

Description of the Contract and Agreement requirements

1. Formal Project Request:

- a. The Formal Project Request is made by filling out the Project Information form. The form consists of three different sections. **The form is to be filled out individually for each project.**

- i. Section 1: Provide Organization and funding information.

1. Client Information: this allows us to communicate with the client for the needs, expectations, questions or concerns in a good timely manner throughout the process. Funding Information: Funding information is used to understand the organization type, who is the project funded by and who will be the billing contact to provide the iLABs registration information.

- ii. Section 2: Contracts and Production Level Information

1. Contracts and Production Level Information: There are total four different types of production levels.

- a. Each production requires different type of agreements, proposals, and different levels of Quality control tests. Depending on the production level, the iLABs registration will also differ. Each production is explained in detail in the Appendix of the form.
- b. Sponsor and iLABs information:
 - i. For all productions, there must be an IND Sponsor and iLABs registration. iLABs registration is explained more in detail in section a of [Resources link](#).
 - ii. Is the product being used in U.S.A or EU? This question is asked because if the product is used in Europe, QP audit along with Client audit is required.

2. Section 3: Client Project Information:

- a. In this section please provided detailed information about the product for the expected yield, vector plasmid, helpers, qPCR, sequence map and any other detail that may be unique and important to the project.

2. CDA- Confidentiality Agreement:

3. iLABs Registration: - iLABs is used for billing and milestones. Depending on the production, iLABs is used by the client to register, fill out project information form and pay. For more details please look at Section 6 - Resources – a for iLABs registration information.

4. MTA: Material Transfer Agreement:

5. Yield Assessment: The Yield Assessment evaluates the expectant titer from a Good Manufacturing Practices (GMP) production. The assessment features three separate transfections of the client's vector (or test vector), in addition to control transfections, in a smaller version of the vessel used in the Clinical Manufacturing Facility (CMF). The harvested material is evaluated by DRPs and the results are presented to the client in a report. The report serves as a basis on which to establish a quote for the clinical production. The test virus is purified and is

tested for yield, titer, endotoxin, and sterility. The client is provided with a purification report and a certification of analysis in addition to the test virus that is produced during the assessment

6. LPA: Limited Production Agreement defines the relationship between the Production Sponsor and RINCH's Clinical Manufacturing team. It is executed once to cover all the AAV-related, Phase 1 GMP productions completed by RINCH; cell banks, diluent and vector.
7. Quality Agreement: This exhibit to the LPA defines the expectations and responsibilities for RINCH and the Production Sponsor, relating to the manufacture, testing and transport activities of AAV-related, Phase 1 GMP productions.
8. IPS: Individual Production Schedule - This exhibit to the LPA describes an individual AAV-related, Phase 1 GMP production. It lists the materials provided by the sponsor, the milestones for the production and release, the product release specifications and the payment schedule.
9. RPP_MPP This is a Master Process Plan or a Research Process Plan. A Controlled Document that details all Phase 1 GMP production specific information. It contains the process flow chart, all specific production steps, the critical production materials to be used, the in-process testing plan, a proposed fill plan, the product label information, and the release testing plan.