NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.℠

Client and Project Information form	
Initiated by: Rina Rajpura	Date Prepared:

Section 1: Organization Information

A. Client Information			
Organization Name			
Organization address			
Organization Phone			
Client Name			
Client Phone (if different from Organization phone)			
Client Email			
Additional contacts related to the project			
Name	*Title*	*Phone*	*Email*
How did you find our Group?			

***B.* Funding Information**			
Organization type (Place X next to all that apply)			
☐	Academic RINCH	☐	Academic OSU
☐	Private Company	☐	Foundation
☐	Academic Other:		
☐	Other:		
Who is the project funded by?(organization, contact name)			
Address			
Phone			
Email			
Who is the billing contact?			

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Section 2: Client Sponsor, Contract and Production level Information

A. Contracts and Production Level Information

Contracts required for the project (Place X next to all that apply. See Appendix A for requirements)

☐	CDA	☐	Yield Analysis Proposal
☐	Material Transfer Agreement	☐	TOX Research Process Plan
☐	GMP Production Agreement	☐	Individual Project Schedule
☐	GMP Master Process Plan		
☐	Other Contracts if not listed:		

What Production Level is this Project? (Place X next to all that apply. See Appendix A for production level descriptions)

☐	Research Grade Production
☐	Plasmid Yield Testing
☐	Toxicology Grade Production
☐	GMP Grade Production

B. Sponsor and iLABs information

*Is this Organization also the IND Sponsor? If No, Provide Contact Information for the IND Sponsor (**only applicable for GMP Clients. If not applicable, please N/A**).*

Is the iLABS Registration Complete? Who is the registered Person? (Contact Andrew Moreo if needed assistance).

What is the expected date for Clinical trial?

Is this Product being used outside of U.S.A? If the product is being used in Europe, QP audit along with Client audit is required.

C. Additional information

Please comment on questions regarding the contracts, agreements and production level below:

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Section 3: Client Project Information:

A. Product information	
What is the Anticipated Yield For the Clinical trial?	
What is the Final Target Titer?	
What is the Minimum Acceptable titer?	
What is the Maximum Acceptable titer?	
What is the Minimum Total required Yield?	
What is the AAV Serotype?	
What is the Product Name? (Ex: Serotype.promoter.gene)	
This virus is being made for which Disease?	
Is this Single Stranded or Self Complimentry Construct?	
B. Vector Plasmid Information	
What is the Vector Plasmid Name?	
Is this Vector Plasmid Shipped? If no, provide information on estimate time when it will be shipped. Whom should we contact to follow up if not shipped?	
What is the quality of this Vector Plasmid? (Place √ next to all that apply)	
☐ Research Grade (Made by Client)	☐ Research Grade (Made by Plasmid MFG)
☐ Research Grade with Single Use Materials (Made by Plasmid MFG)	☐ GMP (Made by Plasmid MFG)
☐ GMP-S (Made by Plasmid MFG)	☐ IND – Ready (Made by Plasmid MFG)
☐ Other (Provide information):	
C. qPCR Information	
Is Linearized standard acceptable for qPCR? Special request for supercoiled standard is required.	
If possible or available, please Provide Previously used Primer Probe sequences for qPCR.	
What is the Endotoxin limit Eu/ml?	
D. AAV and Ad Helper, Production release level and Sequence Map Information.	
Is the AAV Helper Source provided by NCH or supplied by Client? What is the AAV Helper Name?	
Is the Ad Helper Source provided by NCH or supplied by Client? What is the Ad Helper Name?	
What is the quality of the AAV and Ad helpers? (Place X next to all that apply.)	
☐ Research Grade	☐ Research Grade with Single Use Materials
☐ IND – Ready (Made by Plasmid MFG)	☐ GMP (Made by Plasmid MFG)
☐ GMP-S (Made by Plasmid MFG)	
☐ Other (Provide information):	
What is the production release level for this project? [Research(standard), Research(With additional testing), Toxicological(Standard), Toxicological(with additional testing, GMP]	
Please Provide Sequence with map. Provide Digital Copy if possible	

Appendix

Appendix A. Production Level Description

1) **Research Grade Production:**
   a) Produced in the Viral Vector Core Research Laboratory and documented in basic research forms.
   b) General scale of vector delivered: up to 1E+14 DNase Resistant Particles (using linearized plasmid standard). Custom scales possible.
   c) Standard QC Testing with technical review includes: Research Bioburden, Physical Titer (DRP/mL), SDS-PAGE Analysis and Endotoxin (if requested).
   d) Certificate of Analysis delivered to Client.
   e) Confidentiality Agreement required for production start.
   f) Scheduled and billed through Research iLabs.
2) **Plasmid Yield Testing:**
   a) Produced in the Process Development Research Laboratory and documented in research forms followed by a technical review.
   b) Yield Testing Proposal signed by client and NCH to guide actions.
   c) Standard QC Testing with technical review includes: Physical Titer (DRP/mL), Research Bioburden and SDS-PAGE Analysis and Endotoxin if requested.
   d) Yield Testing Report and Product Certificate of Analysis delivered to Client.
   e) Confidentiality Agreement and Material Transfer Agreement Required for production start.
   f) Scheduled and billed through Research or GMP iLabs.
3) **Toxicology Grade Production:**
   a) Produced in the Viral Vector Core Research Laboratory and documented in Research Batch Record documents followed by a technical review.
   b) Varying scale of vector delivered: 1E+13 DNase Resistant Particles and up (using linearized plasmid standard).
   c) Research Process Plan signed by client and NCH to guide actions.
   d) Standard QC Testing with technical review includes: Bioburden, Endotoxin, Physical Titer (DRP/mL), and Total Protein, SDS-Purity, pH and Appearance.
   e) Certificate of Analysis delivered to Client by Quality Control group.
   f) Confidentiality Agreement and Material Transfer Agreement required for production start.
   g) Scheduled and billed through Research iLabs.
4) **GMP Grade Production:**
   a) Produced in the Clinical Manufacturing Facility; a controlled access, clean room facility that follows the GMP Phase 1 guidance recommendations and documented in GMP Batch Record documents followed by a technical review.
   b) Varying scale of vector delivered: 1E+13 DNase Resistant Particles and up (using linearized plasmid standard).
   c) Standard Testing with technical review includes: Sterility, Bacteriostasis/Fungistasis, Endotoxin, Physical Titer (DRP/mL), Infectious Unit Titer, Total Protein, SDS-Purity, pH, Appearance, Osmolality, DNA Identity, Protein Identity, Mycoplasma, In-Vitro Viral Contaminants, Vector Plasmid Titer, Empty: Full Ratio, Residual Host Cell Protein, Residual Host Cell DNA, Residual BSA, Residual Benzonase and Replication Competent AAV Detection and Quantification.
   d) Certificate of Analysis and Copies of Executed Batch Records delivered to Client.
   e) Confidentiality Agreement, Limited Production Agreement, Quality Agreement, signed Master Process Plan (MPP) and Individual Project Schedule required for production start.
   f) Scheduled and billed through GMP iLabs.