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What do Indemnification Clauses mean in Data Use Agreements for Cancer Registry Data?

What is indemnification?

Indemnification is a common obligation in contracts. The parties who enter into a contract together often use the language of the contract to contemplate potential problems and to plan for who will be responsible for such problems. An indemnification clause typically serves to assign responsibility between the parties for harms and damages that may be incurred by a party who is *not* part of the contract itself—that is, not signing the contract, agreeing to it or performing under it in any capacity. This kind of a party is called a "third party."

To indemnify a person or entity in the context of a contract is to accept liability – typically committing to compensation – should the person or entity incur losses or harms resulting from specific types of events or actions. Indemnification provisions thus present a form of security, provided by one party, for the other party's potential legal liability in regard to the specified events or actions.

Indemnification clauses are sometimes referred to as "hold harmless" clauses because this is a typical form of an indemnification clause. In a "hold harmless" clause, one party indicates that it will protect the other from liabilities or damages sought by third parties, often specifying the types of events or actions to which the protection will apply or not apply (such as excluding negligent or reckless actions), and the persons who may benefit from protection (such as the directors, officers, agents and others who act in a capacity on behalf of the party entering the contract). A mutual hold harmless clause is one in which the protections offered and/or excluded are reciprocal between the parties.

Why are there indemnification clauses in Data Use Agreements?

Data use agreements often implicate the rights and interests of various parties who are not parties to the agreement itself. Such parties are referred to as "third parties" and may include individuals about whom data is being used in research, or institutions including central registries that contribute data to research resources, among others. Indemnification clauses allow the parties to allocate responsibilities in the event of liabilities or damages arising among such parties. In the context of a data use agreement for cancer registry data, a third party is typically a party other than the providing institution and the research-recipient institution that also has an interest in the individual-level data and/or its confidentiality, e.g., the cancer patient whose tumor-related data is being shared by a central cancer registry to a research-recipient institution.

What is the purpose of an indemnification clause?

The purpose of the clause is to set expectations in the event that losses, damages, or injuries accrue to third parties in connection with the agreement. Indemnification clauses typically carry common elements including specification of:

- who indemnifies whom,
- the kinds of losses, damages, or injuries that may prompt indemnification,
- the kinds of damages that may be recoverable, and
- any exceptions to indemnification that the parties agree upon.

To whom and to what kinds of acts or events do indemnification clauses apply?

Indemnification clauses typically extend to the legal entity entering into an agreement and a series of actors inclusive of, for example, directors, officers, employees, and contractors. The kinds of events subject to indemnification typically include intentional or grossly negligent acts or omissions in the performance of an agreement. In the context of a data use agreement for cancer registry data, this might include intentional disregard of data security protections in management or use of cancer registry data.

Are there exceptions to indemnification that impact Data Use Agreements?

The most common exceptions to indemnification among data use agreements involving central cancer registries pertain to sovereign immunity. Sovereign immunity is the legal principle that the government cannot be sued without its consent. Governments typically waive sovereign immunity only in certain situations of heightened public interest. This is important because of the roles of various government agencies—federal, state, and local—in the operation of cancer registries, and in research. Such agencies are often restricted from entering into contracts that commit to indemnification, and/or limit their authority to do so to hazardous activities or activities that may result in catastrophic losses and/or may require the contractor to obtain special insurance.

More generally, and where the parties agree, exceptions to indemnification typically pertain to circumstances in which neither party will be liable to the other for any indirect, incidental, special, consequential, or punitive damages, whether caused by negligence or otherwise. Note that indemnification clauses can be unilateral with one party indemnifying the other, or mutual in which the parties agree to reciprocal rights and remedies.

Example Indemnification Clause

"Researcher shall indemnify NAACCR from any and all liability, loss, or damage (including attorneys' fees) suffered as a result of claims, demands, costs or judgments arising out of the failure of Researcher or those acting in connection with Researcher to conform to and obey the provisions of this Data Confidentiality Agreement. In the event a claim should be brought or an action filed against NAACCR in connection with any such failure, Researcher agrees that NAACCR may employ attorneys of its own selection to appear and defend the claim or action on behalf of NAACCR, at the expense of Researcher. NAACCR, at its option, shall have the sole authority for the direction of the defense and shall be the sole judge of the acceptability of any compromise or settlement of any claims or action against NAACCR."

Excerpted from the Data Confidentiality Agreement for NAACCR Researchers, version dated February 5, 2010