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| This Self-Administered Best Practice Review worksheet’s purpose is to help PI’s and research staff self-evaluate if their research protocol is being performed with best practices that support the preservation of integrity of data and the protection of the rights and welfare of human research subjects. This is an abbreviated version of the in-person BPR offered by CU’s QA/QI Program. |

*A research study is a dynamic project that can be daunting to manage for many reasons. Using this checklist may assist you and your staff in confirming that only IRB approved procedures and documents are being used, and practices being implemented are consistent across your entire team. It may also help you self-identify issues that may require additional attention, an IRB submission, or other follow-up.*

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| --- | --- | --- | --- | --- |
| **A. General Information/Documentation** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Is CU Boulder IRB approval current? |  |  |  |  |
| 2. Are the staff/personnel currently working on the protocol consistent with what was approved on eRA during the last protocol approval (Initial Application approval or most recent Amendment)? Current, Approved documents are those downloaded directly from the Approved Docs screen for the study in eRA. |  |  |  |  |
| 3. Are CITI training certifications current for all research staff?  |  |  |  |  |
| 4. Has the funding source for this study changed since the last IRB approval? |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO” (except for #4), PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **B. Informed Consent** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Is the study using the latest IRB approved version of the informed consent procedure?  |  |  |  |  |
| 2. Is the study using the latest IRB approved version of the informed consent form?  |  |  |  |  |
| 3. If a verbal consent procedure is being used, is verbal consent being documented in a systematic way? |  |  |  |  |
| 4. Is there a signed and dated consent form on file for every person who is participating in the study? |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **C. Recruitment** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Are study participants identified and recruited according to the procedures approved by the IRB? |  |  |  |  |
| 2. Have all advertising and/or recruitment materials being used, been approved by the IRB?  |  |  |  |  |
| 3. Has the study eligibility criteria changed since the last IRB approval? |  |  |  |  |
| 4. If more than ‘minimal risk,’ has the anticipated sample size remained consistent with the sample size approved by the IRB?  |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **D. Research Protocol - General** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Do the research activities being conducted comply with the project description and procedures as approved by the IRB? |  |  |  |  |
| 2. Is the study using only those versions of data collection procedures and instruments that have been approved by the IRB? |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **E. Privacy, Data Storage, Confidentiality** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Is identifiable information of participants effectively being protected by the IRB approved procedures put in place to do so (i.e. confidentiality agreements for study staff, names + addresses of subjects)?  |  |  |  |  |
| 2. If the study proposed to collect the data anonymously, has anonymity been maintained in the physical and/or electronic records? |  |  |  |  |
| 3. Are hard copies of any study forms or information containing personal identifiers (such as informed consent documents) stored in a secure, locked location? |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **F. Amendments + Modifications** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Have all changes to the protocol (e.g. procedure changes, data collection changes, participant compensation, duration of study procedures, etc.) been submitted and approved by the IRB prior to implementation?  |  |  |  |  |
| 2. Are copies of previous amendment submissions and approvals organized and maintained for reference and review? |  |  |  |  |
| 3. Are ONLY the most recently approved versions of study forms and procedures available to study staff?  |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |
| **G. Continuing Review** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| 1. Are copies of previous Annual continuing review submissions and approvals organized and maintained for reference and review?  |  |  |  |  |
| 2. Have all adverse events that were *unexpected and related* to the research been reported to the IRB?  |  |  |  |  |
| 3. Has the IRB been informed of any new information that may change the risk to benefit ratio? |  |  |  |  |
| IF ANY ITEMS ABOVE ARE “NO”, PLEASE CONTACT THE IRB OFFICE FOR ASSISTANCE WITH NEXT STEPS. |  |  |  |  |