TDC Specialty Underwriters
TDC GROUP

TDC Specialty Insurance Company
TDC National Assurance Company
(Stock companies owned by The Doctors Company)
(hereafter, the "Underwriter")
Servicing Address: 29 Mill Street
Unionville, CT 06085

# Clinical Research Organizations & Clinical Trials Liability Insurance Application

## APPLICATION INSTRUCTIONS

**NOTICE: PORTIONS OF THE POLICY FOR WHICH THIS APPLICATION IS MADE MAY CONTAIN CLAIMS MADE COVERAGE WHICH APPLIES ONLY TO "CLAIMS" FIRST MADE AGAINST THE "INSURED" DURING THE "POLICY PERIOD" OR ANY APPLICABLE EXTENDED REPORTED PERIOD AND REPORTED TO THE UNDERWRITER DURING THE "POLICY PERIOD" OR DURING ANY APPLICABLE EXTENDED REPORTING PERIOD. PLEASE READ THE ENTIRE APPLICATION CAREFULLY BEFORE SIGNING.**

Prior to completing the attached application, please read and follow these instructions. Please verify that all required attachments are included so that we may process the Application promptly and efficiently.

- Please complete this form electronically or print responses legibly.
- Please sign and date the application where indicated.
- All information requested must be fully and accurately completed.
- If changes or corrections must be made to the completed application, strike out or line through the incorrect information, write in the modification, and initial and date the change.
- If a particular question does not apply, please write "N/A."
- If additional space is needed, please continue answers on a separate page and attach it to the Application.
- Claims information should be provided for a six-year experience period. This applies to open and closed claims and to any incidents reported to a previous carrier. It is important to provide complete and detailed claims information, including current carrier loss runs.

## ACCOUNT INFORMATION

| | | |
|---|---|---|
| 1. | Applicant Name | |
| | Doing Business As (DBA) | |
| | Federal Employee ID# (FEIN) | |
| | State of Domicile | |
| 2. | Address | Street: |
| | | City: State: Zip: |
| | | County: Website: |
| 3. | Risk Manager or Contact Person | Name/Title: |
| | | Email Address: |
| | | Telephone Number: |
| 4. | Applicant's Legal Structure | ☐Individual ☐Corporation ☐ Partnership ☐ Joint Venture ☐LLC ☐Other (describe): |
| 5. | Tax Status | ☐For Profit – Private ☐ For Profit – Publicly Traded ☐Not For Profit |
| 6. | Entity Ownership | ☐Physician Owned ☐ Hospital Owned ☐Independently Owned ☐Other (describe): |
| 7. | Date Established | |
| 8. | Number of years the Applicant has been under present ownership: | |

9. List all states where the Applicant is operating and providing services:

10. Within the past 36 months, has the Applicant merged, acquired, or consolidated with another entity, sold or divested another entity or facility, discontinued any operations or services, or entered into any new business activities or services (including new procedures or products being offered)? ☐Yes ☐No

If "Yes," describe the essential terms of such transaction:

If "No," are there plans within the next 12 months to engage in any of the above activities?

11. List below all subsidiaries, description of operations, date acquired and ownership percentage for entities where you are the majority owner and for which you are seeking coverage under this policy.

| Name & Address | Description of Operations and Date acquired | Ownership % |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

(Please note that coverage for these entities is not automatically included. The policy, if issued, will determine coverage.)

12. Does the Applicant own, operate, or manage any business or facilities other than operations described in this Application? ☐Yes ☐No

If "Yes," please provide details, including name of entity and the Applicant's ownership interest/management role.

13. Is the Applicant owned or controlled by another entity? ☐Yes ☐No

If "Yes," please explain.

## FINANCIAL AND EXPOSURE DETAILS

14.

| | Last 12 Months | Next 12 Months (Projected) |
|---|---|---|
| Total Revenues | | |

15. Select the description below that best describes the applicant:

☐ Independent Research Site
☐ Institutional Review Board
☐ Academic Medical Center
☐ Contract Research Organization
☐Independent Review Board
☐Site Management Organization
☐Other ________________________



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16. Please indicate the phases of research for which coverage is sought and approximate revenue by phase:
☐ Phase I Revenues ___________________ ☐ Phase II Revenues ______________________
☐ Phase III Revenues __________________ ☐ Phase IV Revenues ______________________
☐ Other (i.e. pre-clinical, non-biomedical research) If other, please provide details:

17. Please indicate if the applicant is or will be engaged in the following types of clinical trials:
☐ Pharmaceuticals
☐ Biologics
☐ Medical Devices
☐ Animals (what type?):
☐ Other (describe):

18. Will the applicant provide surgical/invasive procedures? ☐Yes ☐No

19. Will the applicant be providing services or testing products outside of the United States? ☐Yes ☐No

20. Please list all current trials including the type of drug or device, the Phase and the trial start and end dates. Please include trials that may begin within the next 12 months.

21. Have there been any adverse results from previous trials? ☐Yes ☐No

If "Yes," please explain and please confirm whether or not these were reported as claims under a previous policy:

22. What percentage of the Applicant's patients/clients are in the following age ranges?
< 18 years of age: ______ Ages 18-64: ______ >65 years of age: ______

23. How will the Applicant's test subjects be recruited? Check all that apply:
☐ By the applicant
☐ By the trial sponsor
☐ By physicians
☐ Other (describe):

24. Will all test subjects be required to sign an informed consent form? Please provide copy(ies). ☐Yes ☐No
If "No," please explain.

25. Where will the trials be performed? Please check the appropriate response.
☐ Applicant's facility
☐ Hospital
☐ Clinical Research Center
☐ Other (describe):



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26. Please provide the name of the device/pharmaceutical manufacturers for which you are conducting trials.

27. Does the Applicant provide: ☐Yes ☐No

a. Services to entities other than a trial sponsor? ☐Yes ☐No
b. Services to a trial sponsor? ☐Yes ☐No
c. Management of trials? ☐Yes ☐No
d. Evaluation and monitoring of reports and preparation of materials for the FDA? ☐Yes ☐No
e. Development of trial protocol? ☐Yes ☐No
f. Direct patient care services? i.e. drawing blood, taking vitals, dosing patients? ☐Yes ☐No
g. Product development? ☐Yes ☐No
h. Lab services? ☐Yes ☐No
i. Recruitment of test subjects? ☐Yes ☐No
j. Other?

28. Will an Institutional Review Board oversee the trials? ☐Yes ☐No

If "Yes," are you a member of this Board? ☐Yes ☐No
If "No," please explain:

29. Please provide requested information for the Medical Director or Administrator at the Applicant's facility:

Name of Medical Director/Administrator: Specialty:

Coverage (check one): ☐ Coverage on this policy ☐ No coverage needed/covered elsewhere

Responsibilities (check one): ☐Administrative Only ☐Direct Patient Care ☐Both

30. Please provide requested information for each physician providing services at the Applicant's facility: ☐None

| Physician Names | Specialty | To Be Covered On This Policy | Check One | Hours per Month |
|---|---|---|---|---|
| | | ☐Yes ☐No | ☐Employee ☐Contractor | |
| | | ☐Yes ☐No | ☐Employee ☐Contractor | |
| | | ☐Yes ☐No | ☐Employee ☐Contractor | |
| | | ☐Yes ☐No | ☐Employee ☐Contractor | |



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| 31. Allied Health Care Professionals (Indicate number of personnel and annual hours worked in each applicable category) | | | | | | |
|---|---|---|---|---|---|---|
| | Employees | | Contractors | | Volunteers | |
| | Number of: | Annual Hours: | Number of: | Annual Hours: | Number of: | Annual Hours: |
| Addiction Counselor | | | | | | |
| Bioethicist | | | | | | |
| Case Worker or Case Manager | | | | | | |
| Chiropractor | | | | | | |
| Clinical Research Associate | | | | | | |
| Clinical Research Coordinator | | | | | | |
| Clinical Research Monitor | | | | | | |
| Data Manager | | | | | | |
| Dentist | | | | | | |
| EMT / Paramedic | | | | | | |
| Home Health Aide / Caregiver | | | | | | |
| Lab Technician | | | | | | |
| Mental Health Counselor | | | | | | |
| Nurse – RN | | | | | | |
| Nurse – LPN/LVN | | | | | | |
| Nurse Aide or Assistant | | | | | | |
| Nurse Anesthetist | | | | | | |
| Nurse Practitioner / Advanced Practice Nurse | | | | | | |
| Medical Writer | | | | | | |
| Occupational/Speech Therapist | | | | | | |
| Optometrist | | | | | | |
| Pharmacist | | | | | | |
| Physical Therapist | | | | | | |
| Physician | | | | | | |
| Physician Assistant | | | | | | |
| Podiatrist | | | | | | |
| Principal Investigator | | | | | | |
| Psychologist | | | | | | |
| Quality Assurance | | | | | | |
| Quality / Regulatory Compliance | | | | | | |
| Respiratory Therapist | | | | | | |
| Social Worker | | | | | | |
| Statistical Management | | | | | | |
| Sub-investigator | | | | | | |
| Surgical Technician | | | | | | |
| Other: ____________________ | | | | | | |

32. Does the Applicant have any professional staff members who are not licensed or who have restricted licenses or privileges? ☐Yes ☐No

If "Yes," please explain:

a. Do you credential all professional staff that you employ? ☐Yes ☐No
b. If "Yes," how often is credentialing done? ________________________________________
c. If "No," please explain.



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**Risk Management**

33. Is there an individual who is designated with the job title and role of Risk Manager? ☐Yes ☐No

If "No," explain:

34. Is there an ongoing Quality Assessment or Improvement Plan? ☐Yes ☐No

If "No," explain:

35. Are transfer agreements in place with the closest hospital(s) for patients who develop a need for care beyond the scope of the facility? ☐Yes ☐No

36. Is a formal process in place to evaluate and address concerns of unexpected patient outcomes? ☐Yes ☐No

37. Are written policies and procedures in place for reporting of any suspected abuse? ☐Yes ☐No

38. Is an informed consent process in place? ☐Yes ☐No

39. Is there an infection program in place? ☐Yes ☐No

## CURRENT AND REQUESTED COVERAGE

40. Current Coverage:

| | Carrier | Policy Period | Limits | Ded/SIR | Retro Date<br>If Occ – type N/A | Premium |
|---|---|---|---|---|---|---|
| Professional Liability | | | | | | |
| General Liability | | | | | | |
| Excess Liability | | | | | | |

41. Coverage Requested Desired Effective Date: ______________________

☐Professional Liability ☐Claims Made ☐Retro Date (If Claims Made)

☐General Liability ☐Claims Made ☐Occurrence ☐Retro Date (If Claims Made)

☐Non Owned Automobile Liability* Sublimit $

(*If checked, please complete the Hired & Non-Owned Supplemental Application)

☐Employee Benefit Liability Retroactive Date

\# of Employees

Limits of Liability Requested (Each Claim/Aggregate)

__$100,000 / $300,000 __$250,000/$750,000 __$1,000,000/$3,000,000 __$2,000,000/$4,000,000

__$2,000,000/$6,000,000 Other: Excess Limits:

42. Is the Applicant currently enrolled in a Patient Compensation Fund? ☐Yes ☐No

If "Yes," which one(s)?

43. MISSOURI RESIDENTS – DO NOT ANSWER. Has any insurer cancelled or declined to issue Professional or General Liability insurance for the Applicant? ☐Yes ☐No

If "Yes," please provide details:



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## CLAIMS HISTORY

44. During the past five (5) years, has any claim that would fall within the scope of the proposed insurance been made against the Applicant or against any entity or individual proposed for coverage under this insurance? ☐Yes ☐No

If "Yes," please provide dates of loss, claimant name, all defense and indemnity payments, all defense and indemnity reserves (if claims are open), and claim status (open/closed):

**NOTE:** WITHOUT PREJUDICE TO ANY OTHER RIGHTS OR REMEDIES OF THE UNDERWRITER, IT IS AGREED THAT ANY CLAIM REQUIRED TO BE DISCLOSED IN RESPONSE TO QUESTION 44 IS EXCLUDED FROM THE PROPOSED INSURANCE.

45. Is the Applicant or any entity or individual proposed for coverage under this insurance aware of any fact, circumstance, situation, transaction, event, act, error or omission which they have reason to believe may or could reasonably be foreseen to give rise to a claim that may fall within the scope of the proposed insurance? ☐Yes ☐No

If "Yes," please provide details:

**NOTE:** WITHOUT PREJUDICE TO ANY OTHER RIGHTS OR REMEDIES OF THE UNDERWRITER, IT IS AGREED THAT ANY CLAIM ARISING FROM ANY FACT, CIRCUMSTANCE, SITUATION, TRANSACTION, EVENT, ACT, ERROR OR OMISSION REQUIRED TO BE DISCLOSED IN RESPONSE TO QUESTION 45 IS EXCLUDED FROM THE PROPOSED INSURANCE.

## REQUIRED INFORMATION

**Required Attachments**

Please include a current copy of each of the following documents with the application:

☐Declarations Page from current policy, showing policy period, limits of liability, retroactive date, and any exclusions that were applied to the policy

☐Audited financial statements or Pro Forma financial statements if Applicant is newly formed

☐ Schedule of Named Insureds

☐Loss runs from all insurance carriers that insured the Applicant for the past six years (if applicable)

☐Specimen copies of standard contracts used with third parties

☐Copy of corporate by-laws

☐Copy of your facility's most recent license (if applicable)

☐Copy of your facility's most recent inspection report (if applicable)

☐Copy of your facility's current screening, hiring or credentialing guidelines

## FRAUD WARNINGS

Any person who knowingly and with intent to defraud an insurance company or another 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 guilty of committing a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties.

**Alabama:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution fines or confinement in prison, or any combination thereof.

**Alaska:** A person who knowingly and with intent to injure, defraud, or deceive an insurance company files a claim containing false, incomplete, or misleading information may be prosecuted under state law.

**Arizona:** For your protection Arizona law requires the following statement to appear on this form. Any person who knowingly presents a false or fraudulent claim for payment of a loss is subject to criminal and civil penalties.

**Arkansas:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit, or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**California:** For your protection California law requires the following to appear on this form: Any person who knowingly presents false or fraudulent information to obtain or amend insurance coverage or to make a claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

**Colorado:** It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance, and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete, or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

**Delaware:** Any person who knowingly, and with intent to injure, defraud, or deceive any insurer, files a statement of claim containing any false, incomplete, or misleading information is guilty of a felony.

**District of Columbia:** WARNING: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

**Florida:** Any person who knowingly and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony of the third degree.

**Idaho:** Any person who knowingly, and with intent to defraud or deceive any insurance company, files a statement containing any false, incomplete, or misleading information is guilty of a felony.

**Indiana:** A person who knowingly and with intent to defraud an insurer files a statement of claim containing any false, incomplete, or misleading information commits a felony.

**Kansas:** Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

**Kentucky:** Any person who knowingly and with intent to defraud any insurance company or other person files a statement of claim containing any materially false information or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

**Louisiana:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**Maine:** It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines, or denial of insurance benefits.

**Maryland:** Any person who knowingly or willfully presents a false or fraudulent claim for payment of a loss or benefit, or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.



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**Michigan:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**Minnesota:** A person who files a claim with intent to defraud or helps commit a fraud against an insurer is guilty of a crime.

**Nevada:** Pursuant to NRS 686A.291, any person who knowingly and willfully files a statement of claim that contains any false, incomplete or misleading information concerning a material fact is guilty of a category D felony.

**New Hampshire:** Any person who, with a purpose to injure, defraud, or deceive any insurance company, files a statement of claim containing any false, incomplete, or misleading information is subject to prosecution and punishment for insurance fraud, as provided in RSA 638:20.

**New Jersey:** Any person who knowingly files a statement of claim containing any false or misleading information is subject to criminal and civil penalties.

**New Mexico:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

**Ohio:** Any person who, with intent to defraud or knowing that he is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

**Oklahoma:** WARNING: Any person who knowingly, and with intent to injure, defraud, or deceive any insurer, makes any claim for the proceeds of an insurance policy containing any false, incomplete, or misleading information is guilty of a felony.

**Oregon:** Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

**Pennsylvania:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

**Puerto Rico:** Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances be present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

**Rhode Island:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**Tennessee:** It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines, and denial of insurance benefits.

**Texas:** Any person who knowingly presents a false or fraudulent claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

**Virginia:** It is a crime to knowingly provide false, incomplete, or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines, and denial of insurance benefits.

**Washington:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**West Virginia:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

## SIGNATURE AND AUTHORIZATION

The undersigned, as authorized agent of all individuals and entities proposed for this insurance, declares that, to the best of his/her knowledge and belief, after reasonable inquiry, the statements in this Application and any attachments or information submitted with this Application (together referred to as the "Application") are true and complete. For Florida accounts, the preceding sentence is replaced with the following: The undersigned, as authorized agent of all individuals and entities proposed for this insurance, represents that, to the best of his/her knowledge and belief, after reasonable inquiry, the statements in this Application and any attachments or information submitted with this Application (together referred to as the "Application") are true and complete. The information in this Application is material to the risk accepted by us. If a policy is issued it will be in reliance upon the Application, and the Application will be the basis of the contract.

We will maintain the information contained in and submitted with this Application on file and along with the Application will be considered physically attached to, part of, and incorporated into the policy, if issued. For North Carolina, Utah and Wisconsin accounts, this Application and the materials submitted with it shall become part of the policy, if issued, if attached to the policy at issuance.

We are authorized to make any inquiry in connection with this Application. Our acceptance of this Application or the making of any subsequent inquiry does not bind you or us to complete the insurance or issue a policy.

The information provided in this Application is for underwriting purposes only and does not constitute notice to us under any policy of a Claim or potential Claim.

If the information in this Application materially changes prior to the effective date of the policy, you must notify us immediately and we may modify or withdraw any quotation or agreement to bind insurance.

NOTICE TO NEW YORK APPLICANTS: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.

| | |
|---|---|
| Applicant Name | |
| By (Authorized Signature) | |
| Name/Title | |
| Date | |

NOTE: THIS APPLICATION MUST BE SIGNED BY A PARTNER, PRINCIPAL, DIRECTOR OR OFFICER OF THE APPLICANT ACTING AS THE AUTHORIZED AGENT OF ALL INDIVIDUALS AND ENTITIES PROPOSED FOR THIS INSURANCE.

| | | | |
|---|---|---|---|
| Produced By (Insurance Agent) | | | |
| Insurance Agency | | | |
| Insurance Agency Taxpayer ID | | | |
| Agent License No. or Surplus Lines No. | | | |
| Address | Street: | | |
| | City: | State: | Zip: |
| Email Address | | | |

| | | | |
|---|---|---|---|
| Submitted By (Insurance Agency) | | | |
| Insurance Agency Taxpayer ID | | | |
| Agent License No. or Surplus Lines No. | | | |
| Address | Street: | | |
| | City: | State: | Zip: |

NOTE: FOR NEW HAMPSHIRE APPLICANTS, PRODUCER'S NAME AND SIGNATURE ARE REQUIRED.