

RESEARCH EDUCATION / CHECKLIST

Research Partnership Readiness Checklist

A structured planning tool for proposed institutional and principal-investigator collaborations.

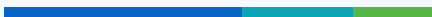
STATUS

Available as a free Institute educational publication. This resource is not peer-reviewed research, individualized medical advice, professional certification, or accredited continuing education.

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How to use this checklist

Document readiness before representing a project as active.

Use this tool during early conversations among investigators, institutions, community partners, funders, and the Institute. For each item, mark complete, in progress, not started, not applicable, or blocked. Record the responsible party, evidence, target date, and stop condition.

STATUS LIMIT

A completed checklist is not protocol approval, IRB or ethics approval, regulatory authorization, funding, site activation, registration, recruitment permission, or proof of results.

Suggested status key

[C] Complete [P] In progress [N] Not started [A] Not applicable [B] Blocked

Project identification

Working project title

Lead institution and proposed principal investigator

Date of review and participants

1 / QUESTION AND PUBLIC BENEFIT

Question and public benefit

Status	Readiness item	Owner / evidence / target
☐	The research question is specific, answerable, and distinct from a marketing claim.	
☐	The public-benefit rationale and intended beneficiaries are documented.	
☐	Existing evidence and important gaps are summarized with citations.	
☐	The project identifies what it is not designed or powered to prove.	
☐	Community or participant perspectives needed during planning are identified.	
☐	Alternative designs or non-research approaches have been considered.	

2 / QUALIFIED LEADERSHIP AND INSTITUTIONAL AUTHORITY

Qualified leadership and institutional authority

Status	Readiness item	Owner / evidence / target
[]	A qualified principal investigator is identified and willing to accept documented responsibility.	
[]	Topic, methods, statistics, clinical, ethics, regulatory, and operational expertise are mapped.	
[]	Each participating institution has identified an authorized contact and review pathway.	
[]	Roles of sponsor, funder, investigator, site, community partner, and data custodian are separated.	
[]	Decision rights, escalation, removal, succession, and termination responsibilities are defined.	
[]	CVs, licenses, training, conflicts, and institutional affiliations are verified where relevant.	

3 / PROTOCOL AND ANALYSIS

Protocol and analysis

Status	Readiness item	Owner / evidence / target
[]	Population, eligibility, recruitment, intervention or exposure, comparison, outcomes, and timeline are defined.	
[]	Primary and secondary outcomes and clinically meaningful interpretation are specified.	
[]	Sample-size rationale and statistical analysis plan are documented.	
[]	Missing data, protocol deviations, withdrawals, subgroup analyses, and multiplicity are addressed.	
[]	Safety monitoring, stopping rules, adverse-event pathways, and referral responsibilities are defined.	
[]	Version control, amendments, protocol access, and investigator sign-off are planned.	

4 / ETHICS, IRB, CONSENT, AND PARTICIPANT PROTECTIONS

Ethics, IRB, consent, and participant protections

Status	Readiness item	Owner / evidence / target
☐	The authorized institution has determined the applicable ethics or IRB review pathway.	
☐	No recruitment or data collection will begin before required approvals are documented.	
☐	Consent, assent, authorization, waiver, and translated-material needs are identified.	
☐	Risk, burden, compensation, alternatives, privacy, and withdrawal information are understandable.	
☐	Vulnerable-population safeguards and equitable selection are addressed.	
☐	Complaints, injuries, unanticipated problems, and participant questions have clear contacts.	

5 / FUNDING, CONTRACTS, AND INDEPENDENCE

Funding, contracts, and independence

Status	Readiness item	Owner / evidence / target
[]	Full funding source, budget, payment schedule, and funding contingency are documented.	
[]	Contracts address responsibilities, insurance, indemnity, intellectual property, data, and termination.	
[]	Related-party and fair-market-value review is completed when applicable.	
[]	Financial, commercial, intellectual-property, governance, and personal conflicts are disclosed and managed.	
[]	Investigators retain appropriate access to data and the ability to report material results.	
[]	Funding does not require endorsement, suppression of limitations, or improper private benefit.	

Data, privacy, security, and quality

Status	Readiness item	Owner / evidence / target
[]	Data elements, sources, collection methods, identifiers, access, and quality checks are defined.	
[]	Privacy, security, storage, transfer, breach, retention, destruction, and audit responsibilities are assigned.	
[]	A data-use or sharing agreement is planned where needed.	
[]	Monitoring, source verification, deviations, corrections, and locked-data procedures are defined.	
[]	Participant-facing privacy information matches actual data practices.	
[]	Future secondary use, sharing, repositories, and de-identification are addressed.	

7 / SITES, STAFF, MATERIALS, AND LAUNCH

Sites, staff, materials, and launch

Status	Readiness item	Owner / evidence / target
[]	Sites, space, equipment, technology, supplies, accessibility, and emergency needs are confirmed.	
[]	Staffing, qualifications, training, delegation, supervision, and workload are documented.	
[]	Recruitment materials, scripts, advertisements, and referral pathways are approved where required.	
[]	Device, intervention, laboratory, imaging, or vendor requirements are validated.	
[]	A launch checklist defines the authorized start date and conditions.	
[]	A stop-launch rule prevents activity when an essential approval, resource, or safeguard is missing.	

Registration, publication, and public communication

Status	Readiness item	Owner / evidence / target
[]	Applicable registry requirements and responsible submitter are identified.	
[]	Registration will occur at the required time and remain current.	
[]	Authorship, analysis, publication rights, negative results, corrections, and data access are addressed.	
[]	Plain-language result communication to participants and the public is planned.	
[]	Public status language distinguishes planning, review, recruiting, active, completed, and results available.	
[]	No claim will extend beyond the protocol, data, or authorized communication.	

Do not hide the unresolved work.

Record every decision that could prevent responsible launch.

Open decision 1 - owner, evidence needed, target date, stop condition

Open decision 2 - owner, evidence needed, target date, stop condition

Open decision 3 - owner, evidence needed, target date, stop condition

Set the status supported by the record.

- [] In development - essential leadership, partners, funding, protocol, or oversight remains unresolved.
- [] Ready for institutional review - a qualified team and sufficiently developed protocol can enter required review pathways.
- [] Approved to initiate - required approvals and agreements are documented and authorized launch conditions are met.
- [] Blocked - a critical safeguard, approval, resource, conflict, or legal/ethical issue prevents progress.

Reason for status

Required next actions

AUTHORIZATION LIMIT
Signatures below document planning review only. They do not replace institutional, sponsor, legal, regulatory, scientific, or ethics/IRB authorization.

Prepared by / date

Reviewed by / date

Track decisions from discussion to evidence.

Date	Decision or action	Owner	Evidence / status

Publication notice

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