

For contract research organizations, including specialty CROs, Phase 1 units, bioanalytical and central labs, and site management organizations. Sponsors buying trial coverage use CWCO-SUP-CLINTRIAL. Complete with ACORD 125, 126, and 140. Attach a services list, a standard master services agreement, a sample sponsor contract with insurance and indemnity terms, recent FDA inspection results, and five years of loss runs.

1 APPLICANT / BUSINESS INFORMATION

LEGAL BUSINESS NAME	DBA	FEIN	YEARS IN BUSINESS
HEADQUARTERS ADDRESS	CITY / STATE / ZIP	WEBSITE	

Entity type:
☐ LLC ☐ Corporation ☐ Publicly traded ☐ PE-backed

PRIMARY CONTACT / TITLE	PHONE	EMAIL

2 OPERATIONS

Services provided (check all that apply):

- ☐ Trial management ☐ Site monitoring ☐ Data management ☐ Biostatistics ☐ Pharmacovigilance ☐ Regulatory / medical writing
☐ Phase 1 unit (dosing on site) ☐ Bioanalytical / central lab ☐ Site management ☐ Patient recruitment ☐ Decentralized trials
☐ Preclinical / GLP studies

SERVICE	% OF REVENUE	LARGEST SPONSOR %	COUNTRIES

Size:

Employees Active studies Active sponsors Participants dosed by applicant per year

2-1 Does the applicant take on sponsor obligations transferred under FDA rules? ☐ Yes ☐ No
 IF YES, EXPLAIN

2-2 Are any services subcontracted to other vendors? ☐ Yes ☐ No
 IF YES, EXPLAIN

3 EXPOSURE & RISK QUESTIONS — DATA INTEGRITY & STUDY CONDUCT

In 2025, FDA rejected a CRO's in vitro study data after finding it had reused one donor's samples and recorded them as another's; sponsors had to repeat the studies at other sites. Errors like this become claims for the cost of redoing the work.

3-1 Are electronic systems validated to FDA's Part 11 requirements? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-2 Is there an independent quality assurance unit? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-3 Are staff trained in good clinical practice before working on studies? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-4 Is every randomization and drug assignment independently verified? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-5 Are serious adverse events tracked to meet reporting deadlines? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-6 Has FDA or another regulator issued a Form 483, warning letter, or untitled letter in the past 5 years? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-7 Has a sponsor had to repeat a study because of the applicant's work? ☐ Yes ☐ No
IF YES, EXPLAIN

3-8 Are vendors and subcontractors audited before use? ☐ Yes ☐ No
IF NO, EXPLAIN

4 EXPOSURE & RISK QUESTIONS — PARTICIPANTS, CONTRACTS & DATA

CROs commonly require sponsors to carry \$10 million in clinical trial liability and name the CRO, because injury suits name everyone and an underinsured sponsor shifts the cost to the CRO.

4-1 Does the applicant dose or treat participants at its own facilities? ☐ Yes ☐ No
IF YES, EXPLAIN

4-2 If yes to 4-1, are physicians and nurses covered by medical professional liability? ☐ Yes ☐ No
IF NO, EXPLAIN

4-3 Does the applicant check each sponsor's trial insurance and its exclusions before a study starts? ☐ Yes ☐ No
IF NO, EXPLAIN

4-4 Do sponsor contracts cap the applicant's liability? ☐ Yes ☐ No
IF NO, EXPLAIN

TYPICAL LIABILITY CAP (E.G., FEES PAID)

LARGEST SINGLE CONTRACT VALUE (\$)

4-5 Do any contracts include uncapped indemnities? ☐ Yes ☐ No
IF YES, EXPLAIN

4-6 Are sponsors required to name the applicant as additional insured? ☐ Yes ☐ No
IF NO, EXPLAIN

4-7 Is participant health data held or processed by the applicant? ☐ Yes ☐ No
IF YES, EXPLAIN

4-8 Is EU or UK participant data processed? ☐ Yes ☐ No
IF YES, EXPLAIN

5 PAYROLL, SALES & REVENUE

ANNUAL REVENUE (\$) REVENUE OUTSIDE U.S. (\$) PASS-THROUGH COSTS (\$) TOTAL ANNUAL PAYROLL (\$)

6 PRIOR INSURANCE & LOSS HISTORY

Attach currently valued loss runs for the last 5 years.

E&O CARRIER / LIMITS RETROACTIVE DATE EXPIRATION DATE

DATE OF LOSS	DESCRIPTION	TOTAL INCURRED (\$)	OPEN / CLOSED

6-1 Has a sponsor made a claim or withheld payment over the applicant's work? ☐ Yes ☐ No
IF YES, EXPLAIN

6-2 Has a participant made a claim against the applicant? ☐ Yes ☐ No
IF YES, EXPLAIN

6-3 Has any coverage been declined, cancelled, or non-renewed? ☐ Yes ☐ No
IF YES, EXPLAIN

6-4 Is the applicant aware of any incident or circumstance that could give rise to a claim?

☐ Yes ☐ No

IF YES, EXPLAIN

7 RISK MANAGEMENT & SAFETY

7-1 Do contracts go through legal review before signing?

☐ Yes ☐ No

IF NO, EXPLAIN

7-2 Is there a written corrective and preventive action (CAPA) process?

☐ Yes ☐ No

IF NO, EXPLAIN

7-3 Is multifactor authentication required for all study systems?

☐ Yes ☐ No

IF NO, EXPLAIN

8 SIGNATURE & FRAUD WARNING

The undersigned declares that the statements and answers given in this supplemental are true, complete and correct to the best of their knowledge, and that no material fact has been withheld or misstated. The applicant agrees that this supplemental, together with all ACORD applications and attachments, forms the basis of any submission to insurers and may be relied upon by them. Signing this supplemental does not bind coverage. This supplemental is an intake document prepared by Cory Washington & Co. LLC to support carrier submission; it does not itself provide coverage.

FRAUD NOTICE: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, may be committing a fraudulent insurance act, which is a crime and may subject such person to criminal and civil penalties. State-specific fraud warnings appear on the insurer's application.

APPLICANT / AUTHORIZED SIGNATURE (TYPE FULL NAME)

TITLE

DATE

PRODUCER — CORY WASHINGTON & CO. LLC

PRODUCER SIGNATURE (TYPE FULL NAME)

DATE