NOTE: For use by Research Compliance Specialists. Please circle response options. Check box if an element is MISSING OR INCOMPLETE. Missing elements must be supplied by the investigator before the application can be given to the IRB.

ELEMENT:
- Contact information
- Signature Assurance Sheet or departmental equivalent
- Investigator/Staff IRB training
- Funding— Yes No UA primary UA secondary recipient
- Background and purpose of study
- Background and expertise of study team
- Research methodology/Study procedures
- Duration of procedures
- Risk assessment/Risk management/minimization
- Benefit assessment
- Population enrollment/Sample size/Sample description
- Special Population supplemental form (s)
- Parent signatures: 2 parents 1 parent Specified Justified
- Inclusion/Exclusion criteria present
- Safeguards for vulnerable population
- Procedures for working with LARS: Identify Educate Evaluate IC additions
- Recruitment/Informed consent process/
- Informed consent includes 8 required elements
- Consent form understandable to subjects
- Individual who obtains informed consent identified
- Child assent
- Waiver of consent
- Adverse event reporting/Management
- Data analysis plan
- Privacy of subjects
- Confidentiality of research data
- Cost to participant
- Compensation
- Advertising material
- Surveys/Questionnaires/Scripts/Debriefing
- Product literature
- Letters from other institutions or resources (support, access, consultation)
- IRB documentation for collaborative studies (involving other IRBs)
- Forms appropriate to proposal (PHI)
- Full scientific proposal to funding agency (no CV or budget)
- IND or IDE involved in study NO YES
- FDA form 1572