Literacy — Agencies: The National Institutes of Health

The largest public funder of biomedical research in the world — and the purest example in this curriculum of a culture that is mission-tied, not buyer-seller. The NIH does not "buy" research; it funds the research community's own agenda in service of public health. That single cultural fact changes how you read its solicitations, how you write your application, and how you think about your own role. This profile maps the grant mechanics, the peer-review system, and the NIH's distinctive SBIR/STTR lane.

Culture: mission-tied, not buyer-seller

Here is the cultural fact that reframes everything about the NIH: **it is not in the business of buying things from you.** It is in the business of *advancing biomedical research and public health* — and it does that by funding the best science, wherever it comes from. The relationship is not customer-vendor; it is *funder-investigator*. The applicant is a peer in the research community, the Principal Investigator drives the work, and the award is a grant that funds a mission the government shares with you.

The practical consequences are immediate and real:

- The application is a *research plan*, not a bid on a specification. There is no statement of work written by the agency; you write the plan, and the agency funds it if the science merits it.
- The "customer" is the *mission* (public health, a specific disease, a research question), not a contracting officer's checklist.
- Your credibility is your science, your record, and your standing in the research community — not your compliance matrix and your win themes.

That is why the NIH rewards a fundamentally different posture from the defense market: where the DoD buys *capability*, the NIH funds *promise*.

The grant mechanics: the R-series

NIH funding runs mostly on **grants**, and the grant family has a vocabulary you will meet constantly — the **R-series**:

- **R01** — the research project grant, the NIH's workhorse. A substantial, multi-year award for a defined research project. The gold standard of NIH funding.
- **R21** — the exploratory/developmental grant: smaller, shorter, for high-risk, early-stage ideas.
- **R03** — the small research grant: a small, short award for limited work.
- **R43 / R44** — the **SBIR** Phase I and Phase II awards (the R-series numbers are how the NIH expresses SBIR).
- **R41 / R42** — the **STTR** Phase I and Phase II awards.

The mechanics are standard grants machinery (the same bones as how-to-read-a-nofo): a **funding opportunity announcement (FOA)** states the program and criteria; you apply through the grants portal (Grants.gov and the NIH's eRA systems) by a receipt date; peer review scores you; the institute makes the funding decision; and the award comes with reporting and compliance. The FOA's *review criteria* are the center of gravity — exactly the lesson of doctrine/02, wearing a lab coat.

Peer review: the two-tier system

The NIH's evaluation engine is **peer review**, run twice — the two-tier system:

1. **Initial peer review.** A **Scientific Review Group** — a panel of independent scientists convened as a "study section" — reviews your application and scores it against the five standard review criteria: **Significance, Innovation, Approach, Investigator, and Environment**. The panel produces an impact/priority score (the lower, the better) and a percentile rank against the pool.
2. **Advisory council.** The institute's National Advisory Council reviews the scored applications and makes the final funding recommendations, applying programmatic priorities — which research areas the institute wants to push this year.

Two lessons for the pursuer:

- **Write to the five criteria, in order.** An NIH study section literally scores against them; a grant application that mirrors the five criteria reads as a well-argued case, and one that does not is a lost cause regardless of the underlying science.
- **The score is a gate.** NIH institutes set a **payline** — the percentile above which (with margin) applications are funded. Percentile and payline are the NIH's version of the threshold gate from doctrine/04. The science has to clear a genuinely high bar, not just a reasonable one.

Clinical and applied SBIR

The NIH is the largest SBIR funder in the federal family, and its SBIR/STTR program has a distinct character: it funds **biomedical and behavioral innovation**, from bench research through clinical development. Three durable features:

1. **The program covers the applied range.** NIH SBIR/STTR topics span therapeutics, diagnostics, devices, digital health, and research tools — and can include clinical trials in Phase II and beyond. The "product" is often a regulated medical product, which means the commercialization path runs through the FDA.
2. **The award sizes are larger than the other agencies' typical SBIR.** NIH Phase I and Phase II caps are among the highest in the program, and

the period of performance is correspondingly longer. The economics still follow the three-phase SBIR ladder from the SBIR/STTR profile: Phase I feasibility, Phase II development, Phase III commercialization on non-SBIR money.

3. **The research-institution partner is natural here.** NIH STTR teams a small business with a university or nonprofit research institution — a natural fit for the academic biomedical world, and exactly the model Ravonics uses with INSTAR Lab in the case study.

Evaluation emphasis and the "score" culture

Because the NIH funds science rather than buying deliverables, its evaluation emphasis is on the *quality of the proposed science and its potential impact* — with the applicant's track record, environment, and feasibility reviewed as supporting evidence. There is no price competition in the grant lane (the budget is reviewed for reasonableness and alignment, not for lowest cost), and there is no past-performance volume in the defense sense — though the *Investigator* criterion is effectively your past performance as a researcher: your record of publications, preliminary data, and demonstrated capability. Your "past performance" is your science.

Vehicles and the set-aside landscape

The NIH is not a vehicle-heavy buyer the way GSA or the DoD is — its dominant instrument is the individual grant. But it also buys what it needs (research services, IT, clinical-support contracts) through standard federal channels, and its SBIR/STTR program is the set-aside lane that matters most for a small firm:

- **Eligibility is the small-business definition** — under 500 employees, U.S.-owned and controlled — with the SBIR/STTR work-share and PI-employment rules from the SBIR/STTR profile.
- **The set-aside pool is the program itself** — the NIH SBIR/STTR solicitations are the small-business door into the world's largest biomedical research budget.
- The general federal set-aside programs (8(a), HUBZone, SDVOSB, WOSB) apply to the NIH's *contract* buying, but the biomedical small-business story is SBIR/STTR.

Learning pointers

Learning pointers. The NIH profile is the course's study of the grant economy and the peer-review culture. - **Doctrine** — doctrine/01 (assistance dollars; the grant as a funded mission), doctrine/02 (the FOA/NOFO as the document shape), doctrine/04 (percentile and payline as the gate). - **Literacy** — how-to-read-a-nofo (the full NOFO anatomy), where-the-money-flows (assistance dollars), acronym-decoder. - **Practice** — the worked exemplar is

an STTR NOFO; swap the DOE flavor for an NIH one and the five review criteria do the same work the merit-review criteria did. - **Case study** — a biomedical variant of Ravonics (small firm + INSTAR Lab + a clinical thesis) is a natural NIH STTR team; the profile shows what would have to change for the case to live here. - **Course** — the MPA track (modules/mpa.md) reads the NIH as a governance story: public money funding research, with peer review as the fairness mechanism. - **Verify** — paylines, institute priorities, FOA receipt dates, and SBIR caps shift every cycle; confirm against the FOA on Grants.gov and the current NIH SBIR/STTR guidance.