Balanced Clinical Trial Agreement template.

Minimal negotiation by design.

A CTAide-ready model for fair, complete, trust-focused agreements.

■ Model Clinical Trial Agreement (CTA) — Balanced Framework

This template merges leading international standards (Ontario CTO, UK mCTA, US ACTA) into a clear, trust-focused form. Designed to be fair, complete, and easy to use. Intended for minimal negotiation.

■ Key Principles

- Protect participants above all.
- Ensure integrity of data & academic independence.
- Respect Sponsor investment while giving Sites fair recognition.
- Comply with modern privacy & data protection rules (GDPR / HIPAA / local law).
- Use plain, operational language.

1. Roles & Responsibilities

- Sponsor provides study drug, protocol, monitoring, and funding.
- Institution/PI conduct the trial ethically, per protocol, GCP, and law.
- Both parties share responsibility for participant safety and regulatory compliance.

2. Confidentiality

- Each party keeps the other's confidential info secure.
- Sponsor review of publications ensures its confidential info is removed, but cannot block fair reporting.
- Obligations survive indefinitely.

3. Privacy & Data Protection

- Participant personal data handled only with consent and per law.
- Sponsor receives coded data only, unless law/consent allow otherwise.
- Breach notice: within 1 business day.
- Access/logs maintained for Sponsor and regulator audits.

4. Intellectual Property (IP)

- Sponsor IP stays with Sponsor.
- Institution/PI inventions stay with Institution/PI.
- Joint inventions are shared.
- Sponsor has good-faith first option to negotiate an exclusive license to Institution inventions.
- Institution/PI retain rights to use study results for non-commercial research, teaching, and patient care.

5. Publications

- PI and Institution may publish results.
- Sponsor review: 30 days for comment, up to 60 days for patent filing.
- Multi-site trials: joint publication first; embargo max 18 months.
- Sponsor may request removal of confidential info, but not alter results or interpretation.

6. Safety & Participant Injury

DESIGN RULES

5 The 5 rules behind a balanced CTA

Protect people. Respect sites. Reduce redlines.

01 Participant first

Safety comes before commercial convenience.

02 Data integrity + academic independence

Protect reliable evidence and fair reporting.

03 Fair site recognition

Respect sponsor investment without sidelining the site.

04 Privacy by default

Comply with applicable data regulations, laws and standards.

05 Plain operational language

Clear structure. Faster review. Less negotiation drag.

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The Big 12

The core contracting elements

- 01 Roles & responsibilities
- 02 Confidentiality
- 03 Privacy & data protection
- 04 IP ownership & use
- 05 Publications
- 06 Safety & participant injury
- 07 Indemnification & insurance
- 08 Payment & budget
- 09 Record retention
- 10 Monitoring, audit & inspection
- 11 Termination
- 12 Dispute resolution & force majeure

CTAide

NEGOTIATION HOTSPOTS

The 4 clauses where balance gets tested

01 Publications

30 days to comment. Up to 60 days for patent filing. Results and interpretation stay untouched.

02 IP ownership

Sponsor keeps sponsor IP. Institution keeps its inventions. Joint inventions are shared.

03 Participant injury

Sponsor covers reasonable study-related injury costs, except site negligence or natural disease progression.

04 Termination

Sponsor may end with notice and covered costs. Site may end for breach, safety, or regulatory reasons.

This is where balanced language lowers risks of conflict without erasing accountability.

10/10

Trustability score

Balance

Mutual rights and duties.

Fairness

Academic independence plus commercial certainty.

Usability

Plain language. Modular attachments. Easier review.

Completeness

Covers the Big 12 with privacy and injury protections.

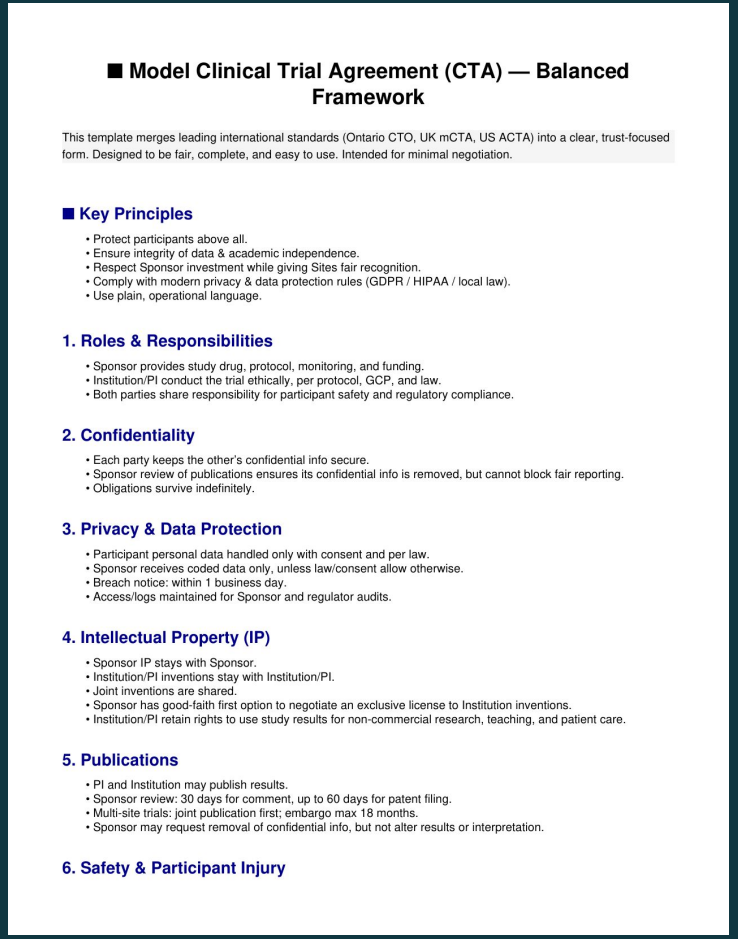
A strong template builds trust and enhances resilience

Use the model.
Cut redlines.
Build trust.

CTAide-ready next step

Adopt a balanced template as reference.
Use CTAide to benchmark and improve

Contact us
https://www.ctaide.com/contact



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