

Delegation of Responsibilities Toolkit

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This toolkit has been developed to help researchers, Chief Investigators (CIs), project managers, Clinical Trials Unit (CTU) staff, and research governance professionals identify the correct Delegation of Responsibilities Matrix for their study. The appropriate matrix depends on the sponsorship and collaboration arrangements in place for the project.

Different responsibilities and oversight structures apply where:

- The University of Warwick is acting as the sole Sponsor.
- The study is operating under a co-sponsorship arrangement.
- The Chief Investigator is employed by another organisation.
- Warwick is providing operational support to a study sponsored by an external organisation.

Using the correct matrix helps ensure that:

- Sponsor responsibilities are clearly allocated.
- Delegated activities are appropriately documented.
- Oversight and accountability arrangements are transparent.
- Governance expectations between collaborating organisations are clearly defined.
- Appropriate supporting agreements are identified and implemented.

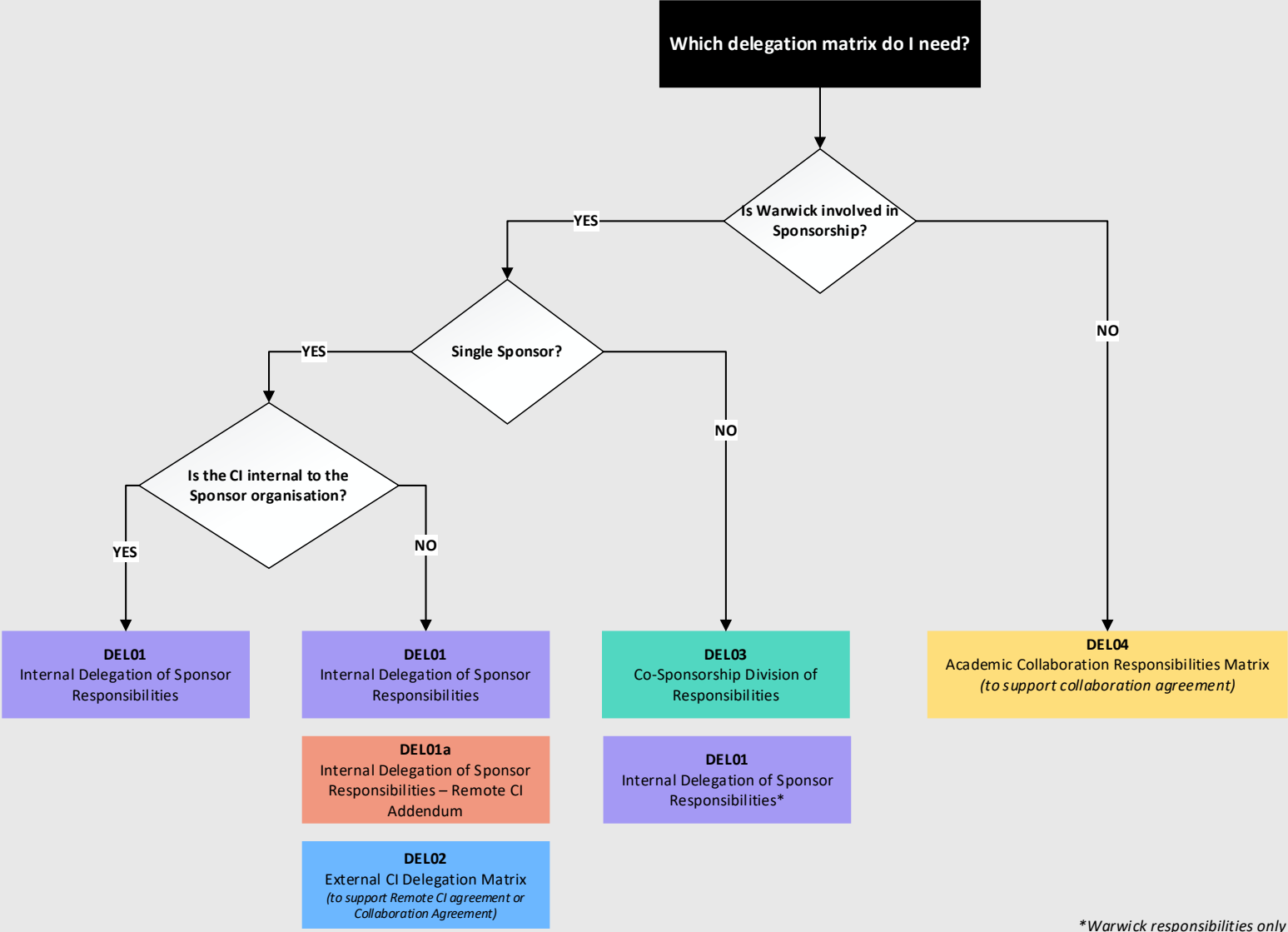
How to use this toolkit

Follow the decision tree on the following page to identify the sponsorship or collaboration model that applies to your study.

The decision tree will direct you to the appropriate Delegation of Responsibilities Matrix and any associated agreements required to document responsibilities and oversight arrangements.

The toolkit should be used during study set-up and whenever sponsorship or collaboration arrangements change during the lifecycle of a project.

Toolkit



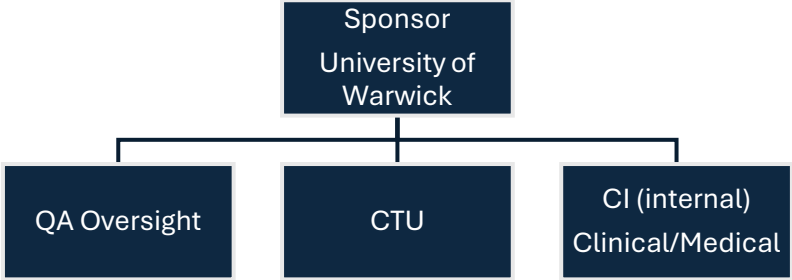
Template	What it does
DEL01	Within Warwick, who performs Sponsor, CI, CTU and QA functions?
DEL01a	In addition to DEL01, how does Warwick maintain oversight when the CI is external?
DEL02	Which responsibilities belong to the CI institution, and which belong to Warwick as Sponsor when the CI is external.
DEL03	How are Sponsor responsibilities are divided between two Co-Sponsors.
DEL04	What operational activities can Warwick undertake when another organisation is the Sponsor.
External CI Agreement	What contractual governance arrangements underpin the external CI relationship?

Outcome A

Template document to use	Purpose
DEL01 Internal Delegation of Sponsor Responsibilities	Record of <i>who does what</i> (CTU, CI, Sponsor, CTU QA) within Warwick.

When to use?

- ✓ Single Warwick Sponsor
- ✓ Internal CI
- ✓ WCTU delivering delegated Sponsor functions
- ✓ Sponsor QA is functioning within/alongside CTU



Outcome B

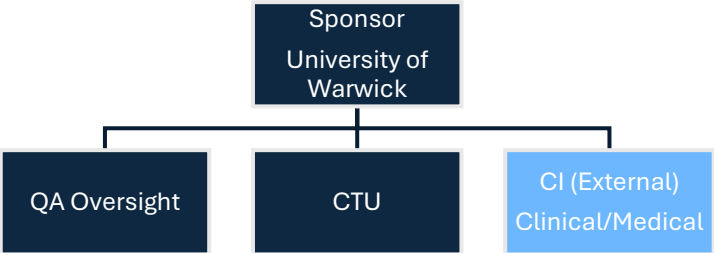
Template document to use	Purpose
DEL01 Internal Delegation of Sponsor Responsibilities	Record of <i>who does what</i> (CTU, CI, Sponsor, CTU QA) within Warwick.

Template document to use	Purpose
DEL01a Internal Delegation of Sponsor Responsibilities – Remote CI Addendum	Record of <i>who does what</i> (CTU, CI, Sponsor QA, Sponsor Retained) within Warwick, including how oversight of the external CI will be ensured.

Template document to use	Purpose
DEL02b External CI Delegation Matrix	To support a remote CI agreement. Outlines the expectations of the Sponsor with regards to delegated clinical functions.

When to use?

- ✓ Single Warwick Sponsor
- ✓ External CI
- ✓ WCTU delivering delegated Sponsor functions
- ✓ Sponsor QA is functioning within/alongside CTU



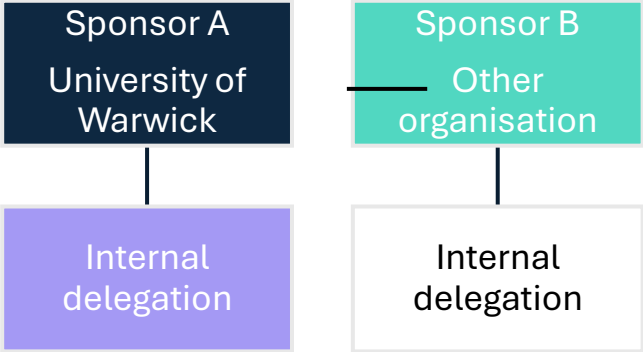
Outcome C

Template document to use	Purpose
DEL03 Co-Sponsorship Division of Responsibilities	Shows which Sponsor does what

Template document to use	Purpose
DEL01 Internal Delegation of Sponsor Responsibilities	Record of <i>who does what</i> (CTU, CI, Sponsor, CTU QA) within Warwick.

When to use?

- ✓ Co-Sponsorship
- ✓ Both organisations share sponsor duties
- ✓ WCTU delivering delegated Sponsor functions
- ✓ Sponsor QA is functioning within/alongside CTU
- ✓ CI may be internal or external



Outcome D

Template document to use	Purpose
DEL04 Academic Collaboration Responsibilities Matrix	Support delegation of operational support tasks to Warwick where the Sponsor is external. Sponsor retains accountability.

When to use?

- ✓ External Sponsor, also employing CI
- ✓ WCTU delivering delegated operational functions

