

## Checklist

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Please complete this checklist to be sure that all the required elements of informed consent (as detailed in the IRDB Handbook, section X) have been included in the form for the proposed project.

1. **Heading: "Informed Consent Form"**
  
2. **Identification:**
  - Responsible institution(s)
  - College, department, other
  - Principal and co-investigators
  - Title of project/study
  
3. **Purpose of this Research Project Study:**
  - Statement that study involves research/investigational new article/article not approved by the FDA for the purpose used in study
  - Name of sponsoring agency for funding source
  - Scope, aims, and purpose
  - Approximate number of subjects to be entered/multicenter
  - Duration of subject's participation
  
4. **Procedures involved in this study:**
  - State procedures to be followed
  - Describe procedures which are experimental
  
5. **Possible risks, discomforts or side effects**
  - For subjects
  - For fetus
  
6. **Possible Benefits**
  - For subjects
  - For others
  
7. **Alternative Procedures or Treatment**
  
8. **Your Participation as a Research Subject:**
  - Decision by subject
  - Terminated by investigator
  - New Information
  - Additional costs to subjects
  - Remuneration
  
9. **Confidentiality**

10. **Contact for Questions:**

- About research
- Rights as a research related injury
- Names and telephone numbers, during and after hours

11. **Compensation for Physical Injury:**

- NEIU statement
- From others

12. **Subject's Consent**

13. **IRB Approval/Review Statement**

14. **Please Double-Check to be sure the Consent Form:**

- Does not try to influence or coerce the subject to participate
- Is written in simple language that can be easily understood by the average person and is appropriate to the subject population
- Does not either appear to or limit the subject's legal rights or release NEIU or its agents from liability or negligence
- Explains that an investigational drug or device is one that has not been approved by the FDA for the purpose used in the study
- Provides a space for the following signatures: subject/parent/child, child's parent(s), legally authorized representative (guardian), investigator, witness (optional)

- Details all medical procedures, including tests, in lay language

Examples:

- "effectiveness" *in lieu of*....."efficacy"
- "injection into a vein" ..... "intravenous infusion"
- "natural growth development"..... "maturation"
- "1 teaspoon of blood" ..... "5 ml. of blood"
- "inactive drug, sugar pill or  
pill that does nothing to the body ..... "placebo"
- "by chance" ..... "randomized"
- "birth defects"..... "teratogenic defects"
- "applied to skin" ..... "topical"
- "needle stick"..... "venipuncture"

- State all risks, benefits or side effects, including those from routine procedures, in layman's language (i.e., catheters inserted, blood drawn, would cultures, study drugs, x-rays, scans, etc.,)

- Has been reviewed by the investigator to correct any procedural, grammatical or spelling errors