



ACTA Template Updates

ARA4US Revised ACTA · November 17, 2025

The updated ACTA form is a moderate revision with substantive edits to roughly twenty clauses. The most significant changes restructure and broaden indemnification (Sections 11.1–11.3), replace fixed insurance minimums with a flexible “sufficient levels” standard (Sections 13.1–13.2), add new Institution protections on Sponsor assignment and study wind-down, and introduce two new provisions (a GMP certification and a Sponsor equipment recall obligation); the rest are narrower clarifications. Our ACTA Profile was updated in lockstep, with each substantive template change mapped to a corresponding profile position. The entire profile was updated separately to conform to our updated Profile drafting conventions.

Section	ACTA Template Change	TCN Profile Change
1.4 (new)	Added: Sponsor certifies Study Drug/Device made/handled per GMP + regs for human use. (Renumbers 1.4→1.5 etc.)	New topic “Good Manufacturing Practices”: added Preferred position — Sponsor certifies Study Drug/Device manufactured/handled per GMP + regs for human use through delivery to Institution.
1.6 (was 1.5)	Deleted “waiver of consent as directed by IRB” option.	N/A (Phrase not addressed in profile)
2	Payment trigger changed: “subjects enrolled” + prorated/non-cancelable language → simplified to “for the conduct of” the Study.	Study Payments: dropped the prorated/actual-work-completed + non-cancelable Preferred position and the “based on budget/payment terms” Permitted; replaced with Preferred — pay per Exhibit A Budget “for the conduct of” the Study.
5.2	“Study Data”→“Data”; breach notice timing “immediately”→“promptly.”	Data Security: “[Study data]”→ “[Data]”; Sponsor breach-notice timing “immediately”→“promptly.”
9.3	Study completion now defined to include “final database lock.”	Publication – Institution Access: added “(including final database lock)” to the 18-month Study-completion trigger.
11.1	Indemnity restructured to (a)–(d) and broadened: adds Sponsor’s material breach, non-compliance w/ law, negligence, use of Data/results.	Indemnification – Institution Indemnified (3rd-party claims): rewrote Preferred to the (a)–(d) structure (conduct of Study; use of Drug/Device; Sponsor breach/non-compliance/negligence; use of Data or results). Trimmed the Permitted enumerated list (removed res. results/negligence sub-items; kept injuries, infringement, PHI, willful misconduct, participant claims).

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11.2	Carve-out reworded: “negligent or wrongful acts” → “negligent acts or omissions or willful misconduct.”	Indemnification – No Indemnification for Institution-Caused Claims: consolidated the three Permitted carve-outs into one “limited to the following” list (1/2/AND-OR 3); item 3 reworded to “negligent acts or omissions or willful misconduct.”
11.3	Added “caps” to preserved limits/immunities.	Indemnification – Sponsor Indemnified: reframed the Institution-negligence position as Permitted “only if” subject to “the limits, caps, or prohibitions” and immunities under applicable law.
12	“a” → “the” Drug/Device; added “prior” before written instructions; imminent-threat deviation now standalone sentence.	Subject Injury – Reimbursement: added “prior” before “written instructions” in carve-out (c); split the imminent-threat deviation protection into its own standalone Preferred position.
13.1	Removed fixed minimums (\$1M/\$3M) → “levels sufficient to support its obligations.”	Insurance – Institution: removed the \$1M/\$3M Permitted ceilings; Permitted now requires insurance/self-insurance “at levels sufficient to support its obligations.” Prohibited now bars specified limits (replace with “sufficient levels” language).
13.2	Removed fixed minimums (\$3M/\$5M) → “levels sufficient”; CGL/clinical trial/products liability still required.	Insurance – Sponsor: Preferred rewritten to “levels sufficient to support its obligations” (still listing CGL/clinical trial/products liability). \$3M/\$5M minimums moved into a conditional “only if” position (limits must be ≥ those floors).
14.4	Added new (c): cease treating subjects per Sponsor direction (where medically appropriate). Added carve-out for Confidential Info held via auto-backups.	Confidential Information – Return or Destruction: added to the Preferred retention right — Institution may also retain Confidential Info held “through Institution’s automatic backup systems.”
14.5	Added “reasonably” to wind-down cooperation duty.	Termination – Wind-Down of Costs: orderly wind-down cooperation reframed as Permitted “only if” the agreement states Institution will “reasonably” cooperate.
14.6	Cross-refs updated for renumbering; survival period generalized (“therein” vs. hardcoded 3.1).	<i>N/A (Specific sections not included in profile)</i>
16.1 (new)	Added: Sponsor must ensure Equipment/materials comply w/ law + notify Institution of recall/withdrawal. (Old equipment text → 16.2.)	New topic “Equipment – Provision and Recall”: added Required position — verbatim language obligating Sponsor to ensure materials/Equipment meet applicable laws and to notify Institution immediately of recall/regulatory withdrawal.
17.2	Added Institution right: 30-day diligence on Sponsor assignee + terminate w/o penalty on Sponsor assignment.	Subcontracting – Sponsor: added condition #3 to the Permitted position — Institution gets, at its sole discretion, 30 days’ diligence on the proposed assignee + right to terminate Agreement/Study without penalty on written notice.

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18	Expanded: states it doesn't govern day-to-day comms; split into "contractual/legal" vs. new "scientific/safety" notice blocks.	Notice – Form and Procedure: added Preferred position that the Notice section doesn't govern day-to-day Study communications; expanded the "deemed given" list to add "upon confirmation of delivery by email."
23	Removed "facsimiles" from accepted signatures (scanned/electronic still OK).	<i>N/A (Facsimiles not mentioned in profile)</i>
25	Choice of Law → "Intentionally omitted."	Governing Law – Location: added a Profile Guidance Disclaimer clarifying this topic is distinct from venue/jurisdiction/courts (positions otherwise unchanged).