**Quality Improvement Project IRB Checklist**

|  |  |  |
| --- | --- | --- |
| *Items answered with a “yes” require that this project be submitted to the IRB for approval prior to project commencement* | **Yes** | **No** |
| 1. Does it assign people or lab specimens to groups for simultaneous comparisons?
 |[ ] [ ]
| 1. Is it being conducted in hopes of contributing to generalizable knowledge in the area of study or a specific project location and not for the sole purpose of improving processes at CHAM? (This includes testing a hypothesis or theory).
 |[ ] [ ]
| 1. Is the initial intent to publish the results?
 |[ ] [ ]
| 1. Does it involve patients/subjects undergoing procedures that normally would not be conducted for their care or at the workplace (i.e. beyond routine care for patients or outside of standard work routine for employees)?
 |[ ] [ ]
| 1. Does it involve randomization of patients/subjects to different treatments, regimens, and or processes?
 |[ ] [ ]
| 1. Does it involve the use of a placebo or any other significant deviation from the standard of care (this includes preventative, diagnostic, and treatment measures)?
 |[ ] [ ]
| 1. Does it involve increased risk or burden to the participants (e.g. additional blood draws, fatigue, embarrassment, or giving personal information)?
 |[ ] [ ]
| 1. Does it involve interactions or observations that do not routinely occur in patient care (for patients) or everyday life?
 |[ ] [ ]
| 1. Does it involve releasing data, protected health information (PHI) or personal information to individuals/entities other than for regulatory/accreditation?
 |[ ] [ ]
| 1. Does it involve processes that you expect may only be of benefit to individuals as an incidental or delayed effect?
 |[ ] [ ]