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# CHOC IRB Reliance Consent Checklist

When relying on an external IRB, it is likely that changes will need to be made to recruitment and consent documents to provide information about CHOC Children's involvement. Please use the checklist below as a guide for what information should be considered.

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| ☐ | **To facilitate readability and comprehension, the consent document should be written at a 12 year old (6-7th grade) reading comprehension level.** |
| ☐ | Add CHOC Children's as part of the heading in the consent and assent document and include in CHOC Children's information in recruitment materials as applicable. |
| ☐ | In the introduction, identify that the study is being conducted at Children's Hospital of Orange County and include the name of the CHOC Children's Principal Investigator. CHOC Children's recommends listing Co-Investigators as well, but this is not a requirement. |
| ☐ | Indicate any specific procedures that will be conducted at CHOC if different from the reviewing IRB site. |
| ☐ | If the research involves pregnancy testing in minors, the following language should be included:<br>Per California Law, pregnancy test results may only be provided to a parent or guardian only with the minor's permission. The study team will not discuss the results of your pregnancy test with your parent or guardian unless you say it is ok. |
| ☐ | Include the approximate number of participants to be enrolled at CHOC. |
| ☐ | In the section that provides information about whom to contact with questions about the study, provide the contact information for the CHOC Children's PI and/or study team. |
| ☐ | Children's Hospital of Orange County's Office of Research Compliance needs to be included in the list of organizations that may look at/and or copy medical records in the privacy section. |
| ☐ | If study procedures will take place at CHOC Children's and the study poses a real or foreseeable risk of biomedical harm (more than minimal risk), the CHOC Children's standard liability language should be included with the reviewing site's liability language :<br>If your child is injured as a result of being in this study, CHOC will provide necessary medical treatment. The costs of the treatment may be covered by CHOC or billed to you or your insurer just like other medical costs, depending on a number of factors. CHOC and the study sponsor do not normally provide any other form of compensation for injury, such as loss wages, disability, or discomfort. For more information about this, you may call the Office of Research Compliance at (714) 509-8869 or by email at ORC@choc.org. |
| ☐ | Cost section of the consent needs to accurately reflect what costs will be covered by the study and what costs subjects are responsible for at both the reviewing site and at CHOC Children's. |
| ☐ | Compensation section of the consent needs to accurately reflect what, if any, compensation will be provided by the study and what costs subjects are responsible for at both the reviewing site and at CHOC Children's. If compensation is offered the CHOC IRS 1099 language should be included: The law requires that CHOC submit |

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| | an IRS 1099 form for individuals to whom it provides compensation exceeding $600 per calendar year. Compensation provided by this research study will count toward the annual total for this purpose. |
| ☐ | If any members of the research team have a financial or other conflict of interest, this information should be added in the appropriate section of the consent form. |
| ☐ | California law requires written assent of minor subjects ages 7 years to 17 years. If subjects in this age group will be enrolled at CHOC Children's, assent document(s) will need to be provided, recommend to include in Consent documents where possible. |
| ☐ | If the study poses a real or foreseeable risk of biomedical harm and takes place in California, make sure the consent form includes language such as the following: "You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep." And ensure that the participant is given a copy in a language in which he or she is fluent. |
| ☐ | Per the California Medical Information Act, CHOC requires a separate HIPAA authorization document. **CHOC Children's requires the use of its approved HIPAA Authorization for Research Purposes template form which may be provided.** |
| ☐ | Utilization of CHOC short forms are required when there will be utilization of short forms within a study. The study team should make provisions for translation after the first use; however, the short form can be utilized while translation approval is sought. |
| ☐ | **At the time of site approval, CHOC requires documentation of risk determination for pediatrics and adults.** |
| ☐ | CHOC Children's is located in an ethnically diverse community. CHOC provides the following translations of short form consent documents and HIPAA authorizations: Spanish, Vietnamese, Chinese, Arabic, Korean and Farsi. Study teams should consider resources available to provide for full translations of consent documents for studies that are greater than minimal risk. |