

2019-2020 BITC Request for Proposals (RFP19-20)

The Biomolecular Interaction Technologies Center (BITC) is an industrial consortium composed of member companies that provide funding to support the advancement of technologies focused on biomolecular interactions. BITC issues this annual request for proposed projects to support its mission of advancing technologies to better characterize, quantify, and/or predict biomolecular interactions within the context of applied biophysics for research, development, and manufacturing of biopharmaceuticals that include: therapeutic proteins; vaccines; gene therapies; and cell-based therapies.

RFP19-20 specifically requests proposals that focus on biophysical characterization techniques for one or more of the following focus areas:

- a. Measuring key quality attributes of new or emerging biopharmaceutical modalities:
 - Cell-based therapies
 - Gene therapies and delivery vectors that are practical for human therapeutics
 - Antibody-drug conjugates
 - Bispecific and other non-natural antibodies

More specifically, key quality attributes include but are not limited to: chemical stability, physical stability, physical properties at high concentrations (e.g., solution viscosity, solubility), heterogeneity of chemical and physical properties of therapeutically active components.

- b. Dynamics, structure, and interactions of CAR-T cells with their target(s)
- c. Quantitative measurement of bivalent binding (avidity), cooperative binding, including *in vitro* and *in vivo* models relevant to the mechanism of action involving but not limited to cell surfaces, monoclonal antibodies, and emerging biopharmaceutical modalities
- d. Software development for prediction of protein-X interactions (X= protein, excipient, surfaces) ultimately including predictions of aggregation rates / long-term stability, solution viscosity, and manufacturing performance.

Proposals that are co-developed with one or more co-principal investigators a from BITC member company (or companies) will be given priority. Projects that do not include a co-PI from a BITC members company will be assigned a subject matter expert from one or more BITC members to serve as a liaison and assure that the project outcomes are best aligned with BITC member priorities. Funded projects will be required to submit semi-annual reports electronically, and may be required to participate in an online webinar to present results and take questions from the BITC industry board (frequency no more than once per year).

Proposals will be accepted on a rolling basis from 1 October 2019 to 30 September 2020, and evaluated by an independent group of subject matter experts from the member companies.

Prior to submitting a proposal, contact the BITC Director (Dr. C. J. Roberts, email: cjr@udel.edu) for a pre-proposal review electronically or by phone appointment. Proposals submitted without a pre-proposal review may be returned without further review if they are not aligned with BITC goals. The maximum 1-year budget for RFP19-20 is \$45,000 USD, renewable for up to 1 additional year upon BITC board approval at the end of year 1. No indirect costs / F&A will be paid by BITC. Additional details regarding allowable expenses are given below. All work supported by BITC is subject to a non-exclusive, royalty-free (NERF) license for all

BITC member companies for IP generated from BITC-sponsored projects. For additional details or questions, contact the BITC Director.

Proposal Formatting:

- document length should be no longer than 5 pages, including figures and tables, but not including references or appendix for budget and budget justification (see below).
- 1 inch margins
- Single space, minimum 11 point Arial or Times New Roman font

Proposal Contents:

1. Title
2. Name of PI and Institution
3. Requested Start Date
4. Project Summary:
 - a. A concise statement of the proposed work, motivation, and expected outcome(s)
5. Project Description:
 - a. A discussion stating the background and proposed approach, novelty of the approach, and a timeline of the methods development and deliverables.
6. List of key personnel, as applicable
7. References (not included in page limit)
8. Appendix for annual budget (not included in page limit): Template available upon request (email: Christopher Roberts, cjr@udel.edu). Maximum annual budget is \$45,000. Budgets may incorporate the following:
 - a. Salaries and benefits, student stipend and/or tuition, supplies, travel (travel expenses are limited to \$2,000 per project year unless otherwise approved by the BITC Director)
 - b. No indirect costs / F&A are allowed
 - c. Initial project duration is 1 year, renewable for up to one additional year upon successful completion of year-one deliverables, and subject to approval of the BITC board.
9. 1-page budget justification (not included in page limit)

Sections 1-9 should be submitted as a single pdf. Submit via email to: Christopher Roberts (cjr@udel.edu)