***View 1***

**Research Involving Children Determinations**

This checklist must be completed under the following circumstances:

* When children are identified for the first time as part of the study population, either during the initial protocol application or a protocol modification.
* During subsequent continuing reviews (CR), except when the CR form specifies that the protocol is in data analysis only.
* When reviewing modifications to the application that are relevant to the vulnerable group.

This requirement applies to transactions reviewed via the Full Board and the Expedited review pathway.

***\**1 Which category (or categories) does the research seem to fall into?**

* 21 CFR §50.51/45 CFR §46.404: Research not involving greater than minimal risk ***(go to View 2)***
* 21 CFR §50.52/45 CFR §46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects ***(go to View 3)***
* 21 CFR §50.53/45 CFR §46.406: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition ***(go to View 4)***
* 21 CFR §50.54/45 CFR §46.407: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children ***(go to View 5)***

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

*NOTE: Q1 is a set of radio buttons.*

***View 2***

**Category 21 CFR §50.51/45 CFR §46.404**

***\**1 Does the research present no greater than minimal risk to children?**

***Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal children or during the performance of routine physical or psychological examinations or tests in normal children.***

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to question 1 go to View 8; otherwise, go to View 20.***

***View 3***

**Category 21 CFR §50.52/45 CFR §46.405**

***\**1 Does the research involve greater than minimal risk to subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If Yes, provide protocol specific findings justifying for the checked determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Does the research present the prospect of direct benefit to the individual subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying for the checked determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Is one of the following true?**

* **The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.**
* **The risk to children is presented by a monitoring procedure that is likely to contribute to the subject’s well-being.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, indicate which one is true and provide protocol specific findings justifying for the determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Is the risk justified by the anticipated benefit to the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If Yes, provide protocol specific findings justifying this determination:**

****

***\**9 Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**10 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to 1, 3, 5, 7, and 9 go to View 8; otherwise, go to View 20.***

***View 4***

**Category 21 CFR §50.53/45 CFR §46.406**

***\**1 Does the research involve greater than minimal risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If Yes, provide protocol specific findings justifying for the checked determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Does the risk represent a minor increase over minimal risk?**

**“Minor increase over minimal risk” means no greater than risk in the daily lives of children with the condition or disorder under study, but still socially acceptable.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 Provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Does the intervention or procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Is the intervention or procedure likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**9 Does the research involve children who are wards of the state or any other agency, institution, or entity ?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to 1, 3, 5, and 7 and No to 9, go to View 9; If Yes to 1, 3, 5, 7 and 9 go to View 6; otherwise, go to View 20.***

***IF 1, 3, 5, OR 7 = No > Error***

***If 9 = Yes > 6***

***Default > 9***

***View 5***

**Category 21 CFR §50.54/45 CFR §46.407**

***\**1 Does the research meet the requirements of 21 CFR §50.51/45 CFR §46.404, 21 CFR §50.53/45 CFR §46.405, or 21 CFR §50.53/45 CFR §46.406?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If No, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Does the research involve children who are wards of the state or any other agency, institution, or entity ?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If No to 1 and 5 and Yes to 3 go to View 18; If No to 1 and Yes to 3 and 5, go to View 7; otherwise, go to View 20.***

**IF 1 = yes OR 3 = no > error. IF 5= Y > 7. Default > 18**

***View 6***

**Research Involving Children who are Wards of the State or Any Other Agency, Institution, or Entity for Research under 21 CFR §50.53/45 CFR §46.406**

***\**1 Is one of the following is true?**

* **The research is related to their status as wards.**
* **The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If Yes, indicate which statement above is true and provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Will an advocate be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Will the advocate have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child’s participation in the research?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Is the advocate associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If No, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to 1, 3, 5 and No to 7 go to View 9; otherwise, go to View 20.***

***If 1=N OR 3 = N OR 5 = No OR 7=Y > error. Default > 9***

***View 7***

**Research Involving Children who are Wards of the State or Any Other Agency, Institution, or Entity for Research under 21 CFR §50.54/45 CFR §46.407 (45 CFR §46.409)**

***\**1 Is one of the following is true?**

* **The research is related to their status as wards.**
* **The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If Yes, indicate which statement above is true and provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 An advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis for research approved under §46.406 or §46.407.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Will the advocate have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child’s participation in the research?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Is the advocate associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If No, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to 1, 3, 5 and No to 7 go to View 18; otherwise, go to View 20.***

***View 8***

**Adequate Provisions for Soliciting the Permission of Parents or Guardians (21 CFR §50.51, 52/45 CFR §46.404, 405)**

***\**1 Which one of the following is true?**

Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. *(go toes to* ***View 13****)*

Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. *(go toes to* ***View 13****)*

Parental permission is waived under 45 CFR §46.116(d) – waiver for no more than minimal risk research. *(go toes to* ***View 10****)*

Parental permission is waived under 45 CFR §46.408(c) – parental or guardian permission is not a reasonable requirement to protect subjects. *(go toes to* ***View 11****)*

Parental permission is waived under 45 CFR §46.116(c) – waiver for a research or demonstration project. *(go toes to* ***View 12****)*

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

NOTE: Q1 is a set of radio buttons.

***View 9***

**Adequate Provisions for Soliciting the Permission of Parents or Guardians(21 CFR §50.53/45 CFR §46.406)**

***\**1 Which one of the following is true?**

Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. *(go toes to* ***View 13****)*

Parental permission is waived under 45 CFR §46.408(c) – parental or guardian permission is not a reasonable requirement to protect subjects. *(go toes to* ***View 11****)*

Parental permission is waived under 45 CFR §46.116(c) – waiver for a research or demonstration project. *(go toes to* ***View 12****)*

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

NOTE: Q1 is a set of radio buttons

***View 10***

**Waiver of Parental Permission - Waiver for No More than Minimal Risk Research 45 CFR §46.116(d)**

***\**1 Is the research is FDA-regulated?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Does the research involve non-viable neonates?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Does the research involve no more than minimal risk to the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If yes, provide protocol specific findings justifying that this research involves no more than minimal risk to subjects:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Does the waiver or alteration adversely affect the rights and welfare of the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If no, provide protocol specific findings justifying that the rights and welfare of the subjects are not adversely affected by the waiver/alteration:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Could the research be practicably carried out without the waiver or alteration?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If no, provide the justification that the research could not be practicably out without the waiver/alteration:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**9 Whenever appropriate, will the subjects be provided with additional pertinent information after participation? (Check “Yes” if it is not appropriate to provide with additional pertinent information after participation.)**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**10 If yes, provide the justification that the subjects will be provided with additional pertinent information after participation or that such information would be inappropriate:**

****

***Logic-If No to questions 1,2, 5 and 7 and Yes to questions 3, and 9 go to View 13; otherwise, go to View 20.***

***View 11***

**Waiver of Parental Permission -Parental or Guardian Permission is Not a Reasonable Requirement to Protect Subjects 45 CFR §46.408(c)**

***\**1 Is the research is FDA-regulated?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Does the research involve non-viable neonates?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Is the research protocol designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Is an appropriate mechanism for protecting the children who will participate as subjects in the research substituted?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Is the waiver inconsistent with Federal, State, or local law?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If No, provide protocol specific findings justifying this determination:**

****

***Logic-If No to questions 1,2 and 7 and Yes to questions 3 and 5 go to View 13; otherwise, go to View 20.***

***View 12***

**Waiver of Parental Permission - Waiver for a Research or Demonstration Project 45 CFR §46.116(c)**

***\**1 Is the research is FDA-regulated?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Does the research involve non-viable neonates?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Will the research or demonstration project be conducted by or subject to the approval of state or local government officials?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**4 If Yes, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**5 Is the research or demonstration project designed to study, evaluate, or otherwise examine one or more of the following?**

* **Public benefit or service programs.**
* **Procedures for obtaining benefits or services under those programs.**
* **Possible changes in or alternatives to those programs or procedures.**
* **Possible changes in methods or levels of payment for benefits or services under those programs.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**6 If Yes, indicate which of the four is true and provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**7 Could the research be practicably carried out without the waiver or alteration?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**8 If no, provide the justification that the research could not be practicably carried out without the waiver/alteration: (In other words, explain why if consent were required, the research could not be practicably conducted.**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If No to 1, 2 and 7, Yes to 3 and 5, go to View 13; otherwise, go to View 20.***

***View 13***

**Adequate Provisions to Solicit the Assent of Children**

***\**1 Who will assent be obtained from?**

* + All children *(go toes to* ***View 17****)*
  + None of the children *(go toes to* ***View 14****)*
  + Some children - note that the protocol/CICERO application needs to describe which children will not be asked for assent. *(go toes to* ***View14***)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***View 14***

**Reason Why Assent is Not Necessary**

***\**1 Which of the following is true? (Check all boxes that are true)**

The capability of these children is so limited that they cannot reasonably be consulted (taking into account the ages, maturity, and psychological state of the children involved). ***(If “Some Children” was selected on View 13, go to View 17. ELSE IF 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; ELSE go to View 21.)***

The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research ***(If “Some Children” was selected on View 13, go to View 17. If 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; Otherwise, go to View 21.)***

Assent is waived under 45 CFR §46.116(d)/21 CFR §50.55(d) - waiver for no more than minimal risk research ***(If 21 CFR §50.53/45 CFR §46.406 was selected on View 1 go to View 20; Otherwise, go to View 15.)***

Assent is waived under 45 CFR §46.116(c) - waiver for a research or demonstration project***(If 21 CFR §50.53/45 CFR §46.406 was selected on View 1 go to View 20; Otherwise, go to View 16.)***

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If the first or second category was selected above, provide protocol specific findings justifying this determination:**

****

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***View 15***

**Waiver of Child Assent - Waiver for No More than Minimal Risk Research 45 CFR §46.116(d)/21 CFR §50.55(c)**

***\**1 Does the research involve no more than minimal risk to the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Does the waiver or alteration adversely affect the rights and welfare of the subjects?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Could the research be practicably carried out without the waiver or alteration?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**4 Whenever appropriate, will the subjects be provided with additional pertinent information after participation? (Check “Yes” if it is not appropriate to provide with additional pertinent information after participation.)**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to questions 2 or 3 or No to questions 1 or 4, go to View 20; If “Some Children” was selected on View 13, go to View 17. If 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; Otherwise, go to View 21.***

***View 16***

**Waiver of Child Assent - Waiver for a Research or Demonstration Project 45 CFR §46.408(a)/45 CFR §46.116(c)**

***\**1 Is the research is FDA-regulated?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Will the research or demonstration project be conducted by or subject to the approval of state or local government officials?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**3 Is the research or demonstration project designed to study, evaluate, or otherwise examine one or more of the following?**

* **Public benefit or service programs.**
* **Procedures for obtaining benefits or services under those programs.**
* **Possible changes in or alternatives to those programs or procedures.**
* **Possible changes in methods or levels of payment for benefits or services under those programs.**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**4 Could the research be practicably carried out without the waiver or alteration?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic-If Yes to 1 or 4 or No to 2 or 3, go to View 20. If “Some Children” was selected on View 13, go to View 17. If 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; Otherwise, go to View 21.***

***View 17***

**Documentation** **of Assent**

***\**1 Will assent be documented?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

**2 If Yes, specify the process for documentation:**

☐Investigator will document assent in the consent signature block.

☐Assent form

☐Other (NOTE: The protocol needs to describe the process of assent documentation)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***Logic If 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; Otherwise, go to View 21.***

***View 18***

**This is research involving children that is NOT otherwise approvable.**

**One or more of the following must be added as modifications required to secure approval:**

* ***FDA-regulated research cannot proceed until FDA has reviewed and approved the research***
* ***DHHS-regulated research cannot proceed until OHRP approves the research***
* ***Research conducted or funded by the Department of Defense (DOD) cannot proceed until the Director, Defense, Research and Engineering approves the research***
* ***All other research cannot proceed until the Organizational Official(s) approves the research in accordance with “SOP: Review of Not Otherwise Approvable Research”***
* ***The research cannot proceed until the Institutional Official has approved the research***

**Click “Continue”**

***Logic: If 21 CFR §50.53/45 CFR §46.406 was selected on View 1, go to View 19; Otherwise, go to View 21.***

***View 19***

**This is research involving greater than minimal risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject.**

**The following must be added as modifications required to secure approval:**

* ***The research cannot proceed until the Institutional Official has approved the research***

**Click “Continue”**

***Go to View 21***

***View 20***

***This error screen will have different language depending on what view throws the error (i.e. “NOT approvable under the selected category,” “Assent cannot be waived,” “Parental permission cannot be waived”).***

**Click “Continue”**

***Go to View 21***

***View 21***

**Final Page**

**1 Attachments - if necessary you may upload any files associated with your review:**

|  |
| --- |
| Add |

|  | Name | Created | Modified Date |
| --- | --- | --- | --- |

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)

***\**2 Have you completed this checklist?**

Yes  No [Clear](https://auragrantstest.uchicago.edu/IRB/ResourceAdministration/Project/ProjectEditor?Mode=smartform&Project=com.webridge.entity.Entity%5bOID%5bF42121A46CAA334E960B3C552744EF82%5d%5d&DestURL=https%3A%2F%2Fauragrantstest.uchicago.edu%2FIRB%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%5BOID%5BD63394C7F949504593586168D1C39F5C%5D%5D&WizardPageOID=com.webridge.entity.Entity%5bOID%5b76600690720E2041831AA15C01A61F45%5d%5d)

Click here to add a concern/contingency: [[Add]](http://134.192.156.36/UM/ResourceAdministration/Project/ProjectEditor?Project=com.webridge.entity.Entity%5bOID%5b395A5D7E7CEB134FAA40EE384B01DD75%5d%5d&Mode=smartform&WizardPageOID=com.webridge.entity.Entity%5bOID%5b4DF5224CA3AF1E47A594C3E0A5BC0411%5d%5d&DestURL=http%3A%2F%2F134.192.156.36%2FUM%2FRooms%2FDisplayPages%2FLayoutInitial%3FContainer%3Dcom.webridge.entity.Entity%255BOID%255BAEC1970CEB856B468DD322866CE3FBFF%255D%255D%26Tab2%3Dcom.webridge.entity.Entity%255BOID%255B480C0413CE67EF48806A574B2CC2B421%255D%255D)