



MEMO: UPDATE TO PIDTC SITE PARTICIPATION AND MEMBERSHIP STRUCTURE

DATE: 12 NOVEMBER 2025
TO: ALL PIDTC SITE PRINCIPAL INVESTIGATORS, REGULATORY AND RESEARCH STAFF
FROM: PIDTC LEADERSHIP TEAM
RE: UPDATE TO PIDTC SITE PARTICIPATION AND MEMBERSHIP STRUCTURE

November 12, 2025

Dear PIDTC Investigators, Regulatory and Research staff,

Due to **the level of R24 funding** for the PIDTC, we have thoroughly re-evaluated how the PIDTC supports and engages with participating sites.

We recognize that patient **enrollment and data entry** are time-consuming and resource-intensive for Principal Investigators (PIs) and staff. This can create a significant burden, especially when sites lack adequate funding from both the PIDTC and internal sources to successfully execute studies.

To address this challenge and ensure the sustainability of our network, we are introducing **two new PIDTC membership tiers**, based on each site's enrollment over the last two years.

Core PIDTC Site Member:

- Core sites have contributed at least one subject to the new protocols (6906/7/8).
- Core sites must enroll and contribute data for a minimum of three new subjects per year in any of the currently open protocols. The performance of Core sites will be reviewed annually in Q2/Q3.
- Core sites will continue all operations as historically conducted.
 - Core sites will continue to receive subcontracts to the R24 grant and will receive ongoing per-patient reimbursement that may be adjusted depending on the overall budget.
 - U.S. Core sites are required by the NIH to use the UCSF single IRB.
 - Investigators from Core PIDTC sites are encouraged to be actively involved in leading clinical protocols, reviewing data, analyzing data, and preparing abstracts, publications, and meeting presentations.

Affiliate PIDTC Site Member:

- Affiliate sites are those that have investigators interested in the work that PIDTC is conducting and who want to participate but lack the resources or patient base to sustain enrollment of at least 3 patients per year.
- Affiliate sites will not enroll patients, have an active PIDTC-related IRB protocol open at their site, or receive an R24 subcontract. Further contracts between the PIDTC and

Affiliate sites who currently have a subcontract will not be executed. Study protocols should be closed at Affiliate sites after any final relevant data entry.

- Investigators at Affiliate Sites are very welcome and are strongly encouraged to remain active in PIDTC. Activities include:
 - Annual Meeting participation.
 - Participation in the Scientific Planning Calls and IEI Board Calls.
 - Participation in PIDTC protocol committees including joining or leading working group efforts related to aggregate data analyses, preparation of abstracts, preparation of manuscripts, presentations at meetings. Note that affiliate site investigators cannot be involved in review of primary data and data cleaning, as this requires that an individual be included in a site designation log for a subcontracted Core PIDTC site. Affiliate investigators can propose and lead PIDTC-sponsored studies using de-identified PIDTC data but need to partner with a Core PIDTC Site investigator who is on a site designation log for activities related to patient-level data.
 - Investigators at Affiliate sites with prior inclusion of patients into the PIDTC database will continue to be eligible for authorship of manuscripts utilizing this data, per the PIDTC Publications Guidelines.

Managing Changes in Status

- **Automatic Transition:** All sites that have not enrolled patients and entered data for any patients to the new protocols will be **automatically transitioned to Affiliate PIDTC Member status** *unless other arrangements have already been discussed*.
- **Annual Review:** Sites that do not meet the minimum three-subject enrollment target for Core status will be moved to **Affiliate status in September of 2026** following the yearly review.
- **Reactivation Process (Affiliate to Core):** Changes in status can be made yearly, typically in **September** to align with contracting timelines. Sites that wish to transition from Affiliate to Core status must:
 - **Arrange a call with the PIDTC PIs before July 1st** of the year in which the site would like to reactivate to Core status.
 - **Be prepared to discuss the specific resources and staffing** that will be in place to ensure successful patient enrollment and data entry moving forward.

We appreciate your understanding and continued commitment to the PIDTC's mission during this necessary restructuring.

Sincerely,

Drs. Chris Dvorak, Elie Haddad, Rebecca Marsh, and Troy Torgerson on behalf of the PIDTC.



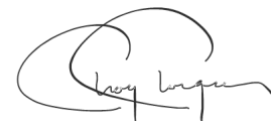
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