

The Clinical Trial Agreement Checklist

The sponsor or CRO writes the agreement to protect the study, the drug, and the data. Before your site signs, here is what to require — and what to reject — read from the side that treats the subjects and stands behind the research.

Protecting the subjects and the science

- ☐ **IRB approval** **Require:** the Study proceeds only under your IRB's prior and ongoing approval.
Watch for: Language that lets the Study start, or continue, without your IRB's review governing.
- ☐ **Informed consent** **Require:** consent obtained under IRB approval and applicable law, with the Sponsor limited to review and comment.
Watch for: A Sponsor given control over the consent form or process, rather than a right to review and comment.
- ☐ **Safety reporting** **Require:** the Sponsor promptly reports safety findings to you, and you may independently communicate them to subjects.
Watch for: One-way reporting, or a bar on telling subjects what you learn about their safety.
- ☐ **Subject injuries** **Require:** the Sponsor bears the cost of trial-related injury to subjects.
Watch for: Known-risk, negligence, or insurance-based exclusions that quietly shift injury costs onto your institution.
- ☐ **No guarantee of results** **Require:** nothing obligating you to guarantee outcomes or warrant that the Study will achieve any result.
Watch for: A warranty of results, enrollment targets treated as promises, or any guarantee of the science.

Who owns the work, and who can publish

- ☐ **Publication rights** **Require:** you and the investigator keep the right to publish, with Sponsor review limited to a defined window to flag confidential information or request a patent-filing delay.
Watch for: Sponsor consent or approval to publish, indefinite review periods, or a right to suppress results.
- ☐ **Study data ownership and use** **Require:** even where the Sponsor owns the data, you retain access and use for research, education, publication, and patient care.
Watch for: Sponsor ownership with no reserved license back to you — leaving you unable to use your own site's data.
- ☐ **Intellectual property** **Require:** the Sponsor owns inventions built on its drug, device, or confidential information; you keep an internal-use license and your pre-existing IP.
Watch for: A sweeping assignment of all inventions, or terms that capture your background IP and know-how.

The risk you carry and the money

- ☐ **Indemnification** **Require:** the Sponsor indemnifies you for claims arising from the Study and its use of the data, carved back only for your negligence or willful misconduct — and you owe no indemnity beyond the same.
Watch for: A one-way indemnity running only from you, or a duty to indemnify the Sponsor for risks inherent in its own protocol.
- ☐ **Sponsor insurance** **Require:** the Sponsor maintains insurance or financial responsibility sufficient to cover liabilities arising from the Study.
Watch for: A Sponsor that carries nothing, or shifts the burden of proof of coverage entirely onto you.
- ☐ **Limitation of liability** **Require:** no cap on the Sponsor's liability for subject injury or its indemnity obligations. A mutual waiver of consequential damages is expected and fine.
Watch for: A cap that reaches the Sponsor's exposure for subject injury or indemnity — especially one that binds only you.
- ☐ **Fair market value** **Require:** payments consistent with fair market value and not contingent on enrollment numbers or Study outcomes.
Watch for: Per-subject bonuses, outcome-based payments, or terms that read as inducement rather than fair compensation.
- ☐ **Termination payment** **Require:** on termination, the Sponsor reimburses costs incurred and non-cancellable obligations.
Watch for: Termination for convenience with no reimbursement, leaving your site holding committed and unrecoverable costs.