OPEN RESEARCHER

Institution Playbook

A practical pathway for researchers, universities, hospitals, research institutes, and approved translation partners.

A clearer, responsible path from mitochondrial-disease question to patient-informed evidence and translation.

WHAT THIS DOCUMENT DOES

This playbook explains who must approve and sign, what researchers receive, what MDA retains, how institutional IP is handled, and when a separate license or spinout process is required.

INTERNAL OPERATING DRAFT

Use for scoping and institutional review. It is not a signed agreement or legal advice. MDA leadership, privacy/IRB advisors, patent counsel, and tax/nonprofit counsel should review the definitive documents.

START HERE

The arrangement in plain language

A qualified researcher brings MDA a focused mitochondrial-disease question, scientific expertise, and a credible plan. MDA helps test feasibility, connects the work to patient priorities, and - after approval - provides purpose-limited access in a controlled workspace.

If the researcher works for a university, hospital, research institute, government laboratory, nonprofit, or company, that institution must approve the project and sign MDA's agreement. The institution is accountable for its people and systems; the researcher remains individually accountable for their conduct.

No institution signature, no nonpublic data access.
No written IP arrangement, no inventive work.
No separate license, no commercial rights.

Why a researcher says yes

- Feasibility before investing months in a protocol or grant.
- Structured, longitudinal, consent-aware information with documented limitations.
- Patient input on important questions, endpoints, and study burden.
- A controlled workspace with provenance and reproducibility support.
- A governed route to approved recontact, recruitment readiness, and follow-up.
- A fair publication path plus defined invention, patent, licensing, and spinout pathways.
- A written path to Researcher Program Pool payouts when qualifying portfolio value is actually realized.

The offer is research acceleration with trust - not unrestricted data access.

VALUE EXCHANGE

What each party gives and receives

Party	Contributes	Receives	Not automatic
MDA	Community infrastructure, governed data, feasibility, stewardship, workspace, patient-input and translation pathways.	Project outputs, data improvements, defined Project IP rights, community return, and approved economics.	A claim to unrelated researcher work or every idea.
Researcher	Question, expertise, effort, disclosure, compliant analysis, reproducible output, publication work, and invention reporting.	Approved access, support, attribution, Researcher Program Pool eligibility, and separately documented patent/license or spinout economics.	MDA Data ownership, guaranteed payout, automatic equity, exclusivity, or license.
Institution	Authority, supervision, approvals, compliance systems, employee/IP commitments, and responsibility for its team.	The approved project, agreed publication rights, Background IP protection, and negotiated IP/license rights.	MDA Data, participant access, or automatic commercial rights.
Participants	Voluntary permissioned information and lived-experience priorities.	Privacy, transparency, lower burden, plain-language findings, and approved community return.	Guaranteed treatment, study eligibility, payment, or individual results.

Bring expertise and a question. MDA brings the governed research system. Agree up front how scientific credit, ownership, costs, and any upside will work.

OUTCOME PARTICIPATION

Supply the work. Share in realized portfolio value.

Before substantive work begins, an approved project should include a written Researcher Outcome Participation Schedule. It identifies which economic channels apply and the conditions for earning, vesting, calculation, and payment.

Milestone award targets

The named individual researcher earns credits under one system, not a separate milestone payment plus credits. Moderate outputs target 2,250-3,450 credits (planning value $22,500-$34,500), strong outputs target 3,500-4,250 credits (planning value $35,000-$42,500), and priority outputs target 5,000-10,000 credits (planning value $50,000-$100,000). The dollar ranges illustrate the same credits at the current $10-per-credit planning reference; actual value depends on an approved distribution and total eligible program credits. They are not an institutional grant, lab budget, overhead allowance, or indirect-cost pool.

Channel	Researcher opportunity	Required structure
Researcher Program Pool	Earn non-transferable outcome participation credits that can participate when MDA receives qualifying portfolio proceeds and approves a legally available researcher distribution.	Written credit schedule, realized cash, defined deductions, eligibility date, eligible-credit denominator, statements, approval, and tax reporting.
Patent and licensing	Receive separately stated participation in net licensing, milestones, royalties, sublicensing, settlements, or other realized proceeds tied to relevant Project IP.	Inventorship/contribution record, institutional and funder rights, cost treatment, no double counting, and definitive economic terms.
Spinout formation	Receive a time-limited first opportunity to propose, help form, or join an approved spinout, with possible founder equity, options, consulting, employment, or other economics.	Founder plan, independent review, valuation, conflict plan, institutional approval, securities/tax review, and separate spinout/license documents.

Researcher payout = approved program distribution x researcher eligible credits / total eligible program credits

Credit fairness

Credits have no fixed cash value and do not promise a fixed percentage. Credit opportunities and acceptance criteria should be disclosed before work begins. MDA may add credits and contributors as the program grows, but should not retroactively reduce accepted credits except through a disclosed correction, lawful clawback, or resolved misconduct process. Researchers receive a credit statement, notice of material adjustments, and a reasonable independent appeal path.

Qualifying value

Program rules may include cash actually received from approved licenses, royalties, milestones, sublicensing, patent settlements, spinout distributions, equity sales or liquidity events, and asset sales. Paper valuations, unrealized gains, forecasts, restricted donations, pass-through funding, and amounts MDA cannot share are excluded.

Integrity guardrail

Participation vests for objective services, reproducibility, documentation, invention and patent support, publication or regulatory work, community return, and compliance - never for a positive result or sponsor-preferred conclusion. No payout, patent, license, company, security, valuation, or liquidity is guaranteed.

ACCOUNTABILITY

Who must approve and sign

Required actor	What approval or signature means
MDA authorized signer	Approves the project, data tier, business terms, and agreement.
Institutional signing official	Legally binds the institution to research, data, security, IP, publication, conflict, and closeout terms.
Principal investigator	Personally acknowledges use restrictions, supervision, disclosure, publication, and invention duties.
Every approved user	Accepts confidentiality, security, acceptable-use, and no-reidentification duties before credentials.
Technology-transfer office	Approves Project IP, patent control, options, licenses, and institutional economics when applicable.
External institutions	Each institution signs a joinder or separate agreement for its own people and systems.

What does not bind the institution

A PI signature, department-chair email, IRB approval, grant award, purchase order, protocol, or technology-transfer conversation does not replace the authorized institutional agreement.

Institutional review checklist

- Scientific/departmental and sponsored-research/contracts approval.
- IRB/human-subjects, privacy/HIPAA, and data-governance determination.
- Information-security review and named security contact.
- Conflict-of-interest and technology-transfer/IP review.
- Funding, sponsor, export-control, collaborators, contractors, systems, and linkages review.

WORKFLOW

From question to governed output

Gate	Required result
1. Apply	Researcher names the question, institution, team, data need, output, funding, and commercial intent.
2. Feasibility	MDA begins with public information and approved aggregate readiness.
3. Institutional review	The institution completes applicable contracts, IRB, privacy, security, conflict, funding, and IP reviews.
4. Sign	MDA and the institution execute agreements; the PI and all users sign individual undertakings.
5. Activate	MDA provisions the minimum-necessary workspace with named users, logging, and expiry.
6. Conduct	The team follows the approved protocol; changes, incidents, conflicts, and inventions are reported.
7. Review output	MDA checks privacy, confidential information, reproducibility, and patent timing.
8. Publish or translate	Findings return to the community; commercial rights require a separate approved license or spinout process.
9. Close	Access ends and the institution certifies return/destruction, outputs, inventions, and continuing duties.

If a required answer is unknown, the project remains in scoping or aggregate feasibility. Prominence, funding, urgency, or an existing relationship never skips a gate.

DATA

MDA's default data position

- MDA retains control of MDA Data, cohort definitions, dictionaries, annotations, provenance, quality measures, and database structure, subject to participant and upstream rights.
- The institution receives only a nonexclusive, nontransferable, revocable, project-only right to use approved data in the approved environment.
- Data remain inside the MDA-controlled workspace unless a specific export is approved.
- No reidentification, participant contact, credential sharing, onward transfer, external linkage, unrelated use, teaching use, repository deposit, or model training without written approval.
- Every new purpose, dataset, user, institution, sponsor, linkage, system, or commercial use requires review.
- Access ends at expiry, termination, change of affiliation, loss of required approval, or material noncompliance.

Minimum agreement package

Document	Purpose
Project charter	Fixes the question, public benefit, scope, users, data, methods, outputs, term, and milestones.
Institutional research agreement	Binds the institution to the overall relationship and allocation of responsibility.
Data Use and Security Addendum	Sets access, security, incident, audit, export, retention, and closeout controls.
PI and user undertakings	Creates individual responsibility for approved use and confidentiality.
IP and obligations schedules	Identifies Background IP, Project IP structure, funding, sponsors, and conflicting rights.
Review records	Documents IRB/privacy, security, conflict, and institutional approvals.
Publication and patent plan	Protects scientific independence, participant privacy, and filing timing.

INTELLECTUAL PROPERTY

Resolve ownership before inventive work

MDA keeps

- MDA Data and infrastructure; MDA software, schemas, methods, documentation, brands, know-how, and existing patent assets.
- MDA-created project materials, defined data improvements, and the Project IP rights accepted in the signed agreement.

The institution keeps

- Specifically scheduled Background IP and independently developed general tools and methods that do not use MDA Data or confidential information.

The researcher receives

- Accurate author, contributor, and inventor attribution; fair publication rights; and only the economics stated in writing.

Inventorship is determined under patent law. Ownership is allocated by written agreement. They are not the same.

If the institution rejects assignment to MDA

Order	Structure	MDA protection
1	Institution assigns defined Project IP to MDA	Present assignment, employee assignments, MDA patent control, further assurances.
2	Institution owns; MDA gets exclusive option/license	Pre-agreed scope and economics, patent rights, diligence, sublicensing, enforcement, and data boundaries.
3	Joint development	Lead patent manager, costs, licensing authority, enforcement, revenue allocation, and deadlock rules.
4	No-IP feasibility	Aggregate-only bounded scope and an automatic stop before inventive work.
5	Decline	No nonpublic access or use of MDA confidential information.

TRANSLATION

Research access is not a commercial license

A later license requires independent approval and a separate written transaction defining the exact assets, field, territory, exclusivity, sublicensing, reserved MDA rights, milestones, patent costs, fees, royalties, equity, reporting, audit, termination, and reversion.

The license ordinarily does not include MDA Data, participant identities, participant contact, MDA trademarks, or unrelated platform IP.

Funding and sponsor obligations

- The institution discloses federal awards, private sponsors, options, licenses, publication rights, data rights, exclusivity, other support, and institutional invention duties.
- If federal funding supports the work, counsel and grants personnel review the exact award and applicable Bayh-Dole provisions before applying MDA's default assignment language.
- The institution cannot promise the same Project IP, dataset, publication control, option, or exclusivity to MDA and another sponsor.

Access stops automatically when

- The PI leaves or changes institutions, a user loses affiliation, or required approval expires.
- A new sponsor, collaborator, contractor, system, linkage, purpose, or commercial use appears.
- A material incident, undisclosed conflict, or competing IP claim arises.

Access resumes only after MDA documents the required amendment, new institutional agreement, or corrective action.

NEGOTIATION

Red lines and flexible terms

Category	Terms
MDA red lines	No institution accountability; institution ownership of MDA Data; unrestricted reuse or transfer; unapproved participant contact; indefinite publication veto; inventive work before IP terms; automatic commercial rights; conflicting sponsor rights; self-approved insider economics.
May be tailored	Governing law, indemnity, insurance, liability, review periods, institution-owned IP with an exclusive MDA option, patent management and economics, equivalent institutional systems, indirect costs, and grant requirements.
Always project-specific	Question, cohort, data, access tier, users, term, outputs, milestones, Background IP, funding, conflicts, linkages, contractors, authorship, community return, patent budget, and approved economics.

Every institutional negotiation ends in one written status

Status	Meaning
Approved	All required terms and reviews are complete.
Approved with conditions	Conditions have owners and deadlines; access waits unless a limited stage is expressly permitted.
Aggregate-only	Approved feasibility outputs may proceed, but there is no nonpublic workspace access.
Revision requested	MDA or the institution must resolve a documented issue list.
Declined	Protections or alignment are insufficient; no access is granted.

There is no informally approved status.

DECISION RECORD

One-page intake questions

#	Required question	Decision / evidence
1	What is the exact question and patient/community benefit?	
2	Who is the PI, legal Research Institution, and authorized signer?	
3	What is the lowest sufficient access tier?	
4	What permission and IRB/privacy pathway applies?	
5	Who are all users, institutions, sponsors, contractors, systems, and linkages?	
6	What does each party bring as Background IP?	
7	Could the work create an invention, software, model, or commercial asset?	
8	Which Project IP structure will apply?	
9	What funding, sponsor rights, government rights, or conflicts exist?	
10	What will be published or returned to participants?	
11	Who pays research and patent costs, and what economics follow?	
12	What event ends or suspends access?	
13	Final status: approved, conditional, aggregate-only, revise, or decline?	

If a required answer is unknown, the project remains in scoping or aggregate feasibility and does not proceed to nonpublic access.

CLOSEOUT

End access cleanly and preserve trust

At completion, termination, or change of affiliation, the PI and an authorized institutional official certify that:

- Every user's access has ended and MDA Data and restricted derivatives were returned or destroyed as required.
- Any permitted archival copy is identified, inaccessible for new use, and subject to continuing controls.
- All outputs, code, publications, incidents, conflicts, inventions, funding, and ownership claims were reported.
- No data remain in an unapproved repository, teaching set, model, linkage, personal device, or collaborator system.
- Continuing confidentiality, IP, audit, publication, and security duties are understood.

The goal is not simply controlled access. It is a trusted collaboration that produces better science, fair recognition, and a responsible route to patient benefit.

NEXT STEP

Bring MDA one focused question, the name of the research institution, the proposed team, and the intended output. MDA will begin with the lowest-risk feasibility review and identify the required institutional pathway.

Full internal framework: docs/MDA_OPEN_RESEARCHER_AND_SPINOUT_FRAMEWORK.md
Web: mitodiscovery.org/researchers