

For drug, biologic, device, and academic sponsors running clinical trials, including virtual sponsors that outsource trials to CROs. CROs use CWCO-SUP-CRO and pre-clinical biotech companies use CWCO-SUP-BIOTECHRD. Complete with ACORD 125. Attach each protocol synopsis, the investigator's brochure, the informed consent form, the CRO and site agreements, any ethics committee or country insurance requirements, and five years of loss runs.

1 APPLICANT / BUSINESS INFORMATION

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

Sponsor type:
☐ Biotech / pharma company
 ☐ Device company
 ☐ Academic / investigator sponsor
 ☐ Nonprofit / foundation
 ☐ Other

PRIMARY CONTACT / TITLE	PHONE	EMAIL

LEAD CRO (IF ANY)	PROPOSED EFFECTIVE DATE

Business size:
☐ Employees
 ☐ Clinical staff
 ☐ Active trials
 ☐ Locations

Facilities (check all that apply):
☐ Office only
 ☐ Own lab
 ☐ Own manufacturing
 ☐ Fully outsourced (virtual)

2 TRIALS TO BE INSURED

One row per protocol. Attach a schedule if more rows are needed.

PROTOCOL NO. / PRODUCT	PHASE	COUNTRIES	PARTICIPANTS	HEALTHY VOLUNTEERS? (Y/N)	START / END

Products being studied (check all that apply):
☐ Small molecule
 ☐ Biologic / antibody
 ☐ Vaccine
 ☐ Cell or gene therapy
 ☐ Medical device
 ☐ Diagnostic
☐ Psychedelic or controlled substance
☐ Reformulated approved drug

2-1 Is any trial first-in-human? ☐ Yes ☐ No
 IF YES, EXPLAIN

2-2 Do any trials enroll children, pregnant women, or other vulnerable groups? ☐ Yes ☐ No
 IF YES, EXPLAIN

2-3 Do any trials include participants in countries that require local compulsory trial insurance? ☐ Yes ☐ No
 IF YES, EXPLAIN

3 EXPOSURE & RISK QUESTIONS — PRODUCT & PROTOCOL SAFETY

Clinical trial injury suits typically name the sponsor, the CRO, the sites, and investigators together. In a March 2026 ruling a federal court dismissed claims against a sponsor, finding that informed consent and patient care rest with investigators and sites — but that is one district court, and sponsors still carry the risk of injury from the study product.

3-1 Has the product shown serious adverse events in prior studies? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-2 Is there an independent data safety monitoring board for each trial? ☐ Yes ☐ No
 IF NO, EXPLAIN

3-3	Do protocols include stopping rules for safety signals?	☐ Yes ☐ No
IF NO, EXPLAIN		
3-4	Are first-in-human doses given in staggered cohorts with sentinel dosing?	☐ Yes ☐ No
IF NO, EXPLAIN		
3-5	Are serious adverse events reported to FDA and ethics committees within required timeframes?	☐ Yes ☐ No
IF NO, EXPLAIN		
3-6	Does the product have potential for delayed or long-term injury (e.g., gene therapy)?	☐ Yes ☐ No
IF YES, EXPLAIN		
3-7	Is the study product made under GMP by a qualified manufacturer?	☐ Yes ☐ No
IF NO, EXPLAIN		

4 EXPOSURE & RISK QUESTIONS — CONSENT, SITES & CONTRACTS

CROs commonly ask sponsors for \$10 million in clinical trial liability and additional insured status. UK inspectors found Phase 1 units assumed ethics review confirmed the sponsor's cover was adequate, without reading its exclusions.

4-1	Does the informed consent promise to pay for trial-related injuries?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-2	Has the insurer or counsel reviewed the injury language in the informed consent?	☐ Yes ☐ No
IF NO, EXPLAIN		
4-3	Do site agreements require each site and investigator to carry their own professional liability?	☐ Yes ☐ No
IF NO, EXPLAIN		
4-4	Does the sponsor indemnify sites or the CRO for injuries from the study product?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-5	Do CRO or site contracts require them to be named as additional insureds?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-6	Do any contracts require limits higher than those being requested?	☐ Yes ☐ No
IF YES, EXPLAIN		
4-7	Are any trials decentralized, with home visits or remote dosing?	☐ Yes ☐ No
IF YES, EXPLAIN		

LIMIT REQUESTED PER CLAIM / AGGREGATE (\$)

EXTENDED REPORTING PERIOD REQUESTED (YEARS)

5 PAYROLL, SALES & REVENUE

ANNUAL REVENUE (\$)	ANNUAL CLINICAL SPEND (\$)	TOTAL FUNDING RAISED (\$)	TOTAL ANNUAL PAYROLL (\$)

6 PRIOR INSURANCE & LOSS HISTORY

Attach currently valued loss runs for the last 5 years.

CURRENT TRIALS / PRODUCT CARRIER	LIMITS / RETROACTIVE DATE	EXPIRATION DATE

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

6-1 Has a participant claim or demand been made in any trial? ☐ Yes ☐ No
IF YES, EXPLAIN

6-2 Has FDA placed any trial on clinical hold? ☐ 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 Are sites qualified and monitored under a written monitoring plan? ☐ Yes ☐ No
IF NO, EXPLAIN

7-2 Is there a written plan for notifying the insurer of serious adverse events? ☐ Yes ☐ No
IF NO, EXPLAIN

7-3 Are insurance certificates for each country kept in the trial master file? ☐ 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