|  |
| --- |
| **CIRB Checklist** |
|  |
| **Consent Form Items** |
| **Upload ‘clean’ versions of the CIRB-approved consent form with and without Geisinger language inserted. Do not submit with track changes.** |
| **For all CIRB-approved (MAIN) consent forms, the following information must be added to ensure that local laws and policies are being reflected.**  |
| ***Title Page*** |
|  | **TITLE** of document should be **Research Consent/Authorization** **Form (for PEDs: Research Consent/ Parental Permission/Authorization Form)** - Please remove any reference such as **MODEL CONSENT** or **TEMPLATE**, etc. |
|  | **ADD** Geisinger Protocol # |
|  | **ADD** Principal Investigator Phone numbers *[List office number and 24-hour number]* |
| ***“What About Confidentiality?”*** section, **ADD** the following statements: |
|  | “Geisinger Clinic has several departments, including Geisinger IRB, that are responsible for making sure research is performed according to federal and state regulations. The staff members of these departments may review your medical record and research data for this study. This review will be administrative in nature and no Protected Health Information (PHI) will be sent outside of Geisinger”. |
|  | The study results will be retained in your research record for data analysis or required governmental review *[for at least six years or until after the study is completed, whichever is longer]* OR *[indefinitely].* At that time the research information not already in your medical record will be destroyed or information identifying you will be removed from the study results at Geisinger Clinic. Any research information in your medical record will be kept indefinitely.  |
| ***“What are my Rights if I take Part in This Study?”* section, ADD the following statements:** |
|  | “You have the right to access your medical records.” |
|  | ***“***Access to your medical record may be limited during your participation in this study.” *[Only add if the study is “blinded”.]* |
|  | “You may withdraw your consent/authorization for us to use your data. Data that have already been sent to the sponsor cannot be withdrawn. If you decide to withdraw your consent/authorization for us to use your data, you must send written notice to your study doctor at *[Add Name and address of PI]*.” |
| ***“What Happens if I am injured Because I took Part in This Study?”*** section, **ADD** the following statements: |
|  | In the case of injury or illness resulting from this research study, medical treatment is available but will be provided at the usual charge. Immediately contact your study doctor, *[insert name and phone number].*  |
|  | You or your insurance company will also be charged for continuing medical care and/or hospitalization required for any such injury or illness.  |
|  | Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study. No funds have been set aside to compensate you in the event of injury or illness. |
| ***“Whom Do I Call If I Have Questions or Problems?”***section, **ADD** the following: |
|  | For questions about your rights as a research participant, contact Geisinger’s Human Research Protection Program staff at (570) 271-8663. |
| ***“Signatures”***section, **ADD** the following (if not included in the cooperative group template): |
|  | Person obtaining consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |