SUNY RF
The Research Foundation for
The State University of New York

AMSURE

# SUNY Insure Qualified Party Referral Form

Qualified Party Contact Information *(To Be Completed by Applicant)*

Entity to be Insured: _____

Primary contact: _____

Address: _____

Federal Tax ID: _____

Phone: _____

E-mail: _____

Website: _____

Technology Type: _____

For Licensees: Development and Commercialization (D&C) Plan Attached? Yes No N/A

For Business Partners: Business Plan Attached? Yes No N/A

Areas of Operations Outside of D&C Plan: _____

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RF to be named as primary additional insured? Yes No

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*To Be Completed by RF Authorized Representative*

The undersigned represents that the entity to be insured is a Qualified Party pursuant to the March 28, 2012 Amended Memorandum of Understanding between The Research Foundation of State University of New York and Amsure Associates, Inc. Please submit a completed form and any requested information to Guy Alonge at guy@amsure.net.

Signed: _____

Print Name: _____

Title_____

Date: _____

## Qualified Party Insurance Guidelines

| Insurance Type | Comment |
|---|---|
| Statutory Workers Compensation | Not required under RF license so long as the contract includes the following language:<br><br>The relationship between the parties shall never be construed to be that of employer-employee. |
| Commercial General Liability<br>Including Products Liability | Required under RF license. See schedule below for limits based on class. |
| Products Liability Exclusions | Underwriting will determine whether specific treatment is required. |
| Directors and Officers Liability | Not required under RF license |

| **Product/Service** | **Description**<br>*Indicates Wikipedia definition | **Limit**<br>Aggregate<br>Per Occurrence |
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| Medical Test (three types) | A diagnostic test is a procedure performed to confirm, or determine the presence of disease in an individual suspected of having the disease, usually following the report of symptoms, or based on the results of other medical tests.*<br><br>A screening is a medical test or series used to detect or predict the presence of disease in individuals at risk for disease within a defined group, such as a population, family, or workforce. Screenings may be performed to monitor disease prevalence, manage epidemiology, aid in prevention, or strictly for statistical purposes.*<br><br>Evaluation: Some medical tests are used to evaluate the progress of, or response to medical treatment. They are also used to monitor the course (prognosis) of a disease. | $2M<br><br>$2M<br><br>Considerations: some medical testing procedures have health risks, and some may require general anesthesia. Other tests, such as the blood test or pap smear have little to no direct risks. Medical tests may also have indirect risks, such as the stress of testing, and riskier tests may be required as follow-up for a (potentially) false positive test result.* |
| Medical Device | FDA classifies medical devices in one of three categories | |
| • Class I | Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury. Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.* | $2M<br>$2M |
| • Class II | Devices in Class II are held to a higher level of assurance than Class I devices, and are designed to perform as indicated without causing injury or harm to patient or user. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.* | $2M<br>$2M |

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| • Class III | Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Examples of Class III devices which currently require a premarket notification include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.* | $5M<br>$5M<br><br>Note: These limits can be met through a combination of primary or primary/excess/umbrella coverage. |
| Food or Supplement | The regulation of food and dietary supplements by the U.S. Food and Drug Administration is governed by various statutes enacted by the United States Congress and interpreted by the U.S. Food and Drug Administration ("FDA"). Pursuant to the Federal Food, Drug, and Cosmetic Act ("the Act") and accompanying legislation, the FDA has authority to oversee the quality of substances sold as food in the United States, and to monitor claims made in the labeling about both the composition and the health benefits of foods.<br><br>Substances which the FDA regulates as food are subdivided into various categories, including foods, food additives, added substances (man-made substances which are not intentionally introduced into food, but nevertheless end up in it), and dietary supplements. The specific standards which the FDA exercises differ from one category to the next. Furthermore, the FDA has been granted a variety of means by which it can address violations of the standards for a given category of substances.* | $2M<br>$2M |

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| OTC Drug | Over-the-counter (OTC) drugs are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, as compared to prescription drugs, which may be sold only to consumers possessing a valid prescription. In many countries, OTC drugs are selected by a regulatory agency to ensure that they are ingredients that are safe and effective when used without a physician's care. OTC drugs are usually regulated by active pharmaceutical ingredients (APIs), not final products. By regulating APIs instead of specific drug formulations, governments allow manufacturers freedom to formulate ingredients, or combinations of ingredients, into proprietary mixtures.* | $2M<br>$2M |
| Drug | A drug, broadly speaking, is any substance that, when absorbed into the body of a living organism, alters normal bodily function.* | $5M<br>$5M<br><br>Considerations: Development will typically involve animal testing followed by human clinical trials. Commercial use is directly in humans. Phased limit increases may be acceptable. |
| Research Tool | An assay or compound that is sold in a kit or alone that is used by scientists in conducting experiments. | $1M<br>$2M |
| Research Equipment | A device or machine that is used by scientists to conduct research. | $1M<br>$2M |
| Software | Self-explanatory; software may have many uses, some may pose higher risk. | $1M<br>$1M<br><br>Add: Computer software errors and omissions $1M |

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| Consumer Product | Any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but does not include— (A) any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer. U.S. Consumer Product Safety Act. | $1M<br>$2M |
| Industrial Product | An article, or component part thereof, produced or distributed for sale to an industrial user. | $1M<br>$2M |
| Directors and Officers Liability | An insurance payable to the directors and officers of a company, or to the organization itself, as indemnifications for certain damages (losses) or advancement of defense costs in the event any such insured suffers such a loss as a result of a legal action brought for alleged wrongful acts in their capacity as directors and officers or against the organization.* | $1M |