the study in the manner described on the narrative. If I make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report these to the IRB.

|  |  |
| --- | --- |
| **Principle Investigator Signature** | **Date** |
|  |  |

If the investigator is a student, a faculty advisor must sign below and agree: I read and approve this protocol. This is research as defined by DHHS and the student is competent to conduct the activity as described.

|  |  |
| --- | --- |
| **Faculty Advisor Signature** | **Date** |
|  |  |

1. **Screening Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Question** | **Yes** | **No** |
| 1. | Is the primary aim or motive of the project either to improve care right now for the next patient seen or improve operations or efficiency? |  |  |
| 2. | Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: literature, consensus statements, or consensus among clinician team? |  |  |
| 3. | Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes? |  |  |
| 5. | Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)? |  |  |
| 6. | Will the activity only involve participants (patients, parents, or Phoebe staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place? |  |  |
| 7. | Is the project limited to analysis of de-identified publicly available data? |  |  |
| 8. | Do the methods include any of the following?  • Control group  • Randomization  • Fixed protocol |  |  |
| 9. | Is the project limited to course-related activities designed specifically for educational or teaching purposes? |  |  |
| 10. | Is the project funded by any of the following:  • An outside organization with an interest in the results  • A manufacturer with an interest in the outcome of the project relevant to its products  • A non-profit foundation that typically funds research, or by internal research accounts |  |  |
| 11. | Does the project employ a systematic approach involving predetermined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory? |  |  |
| 12. | Is the project intended to contribute to generalized knowledge by extending the results beyond a single individual or an internal unit? |  |  |

Please submit the IRB Determination Form, Screening Checklist and narrative to the IRB Coordinator for review and determination.

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| **IRB Office Only**  Date of Receipt: \_\_\_\_\_\_\_\_\_\_\_\_ Are all forms complete:  YES  NO  Does the activity meet the DHHS definition of human subject’s research?  YES  NO |