** **

**LEGACY HEALTH IRB**

**FORM D: CHECKLIST FOR EXEMPTION DETERMINATION**

**Only use this form for request of an exemption from IRB oversight, for a determination for a quality improvement exemption determination, a case review determination, a request for finding that the project is not human subject research, or that Legacy is not engaged in research for your project.**

The Legacy IRB staff makes the final assessment of whether an activity constitutes research involving human subjects, requires some level of IRB review or can be determined to be exempt from IRB oversight. An exempt determination assures that the submitted project is allowed to go forward as a formal exemption, quality improvement, or a case study, or is found to be not human subject research, and can be offered as documentation that the investigator has submitted the project to an IRB for ethical review, which helps in publication or presentation plans of the investigator.

**CHECKLIST FOR EXEMPTION DETERMINATIONS**

The following minimal information is needed by Legacy IRB office to adequately determine whether a project/proposal meets the requirements for an exemption; additional information may be requested from the IRB office:

* A clear description of project/proposal, including a final title of the project:
* A named principal investigator:
* The subjects of the research (including Legacy employees/providers):
* The Legacy site of the research:
* The funding for the project (if any):
* The design of the project (describe in detail what you are doing):
* The risks (including the data gathering of sensitive information) for the project:
* A clear description of the informed consent process, including submission of the consent documentation (consent form, information sheet, verbal script, survey form):
* Submission of all documents given to subjects (including surveys, questionnaires, training documents, etc.):
* A written plan for the gathering, use and protection of confidential data obtained from subjects or from Legacy data sources:
* A written assurance that all patient data will be de-identified after recording:
* A written assurance that all Legacy employee data will not be used for personnel purposes:
* An assurance that for presentation and publication purposes, all subject data will be de-identified:
* An assurance the approved project will not be altered before re-submission to the IRB for re-review:
* An assurance that all Legacy policies will be followed during the conduct of the project:
* The name of the Legacy manager(s) who has granted permission for this project:

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| --- | --- |
|  | Click or tap to enter a date. |
| Investigator Signature  | Date:  |

**WHO TO CONTACT FOR FURTHER INFORMATION OR IF YOU HAVE QUESTIONS:**

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**HOW TO SUBMIT THE FORM**

Sign and return or confirm via email the accuracy of this form and send the form with all relevant documents via email to irbsubmissions@lhs.org.