

Terms & Conditions

Prince Sterilization Services, LLC. (PRINCE) is an independent contract sterilization services provider. PRINCE also provides consulting services. Sponsors of PRINCE include public and privately held companies, private citizens or others who request PRINCE to perform a service for a fee. The Sponsor is defined as the person or organization that requests our services and is responsible for payment of the work.

The following terms, conditions and pricing policies apply to all Sponsors:

1. A written request for sterilization, processing and their associated testing services must be submitted by way of a Sample Submission Form [SSF]. A SSF must be included in the same shipment as the test material. PRINCE provides a Sample Submission Form for this purpose, which must be completed and sent in with every sample shipment. Clients are 100% responsible for accurately submitting all facts and details requested on the SSF. The completed form identifies the test material, the service(s) requested, the purchase order number or authorization for funding, the PRINCE quotation number, the person to whom the report should be mailed, and appropriate billing information. Standing blanket purchase orders are required for efficiency. Revisions to service requirements must be submitted in writing, preferable by a revised Sample Submission Form. The requested services will not initiate unless the PO and SSF is properly completed. Note: If certification testing is to be performed such as a test for sterility, bacterial endotoxin or particulates, the sponsor must use the SSF to record the sample test specification and its decision in the event that the test result does not comply with the specification to authorize PRINCE for charges to perform and supply to the sponsor a formal written OOS investigation.

2. Prince Sterilization Services Upstream QA™. Upon receipt of a SSF PRINCE will email the Sponsor a written Acknowledgment Notification. Such Notification will inform the Sponsor of PRINCE's receipt of the test material, description of the test material, the service(s) requested,

and the proposed initiation and completion dates and other information.

3. Non-Solicitation: The Sponsor shall not solicit nor hire Prince Sterilization Service employees. This is a material clause in this Contract.

4. The Sponsor must review the Acknowledgment Notification (see 2 above) and return same to PRINCE within 24 hours if any revisions or changes are necessary. Failure by the sponsor to timely return the Acknowledgement Notification subjects the Sponsor to administrative fees. Clerical errors by PRINCE are corrected gratis. Errors by the Sponsor, which require correction are subject to an administrative fee of \$200.00 per incident. In addition, extensive changes to written final or draft reports are billed @ \$250.00 per hour. Note: Services that are scheduled for same day as arrival may contain Sponsor errors on the SSF that are not known to PRINCE and are not corrected prior to initiating the requested service. Accordingly, PRINCE does not accept any liability for such.

5. Sponsors may not use PRINCE reports or correspondence of any kind for advertising or other promotional purposes without the advance written permission of PRINCE.

6. Sponsors shall not be entitled to retain or defer payment of any sums due to the Company on account of any dispute, counter claim or set off which it may allege against the Company.

7. In order to protect confidentiality, PRINCE does not reveal service or test results or any information pertaining to the test materials. The Sponsor's logo may be used by PRINCE to publicly indicate our business relationship. In the event a Confidentiality Agreement is required, PRINCE may provide an agreement for the Sponsor to review.

8. It is not possible to anticipate all situations that may require further US FDA or other global regulatory agency analysis. Subsequent to PRINCE fulfilling it's the Sponsor's service request(s) a regulatory authority may require of the Sponsor additional data or to present data in another format or to provide more detailed explanations of the information submitted. PRINCE will support the Sponsor to full fill these new requirements. A new quotation for such services will be

prepared for the approval by the Sponsor. The new quote will describe the PRINCE service or testing costs which are solely the Sponsor's responsibility. A new or amended PO to cover same is required.

9. Limitation of Liability: The Company is neither an insurer nor a guarantor and disclaims all liability in such capacity. Sponsors seeking a guarantee against loss or damage should obtain appropriate insurance. Reports of Findings are issued on the basis of information, documents and/or samples provided by, or on behalf of, Sponsor and solely for the benefit of Sponsor who is responsible for acting as it sees fit on the basis of such Reports of Findings. Neither the Company nor any of its officers, employees, agents or subcontractors shall be liable to Sponsor nor any third party for any actions taken or not taken on the basis of such Reports of Findings nor for any incorrect results arising from unclear, erroneous, incomplete, misleading or false information provided to the Company. The Company shall not be liable for any delayed, partial or total non-performance of the services arising directly or indirectly from any event outside the Company's control including failure by Sponsor to comply with any of its obligations. The liability of the Company in respect of any claim for loss, damage or expense of any nature and howsoever arising shall in no circumstances exceed the fee of the service performed by PRINCE or US \$10,000 whichever is the lesser. The Company shall have no liability for any indirect or consequential loss (including loss of profits). In the event of any claim, Sponsor must give written notice to the Company within 30 days of discovery of the facts alleged to justify such claim and, in any case, the Company shall be discharged from all liability for all claims for loss, damage or expense unless suit is brought within one year from: the date of performance by the Company of the service which gives rise to the claim; or the date when the service should have been completed in the event of any alleged non-performance. PRINCE's responsibility for all aspects of work product (protocols, results, reviews, audits, submittals, etc.) is limited to the Sponsor of the study and not necessarily to third parties (consultants, assignees, successors, licenses, etc.). Results reported pertain only to the samples tested and are not intended to extrapolate to the universe of items which may

have been manufactured in parallel. PRINCE results pertain only to the sample submitted. The sample plan pertaining to sample(s) submitted to PRINCE for testing is the sole responsibility of the sponsor. PRINCE makes no representations that the amount of Product and/or sample(s) submitted are sufficient or adequate to predict the state of the entire population from which the Product and/or sample(s) was taken and the results may not be extrapolated.

PRINCE shall not be held responsible for any irregularities resulting from the sampling process. No predictions, guarantees or warranties of any kind are made by PRINCE that the work will be performed in a manner that will yield favorable results and/or result in approval by a regulatory agency such as United States FDA or other regulatory agency. Payment for PRINCE services performed is not contingent upon, or linked in any manner to, review or approval of the results by the Sponsor, its representative, or any regulatory agency.

Unanticipated technical issues, which require an excessive effort on PRINCE's part to overcome, are billable at a rate of approximately \$200.00 per hour.

10. Indemnification: Sponsor shall guarantee, hold harmless and indemnify the Company and its officers, employees, agents or subcontractors against all claims (actual or threatened) by any third party for loss, damage or expense of whatsoever nature including all legal expenses and related costs and howsoever arising relating to the performance, purported performance or non-performance, of any services.

11. Invoice, Payment & Payment Terms

1. A sterilization or processing report is issued upon completion of the study. An invoice containing reference to the sponsor's PO#, PRINCE report# and sample # will be issued for each report. Our standard practice is to send all forms of communication including reports, certificates and invoices by email. Other forms of delivery requested by Sponsor are charged to the Sponsor at cost plus handling and service fee of \$75.

2. Payment Terms: Net 30 days from invoice date. In addition, when a prepayment is listed in the quote that amount is due upon receipt. Balances past due over 60 days must be brought current before new

work will be accepted. In addition, the account will be placed on credit hold. A late payment fee of the lesser of 1.5% or the maximum interest rate allowed by law, of the invoice total will be charged for each month (or portion thereof) that an invoice remains unpaid by you. The Sponsor shall be responsible for any costs, including attorney's fees, incurred by PRINCE in the collection of any invoice balance not paid within the previously stated time period.

3. PRINCE accepts wire transfer, checks drawn on US Banks, or Visa, Master Card and American Express credit cards. We use the purchase express system to process American Express Credit Cards or you may process your credit transaction by calling 973-582-1520. For questions regarding credit application or wire transfer routing number, please contact our accounting department at 973-582-1520.

4. GLP Studies: Reports intended for submission to the Food and Drug Administration (FDA) in support of a marketing request may need to be conducted under the Good Laboratory Practice (GLP) regulations of the specific agency. Sponsors must notify the laboratory prior to initiation of such tests. GLP studies must be pre-approved by both sponsor and laboratory, performed according to a specific protocol, recorded on the GLP study master schedule, and inspected by the quality assurance department. PRINCE. complies with all phases of the FDA GLP or other regulatory agency regulations. If you are required to submit final reports in a specific format, please request the format when you submit the samples. If you need additional assistance, please contact us. *Additional charges for GLP, protocol studies and special projects will be quoted separately.

12. Quotations: Our fees are established by quotation or contract. Samples which require special handling, extra processing or manipulations, may incur additional charges. Further, charges for materials required in the performance of testing will be billed as a pass through cost to the client. PRINCE. will provide price quotations after evaluation of the product or protocol, prior to initiation of the work. The sponsor must approve the quote or contract in writing and submit a Purchase Order number. Most prices include submission of a final report by email or US Mail and maintenance of records and raw data for five years. Requests for overnight delivery, extra or additional

copies of reports, sample returns, and archiving of samples will be charged and invoiced to the Sponsor. Sponsor requests for various administrative services pertaining to final reports are subject to an administrative fee. Discounts are offered to companies who maintain prepaid balances. Special negotiated volume price quotes will be reviewed and are subject to change on an annual basis. **MINIMUM BILLING CHARGE FOR TEST AND REPORT: \$200.00**

13. Rush Charges: Sponsors frequently need samples processed urgently rather than the normal turnaround time based on the workload at the time samples are received. These requests will be honored when capabilities permit. Since "RUSH" requests require staff to interrupt scheduled tests and may require overtime, after-hours, weekend, or holiday readings, a minimum "RUSH" charge of 100% is assessed. RUSH services and/or testing must be requested in writing on the sample submission form.

14. Prepayment Policy: PRINCE reserves the right to request a prepayment of up to 100% in advance of services being performed. In some cases, PRINCE may require a 50%, etc. prepayment with the remaining balance due upon presentation of a written draft report. Established customers (with a current account) are invoiced after their studies are completed and results are received. Some studies require a 50% prepayment to help cover the initial cost of doing the test or to establish credit. 100% prepayment will be required for protocol preparation, set up fees, and cost of supplies (e.g. vials, seals, stoppers, packages). Prepayments will be indicated in the quotation and invoiced upon acceptance of the quotation.

15. OOS Charges: \$1,195 for the preparation and issuance by PRINCE of a written OOS Investigation report. In addition, the Sponsor will be invoiced by PRINCE for any repeat sterilization, depyrogenation, any other service request or any repeat testing that is needed, as determined by PRINCE, to conduct the OOS investigation. However, no fee shall be invoiced to the Sponsor for an OOS investigation that concludes that the assignable cause is solely assignable to PRINCE.

16. Miscellaneous Charges: Documents that are sent at the request of the sponsor by federal express will be charged to the sponsor and will

appear on their invoice. PRINCE reserves the right to charge for Speed Reports. A \$10.00 fee per speed report will be added to the final invoice if a Speed Report is requested/generated prior to final report. The information presented on a speed report is for informational purposes only. The report is not intended for product release or as a statement of the results to be presented on the final report. PRINCE does not take responsibility for actions taken by the client utilizing the information, nor will any reimbursement or remuneration be considered should the client choose to use the information for any other purpose than informational. In the event any unforeseen problems, additional sterilization, testing or expenses arise in the course of carrying out the services, the Company shall endeavor to inform Sponsor and shall be entitled to charge additional fees to cover extra time and cost necessarily incurred to complete the services.

17. Shipping, Special Handling and Sample Retention: The Sponsor is responsible for the shipping and handling charges, and the disposal of supplies, specialized equipment and unused test materials. A minimum handling charge of \$75 will be applied. In addition, the sponsor will be invoiced for the shipping costs incurred by us to return the samples, unless a provision is made for shipping to be charged to the sponsor's UPS or FED EX account. Minimum charge = \$75.00 handling fee + shipping price. FDA typically requires retention of reports and related documentation for five years. Documentation Storage Fee is \$100.00 per month for records over 5 years old.

18. Cancellation of Services: In order to cover administrative costs, a charge of \$350.00 is assessed at the time a service is canceled. In addition, the sponsor will be billed for all PRINCE costs incurred that relates to the services and testing canceled. Cancellation of stability storage services will be billed at 50% of the total plus \$250 per hour administrative fee.

19. Suspension or Termination of Services: PRINCE shall be entitled to immediately and without liability to either suspend or terminate provision of services in the event of: Failure by the Sponsor to comply with any of its obligations and such failure is not remedied within 7 days that notice of such failure has been notified to the Sponsor. Any

suspension of payment, bankruptcy, insolvency, receivership or cessation of business by the Sponsor If the Company is unable to perform all or part of the services for any cause whatsoever outside the Company's control including failure by Sponsor to comply with any of its obligations, the Company shall be entitled to payment of the amount of all non-refundable expenses incurred by the Company, and a proportion of the agreed fee equal to the proportion of the services actually carried out.

20. International Customers: All shipments sent to PRINCE from outside the United States must pass through customs. There will generally be a cost associated with shipping to/from PRINCE that cannot be determined until the shipment arrives. Please note all customs costs will be billed to the final invoice.

PRICES QUOTED ARE FOR US DOLLARS OR CHECKS DRAWN ON US BANKS.

Terms, Conditions, and Policies Acceptance Sheet

The above Terms, Conditions and Pricing Policy are accepted by:

Company Name (Please Print)

Authorized Signature

Date

Print Name

Please return this form to:

Accounting Manager

Prince Sterilization Services, LLC

122 Fairfield Road

Fairfield, New Jersey 07004-2405

Tel: (973) 227-6882

Fax: (973) 227-0812

accounting@princesterilization.com