

FOR HEALTH SYSTEMS AND EMPLOYERS

Implementation Hub *Guide.*

What to expect at every gate, written for your
program lead, counsel and compliance team.



Close a care gap.

Measure and scale what works.

An Implementation Hub is a health system or employer that runs an Implementation Support Program (ISP) on one care gap for its own patients or workforce. Sponsors fund the work, AHIS governs it, and the results are published on ahis.org.

An Implementation Hub is

- A site that runs a defined protocol on one care gap
- Funded by sponsors under written agreements
- Governed by AHIS, an independent 501(c)(3)
- Measured against a baseline set before launch
- Published on ahis.org, whatever the results show

An Implementation Hub is not

- A vendor contract or a purchase
- A substitute for clinical judgment
- Directed by a sponsor
- A marketing or promotional program
- A guarantee of any clinical outcome

Two ways in. *Same four gates.*

1

Join an ISP already recruiting

The protocol, IRB determination and funding are already in place. You review the protocol and sign on.

2

Start your own

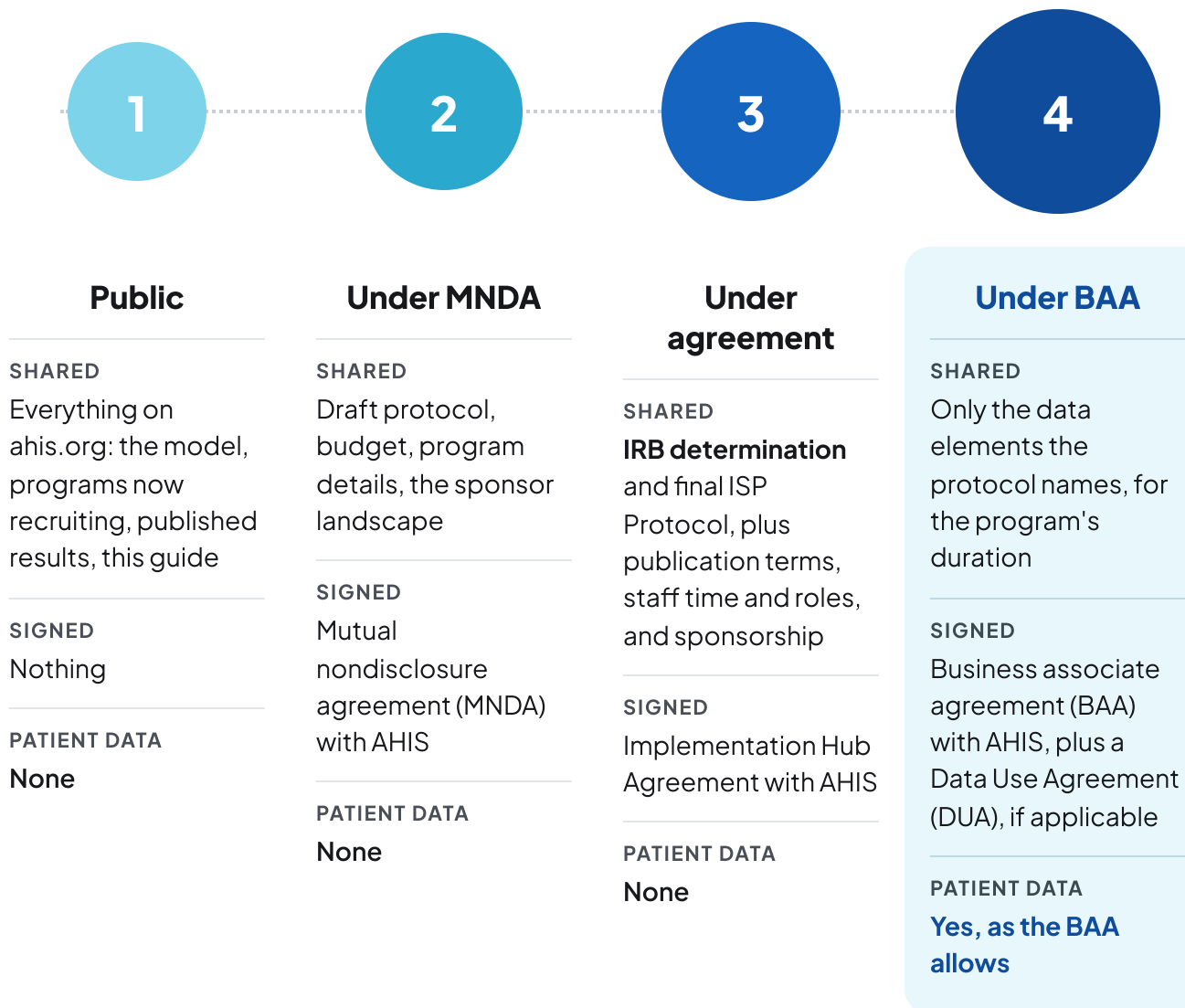
We build the protocol and budget with you, from scratch or from an existing ISP, then seek funding.



Care decisions stay with patients and their clinicians. Programs support identification, navigation and follow-up. AHIS is non-promotional and does not endorse therapies, products or providers.

Four gates. *One counterparty.*

Each gate opens only after the one before it closes, and each defines exactly what is shared and what is signed. AHIS is your counterparty at every gate: one relationship, one contracting package, one counsel review.



If a program isn't funded, it stops at Gate 3.
 It doesn't go live, and no patient data move.

From one call *to published results.*

IRB and publication are set through AHIS governance, not by sponsors.

GATE 1 · PUBLIC

- 1 Discovery call**
30 minutes on one care gap and your patients.

GATE 2 · UNDER MNDA

- 2 MNDA with AHIS**
So drafts, budgets and program details can be shared openly.
- 3 ISP Protocol and budget**
Built with you, from scratch or from an existing ISP.

GATE 3 · UNDER AGREEMENT

- 4 IRB determination**
Obtained before launch. The IRB decides, not AHIS.
- 5 Publication determination**
How and where results are published, set in advance.
- 6 Sponsorship**
Sponsors sign onto the finished protocol.
- 7 Implementation Hub Agreement**
Staff time, roles, publication and naming terms, signed with AHIS.

GATE 4 · UNDER BAA

- 8 BAA with AHIS**
Signed before any patient data move.
- 9 Deployment**
Live with your care teams, in as little as four weeks once agreements are signed.
- 10 Published results**
Snapshots while it runs, or a final report at a set end date, on ahis.org.

Joining a recruiting ISP?

Steps 3 to 6 are already done. You review the protocol, confirm the IRB determination with your own IRB office, and move to the Hub Agreement.

Not funded?

If no sponsor signs on, the program stops at step 6. It doesn't go live, and no patient data move.



Set by governance. *Never by a sponsor.*

Sponsors can't change a protocol's design or whether its results are published. Amendments, including changes made as a program learns, follow the same path: AHIS governance review, IRB review where required, and your agreement.

What the protocol sets out

The care gap, the eligible population and the baseline

What the program does, step by step, and who does each step

The measures, set before launch, and how they're reported

The data elements needed, and nothing beyond them

Staff time, roles and the budget

The publication plan

How the IRB determination works

Each protocol goes to an institutional review board (IRB) for a determination before launch.

Implementation work is often found to be quality improvement rather than human-subjects research, but the IRB decides, not AHIS.

PUBLICATION POLICY

Every result is published. *Whatever it shows.*

01 Always on ahis.org

Results that show no change are published too.

03 Publish and present

Your clinicians may have opportunities to publish in journals, present at conferences and speak at AHIS events, under the protocol's publication plan.

05 You review first

You see results before anything goes public, within the review window in your Hub Agreement.

02 Snapshots or a final report

Rolling programs publish snapshots; others, a final report at a set end date.

04 Naming is your choice

Named only with your approval; otherwise, for example, "a community health system in Tennessee."

06 Aggregate only

Published results never include patient-level data.

Your data *stays yours.*

Patient data move only under a BAA with AHIS, and sponsors receive aggregate, de-identified results only.

Who	What they see	Under what
Your institution	Everything about your program, including your own patient-level data	Your own systems and policies
AHIS	The minimum data elements authorized by the ISP Protocol and BAA to administer and measure the program	BAA with AHIS
Sponsors	Aggregate, de-identified results only; never PHI or patient-level data	Sponsor agreement with AHIS
The public	Published results on ahis.org; your institution's name only if you choose	Publication terms in the Hub Agreement

AHIS may use contracted technology and implementation service providers to operate ISPs. Any service provider that handles PHI does so as a permitted subcontractor subject to applicable HIPAA requirements and a subcontractor BAA.

It stays yours

Neither AHIS nor its service providers own your patient records or PHI. Your BAA, the protocol and the law control how they're used.

De-identified only as allowed

De-identification happens only where your agreements allow it, and the result is used only as they permit.

Sponsors see results, not records

Funding an ISP never gives a sponsor PHI or patient-level data. Anything else would be set out in that program's agreements.

INDEPENDENCE GUARDRAILS

Never tied to product selection or volume.

Funding doesn't depend on what is prescribed, ordered or used.

Sponsors are named publicly. Their input through the Sponsor Advisory Council is advisory only.

Non-promotional. AHIS doesn't endorse therapies, products or providers.

Sponsors don't set the protocol. Design, amendments and publication go through AHIS governance.

Care decisions stay with clinicians. Programs support identification, navigation and follow-up.

Independent governance. The AHIS Board oversees the work, including AHIS's service providers.

A named lead. *A clear scope.*

A hub provides a named lead, the staff time the protocol scopes, and access to the data the protocol names. Everything is scoped with you up front, in writing.

What	Who on your side	When
A named program lead	Service line, quality or population health leader	From Gate 2
Agreement review	Counsel and compliance	Gates 2 to 4
IRB confirmation	Your IRB or research office	Gate 3
Staff time and roles	The teams the protocol names	Scoped at Gate 3, used from launch
Data access	IT, analytics and privacy	Gate 4

Programs run inside your existing workflows and can go live in as little as four weeks once agreements are signed.

Funding and exit

Funding. Sponsors fund implementation under written agreements with AHIS. Staff time is scoped with you in the Hub Agreement.

If a program isn't funded. It doesn't go live, and no patient data move.

Membership is separate. You don't need to be an AHIS member to be an Implementation Hub.

Ending participation. Termination rights for both sides are set in the Hub Agreement.

Data at the end. Your BAA sets how data is returned or destroyed when the program ends.



For employers

Employers pass through the same four gates. The difference is whose data it is and who sees it.

No individual employee data to the employer. Results are reported in aggregate only.

Plan data follows the plan's rules, settled with your counsel at Gates 3 and 4.

Coalitions can take part as partners and convening channels.

Up to four agreements. *All with AHIS.*

You will see them in this order, each finalized with your counsel. You also receive the ISP Protocol and its IRB determination at Gate 3.

Gate	Agreement	What it covers
2	Mutual nondisclosure agreement (MNDA)	Confidentiality for draft protocols, budgets and program details. Our form or yours
3	Implementation Hub Agreement	The ISP Protocol, staff time and roles, publication terms, naming, termination
4	Business associate agreement (BAA)	How PHI is used and protected by AHIS and its permitted subcontractors in operating the ISP, and what happens to it at the end
4	Data Use Agreement (DUA), if applicable	Data disclosures or uses requiring terms beyond the BAA and Hub Agreement

This guide explains how the process works. It is not an agreement. Your institution's specific terms are set in agreements finalized with your counsel.

Our next step: *an MNDA.*

A mutual nondisclosure agreement with AHIS opens Gate 2, so we can share draft protocols, budgets and program details. No patient data are involved.

Request an MNDA

info@ahis.org

Prefer to talk first? Book a discovery call: ahis.org/health-systems



Scan to discuss
next steps

Inside an ISP Protocol.

Every ISP Protocol follows the same structure. You see a draft under the MNDA at Gate 2 and the final protocol at Gate 3.

- | | |
|---|---|
| <p>01 ISP synopsis
The program on one page</p> | <p>10 Implementation strategies and procedures
Strategies, workflow, channels and follow-up</p> |
| <p>02 ISP and data collection schema
How the program and each data collection fit together</p> | <p>11 Data sources and data management
Sources, variables, management and quality checks</p> |
| <p>03 Purpose and operating standard
How the ISP follows the standard every ISP uses</p> | <p>12 Analysis and learning plan
Analysis, optimization, missing data, bias and limitations</p> |
| <p>04 Responsible parties and governance
Program operator, advisory committee, sponsors, scientific leads, hubs and partners</p> | <p>13 Human subject protection, privacy and safety
Consent and authorization, IRB review, privacy, safety and incentives</p> |
| <p>05 Implementation gap and rationale
The gap, its size and burden, and why this ISP</p> | <p>14 Data collection specifications
Each defined data collection, specified on its own</p> |
| <p>06 Objectives and measures
Primary and secondary objectives, measures and the implementation pathway</p> | <p>15 Amendments, deviations and change control
How changes, deviations and early termination are handled</p> |
| <p>07 Regulatory, research and evidence determination
How each data collection is classified</p> | <p>16 Reporting, dissemination and results
Program reporting, publication and data outputs</p> |
| <p>08 Design and setting
Design, setting, geography, program period and milestones</p> | <p>17 References and appendices
Supporting documents, including the research and IRB applicability framework</p> |
| <p>09 Target population and eligibility
Who is eligible, with inclusion and exclusion criteria</p> | <p>18 Governance review and activation
The sign-offs required before the ISP goes live</p> |