University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

Table of Contents

Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.*
    - *For exempt research: Sections 31 and 32 do not apply.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response:

Intervention Group:

Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response: Controlled evaluation of Innovation Labs for enhancing CTSA network capacity

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Larry Hawk, Ph.D.

Psychology

716-645-0192

lhawk@buffalo.edu

VERSION:

Include the version date or number.

Response: 2018-06-22

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: This project is funded by NCATS; all aims of the grant are covered by this proposal. The grant application is attached.

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: Lab of Larry Hawk

Address: Diefendorf Hall, 3rd Floor, Room 304, 306-307, 308a, 311, or 316

Department: Psychology

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response: Our Innovation Labs will be focused on creating new transdisciplinary, trans-CTSA teams of early career investigators. **Specific Aim 1: With ongoing input from multiple stakeholders (NCATS, CTSA hubs and Domain Task Forces), we will develop, run, and track the impact of two pilot Translational Workforce Development Innovation Labs.** Initial scoping activities, including a CTSA-wide survey, will identify the grand challenge focus of each Lab. We will then invite applicants from all CTSA hubs and invite a subset (from 12+ hubs) to the first 5-day immersive Lab in Buffalo in late 2017. We will replicate the process with a second Lab in 2018 at the Airlie Hotel and Convention Center in Warrenton, VA. Based in leading science-of-team-science (SciTS) frameworks and assessment approaches (e.g., Stokols et al., 2008; Wooten et al., 2013; see also IOM report), we hypothesize that Innovation Labs will facilitate short-term markers of team science (e.g., attitudes; objective depth and breadth of networks), as well as targeted intermediate outcomes (i.e., increased number and novelty of collaborative NCATS/CTSA grant proposals).

Innovation Labs address the critical challenges of fostering collaboration in the CTSA network while enhancing career development and innovation in translational research. Thus, we respond to the repeated calls for advancing, sharing, and disseminating "best practices." We also believe it is important to go further, to consider how to evaluate "best practices" as well as to describe the efficacy of Innovation Labs. At present, the determination of best practices frequently relies on "case studies", anecdotal reports, and expert opinion. Though these are critical for hypothesis generation, we share the NCATS perspective that a more rigorous translational science approach should be used. **Specific Aim 2: We will take the innovative step of evaluating the impact of the Innovation Labs in a Randomized Controlled Trial (RCT) in which we randomly assign matched applicants to an Innovation Lab or "treatment-as-usual" control group.** This experimental approach embodies the best of translational science, subjecting promising ideas to rigorous, controlled evaluation.

Should the Innovation Lab approach prove efficacious in generating new cross-CTSA collaborations, the proposed work opens promising future avenues. Innovation Labs could be broadly disseminated to increase CTSA network capacity. Innovation Labs could become an important part of the NCATS/CTSA approach to developing the desired "integrated and collaborative national network" that can be brought to bear on a range content-based grand challenges targeted by the CTSAs (e.g., Big Data to Knowledge [BD2K], 2015). In addition, Innovation Labs may be turned to a hybrid of process and content grand challenges (e.g., engaging the community in combatting obesity; maximizing the impact of pilot study mechanisms)

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response: We hypothesize that Innovation Labs will facilitate short-term markers of team science (e.g., attitudes; objective depth and breadth of networks), as well as targeted intermediate outcomes (i.e., increased number and novelty of collaborative NCATS/CTSA grant proposals).

2.0 Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response: Primary outcomes will be measures of the depth and breadth of participants' collaborative networks and attitudes towards collaboration, which we predict will be enhanced in the Innovation Lab group compared to the treatment as usual control group. We will also gather initial data on the degree to which Innovation Labs result in increased transdisciplinary collaborative output, including grant proposals, publications, and presentations.

3.0 Background

3.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: As the 2013 IOM report (Leshner et al., 2013) documents and PA-16-328 summarizes: "…A major challenge for the next phase of the CTSA Program

will be to establish a more integrated and collaborative national network that will further catalyze the development of new interventions while driving innovation in clinical and translational science." Enhancing collaboration, particularly collaboration across CTSAs, is central to the program but faces many barriers. This may be particularly true for a critical part of the translational workforce, the early career investigators who are establishing their independent research. Having benefited from the successful early phases of training (e.g., the T and K programs), these emerging independent investigators are especially well positioned to benefit from targeting increased collaborative translational science. However, given their limited scholar network, limited practical knowledge about developing collaborations, and existing barriers to collaboration, they may be disadvantaged in pursuing and obtaining collaborative funding (via e.g. PAR-15-172; see, e.g., Daniels, 2015) – without a substantive "nudge".

Addressing key barriers to cross-CTSA collaboration among the critical community of independent, early career investigators, we will implement two Innovation Labs, one in Buffalo (2017) and one at the Airlie Hotel and Conference Center (2018) in Warrenton VA, in order to foster the development of new transdisciplinary, multi-CTSA teams that will pursue innovative translational science. Innovation Labs are carefully structured meetings designed to encourage the creation of novel transdisciplinary research proposals. The Innovation Lab structure was originally defined in 2003 by the United Kingdom's Engineering and Physical Sciences Research Council (EPSRC), in partnership with Knowinnovation, a creativity research and facilitation organization that is also the industry partner on the proposed Labs. At the core of any Innovation Lab is the combination of a difficult problem, a diverse group of participants, and a facilitated journey through the creative problem-solving process. Innovation Lab attendees fall into four distinct groups: 1) 25-30 participants who have applied to attend the event; 2) 2-3 facilitators whose focus is on guiding the participants through the creative problem-solving process; 3) 4-6 subject matter experts guide participants at the scientific level but typically are not involved in forming teams, nor are they typically eligible to apply for grants; and 4) representatives from the funding agency, whose role is to both encourage the creation of novel research proposals, and to provide guidance with regard to what sort of proposals are within scope.

Since 2003, Innovation Labs (a.k.a. "sandpits" and "ideas labs" depending on the funding agency and parameters) have been run by NSF and NIH on a wide range of problems (e.g., synthetic biology, security of cyber physical systems, mobile health, cancer risk behavior), and several more are being developed. Innovation Labs have been very well received by participants, host organizations, and funding agencies. They appear effective for fostering new transdisciplinary teams who generate innovative research that is well-funded (see Prelim Study 1). Indeed, we have been very pleased with the process and products of our own work with Knowinnovation (for details, please see Preliminary Study 2).

Nevertheless, empirical research on the effectiveness of these workshops is scarce. The proposed work is significant in assessing the degree to which the

Innovation Lab method actually works. Specifically, two preliminary randomized controlled trials (RCTs) will evaluate the efficacy of Innovation Labs against "treatment as usual" controls for generating new transdisciplinary, cross-CTSA collaborations. Although the Innovation Lab that is part of RCT 2 will be held at the Airlie Convention Center in Warrenton, VA, data collection for both RCTs will be collected and maintained on University at Buffalo servers (REDCap, UBBox).

How will we know if the Labs work? Masse et al. (2008) provide a useful framework of immediate and intermediate markers and long-term outcomes. Though long-term changes in practice, policy, and public health are compelling outcomes, they are not appropriate metrics for preliminary evaluation of methods to increase CTSA network collaboration and capacity. Given the target of facilitating new collaborations, we will focus on immediate and short-term indicators of that target. Following recommendations from the science of team science (SciTS), we will assess multiple prospective immediate/short-term markers (e.g., self-reported attitudes towards collaboration; indices of the number, breadth, and depth of collaborations; and participation in collaborative science networks such as EdgeforScholars [Preliminary Study 5]; see Measures for details).

Intermediate markers are intriguing in the present context. New collaborations typically take years to produce funded grants and publications (indeed, quasi-experimental evidence suggests that the benefits of transdisciplinary teams may be preceded by a short-term lag in traditional productivity metrics as teams work to nurture the process; Hall et al., 2012). That said, Innovation Labs are by design far from typical. They begin with a grand challenge developed in consultation with one or more funding agencies and are frequently tied to dedicated funds. In the proposed RCTs, Lab teams will target development of proposals for specific funding targets, the centerpiece of which are grants funded by NCATS to support cross-CTSA collaborations (i.e., PAR-15-172). Importantly, the ability to track submissions to PAR-15-172 yields a narrow but important set of intermediate markers of successful collaboration. Evidence that Innovation Lab participants outperform controls on these intermediate markers would support Labs as a best practice and pave the way for large-scale dissemination and evaluation of their ability to accelerate progress across the full spectrum of clinical and translational science outcomes.

More generally, the proposed RCTs are significant for advancing a science-of-science approach to evaluating "best practices" in achieving core CTSA goals. The IOM report (Leshner et al., 2013) mentions "best practices" more than two dozen times, calling for their identification, fostering, sharing, and dissemination in multiple target areas, including collaboration. Although members of the CTSA consortium have developed a range of approaches to facilitate collaborative cross-disciplinary translational science (see https://ctsacentral.org/consortium/best-practices/), best practices for collaboration are not well studied or well established. Though there are many candidate "best practices", the strength of the evidence in support of these practices pales in comparison to the evaluation methods we use every day as clinical and translational scholars, where the strong recommendations require evidence of efficacy, effectiveness, cost-effectiveness, and acceptability

(e.g., Glasgow et al., 2013; Guyatt et al., 2008). By contrast, the strength of the evidence for most methods for training, enhancing collaboration, etc. is quite weak (see e.g., Stokols et al., 2008). Case studies and consensus recommendations based on anecdotal reports are a natural starting point, but CTSA 2.0 should employ strong tests and standards of evidence to make the most rapid advances in translational research.

To help shift the paradigm for evaluating and disseminating "best practice" methods, we apply the clinical and translational science model with which we are familiar -- strong ideas from basic science and/or clinical experience are subjected to a sequence of rigorous trials, with an eye for dissemination and implementation. If Innovation Labs are efficacious in the proposed RCTs, we can move towards dissemination and implementation across the CTSAs to evaluate the impact of Innovation Labs on other problems and populations. This research will also guide refinements in Innovation Labs to enhance their efficacy. More broadly, developing a science of science translational pipeline should accelerate the pace of discovery in many disease and health domains, benefitting public health.

The proposed RCT will also evaluate the processes and mechanisms by which Innovation Labs exert their clinical effects. It is increasingly clear that to maximize the value of CTR research, we must assess and evaluate theorized mechanisms by which our interventions work (e.g., Kraemer et al., 2006). By extension, the same is true in developing best practices and methods for translational science. Thus, in the proposed work we will evaluate the impact of Innovation Labs not only on intermediate outcomes (specific grant proposal characteristics described in Significance) but also on short-term markers and processes that may drive later outcomes (i.e., attitudes about collaboration, changes in the depth and breadth of collaborative networks). Thus, our approach will deliver promising targets for mechanism-enhancement approaches (e.g., MacKinnon, 2008) to facilitate further improvements in our translational science "intervention". The highly competitive nature of current NIH paylines has resulted in a disincentive for innovation, which by its nature is risky. "Safe" grant applications designed to avoid criticisms by reviewers invariably receive better scores when paylines are low, encouraging incremental science rather than innovative science. In contrast, theories of creativity and innovation emphasize the importance of novel combinations of ideas and approaches (e.g., Runco & Jaeger, 2012; Sawyer, 2012; Simonton, 2004). "Across the sciences, the propensity for high impact work is sharply elevated when combinations of prior work are anchored in substantial conventionality, while mixing in…combinations that are rarely seen together" (Uzzi et al., 2013, p. 471).

Such is the case with the proposed study. Innovation Labs strongly support this process of combinatorial creativity. Participants will be selected to share interest/expertise relevant to the grand challenge topic of each Lab but to be maximally diverse in terms of their disciplines and approaches to the topic. Innovation Labs both select for and foster tolerance for ambiguity, openness to novelty, and trust in forming new collaborative relationships, factors emphasized in the SciTS (e.g., Hall, Vogel, et al., 2012) and reinforced by our experience (see

Preliminary Studies). Reflecting the essence of creativity and innovation, we combine the best elements of basic preclinical science, theory, and treatment outcome research to propose an outstandingly novel and rich project that: a) aims to facilitate and accelerate collaboration across the entire CTSA network, b) targets an underserved but vitally important segment of the translational workforce, c) employs a bold new path in translational science – applying rigorous CTR/RCT methodology to empirically evaluate a promising translational science method, the Innovation Lab, for its efficacy and dissemination potential, and d) collects critical process data for further programmatic work in these areas.

3.2 Include complete citations or references.

Response:

Collins, T., Kearney, M., & Maddison, D. (2013). The ideas lab concept, assembling the tree of life, and AVAToL. PLOS Currents Tree of Life. Mar 7 . Edition 1. doi: 10.1371/currents.tol.0fdb85e1619f313a2a5a2ec3d7a8df9e.

Daniels, R. J. (2015). A generation at risk: young investigators and the future of the biomedical workforce. Proceedings of the National Academy of Sciences, 112(2), 313-318.

Glasgow, R. E., Brownson, R. C., & Kessler, R. S. (2013). Thinking about Health-Related Outcomes: What Do We Need Evidence about?. Clinical and translational science, 6(4), 286-291.

Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., & Schünemann, H. J. (2008). Rating Quality of Evidence and Strength of Recommendations: GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ: British Medical Journal, 336(7650), 924.

Hall, K. L., Stokols, D., Stipelman, B. A., Vogel, A. L., Feng, A., Masimore, B., ... & Berrigan, D. (2012). Assessing the value of team science: a study comparing center-and investigator-initiated grants. American journal of preventive medicine, 42(2), 157-163.

Hall, K. L., Vogel, A. L., Stipelman, B. A., Stokols, D., Morgan, G., & Gehlert, S. (2012). A four-phase model of transdisciplinary team-based research: goals, team processes, and strategies. Translational behavioral medicine, 2(4), 415-430.

Hawk Jr, L. W., Ashare, R. L., Lohnes, S. F., Schlienz, N. J., Rhodes, J. D., Tiffany, S. T., ... & Mahoney, M. C. (2012). The effects of extended pre-quit varenicline treatment on smoking behavior and short-term abstinence: a randomized clinical trial. Clinical pharmacology and therapeutics, 91(2), 172.

Kraemer, H. C., Frank, E., & Kupfer, D. J. (2006). Moderators of treatment outcomes: clinical, research, and policy importance. JAMA, 296(10), 1286-1289.

Leshner, A. I., Terry, S. F., Schultz, A. M., & Liverman, C. T. (Eds.). (2013). The CTSA program at NIH: Opportunities for advancing clinical and translational research. National Academies Press.

MacKinnon, D. P. (2008). Introduction to statistical mediation analysis. New York: Erlbaum.

Mâsse, L. C., Moser, R. P., Stokols, D., Taylor, B. K., Marcus, S. E., Morgan, G. D., ... & Trochim, W. M. (2008). Measuring collaboration and transdisciplinary integration in team science. American journal of preventive medicine, 35(2), S151-S160.

Mallinson, T., Lotrecchiano, G. R., Schwartz, L. S., Furniss, J., Leblanc-Beaudoin, T., Lazar, D., & Falk-Krzesinski, H. J. (2016). Pilot analysis of the Motivation Assessment for Team Readiness, Integration, and Collaboration (MATRICx) using Rasch analysis. Journal of Investigative Medicine, jim-2016.

Puccio, G. J. (2002). FourSight: Technical manual. Evanston, IL: THinc Communications.

Raudenbush, S. W., & Bryk, A. S. (2002). Hiearchical Linear Models: Applications and Data Analysis Methods (2nd edition). Thousand Oaks, CA: Sage.

Runco, M. A., & Jaeger, G. J. (2012). The standard definition of creativity. Creativity Research Journal, 24(1), 92-96.

Sawyer, R. K. (2012). Explaining creativity: The science of human innovation. OUP: USA.

Simonton, D. K. (2004). Creativity in science: Chance, logic, genius, and zeitgeist. Cambridge University Press.

Stokols, D., Hall, K. L., Taylor, B. K., & Moser, R. P. (2008). The science of team science: overview of the field and introduction to the supplement. American journal of preventive medicine, 35(2), S77-S89.

Wooten, K. C., Rose, R. M., Ostir, G. V., Calhoun, W. J., Ameredes, B. T., & Brasier, A. R. (2013). Assessing and evaluating multidisciplinary translational teams: a mixed methods approach. Evaluation & the health professions, 0163278713504433.

Uzzi, B., Mukherjee, S., Stringer, M., & Jones, B. (2013). Atypical combinations and scientific impact. Science, 342(6157), 468-472.

4.0 Study Design

4.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: We will critically evaluate the impact of Innovation Labs in two preliminary randomized controlled trials (RCTs). A diverse applicant pool of early career investigators invited from every CTSA hub in the consortium will be

reviewed. Top applicants will be randomized to a 5-day residential Innovation Lab or "treatment as usual" control group (n=25/group/RCT). Measures of process and outcome will be collected all applicants from the application phase through 15-month follow-up and aggregated across the two RCTs.

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: In each RCT, we will employ a two-group, balanced, randomized parallel-group design in which we randomize 40-50 early career applicants to either a 5-day Innovation Lab or a treatment-as-usual control group. All remaining applicants will also be followed to provide a second comparison group. Thus, the total sample size will be approximately 100-200.

5.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: For each Innovation Lab, we anticipate receiving 50-100 applications; all applicants will be followed. The top 40-50 applicants will be randomly assigned to Lab or control. In prior Innovation Labs, there has been virtually no attrition; however, there was no control condition. To enhance retention in the proposed trials, modest remuneration will be provided for completing study measures. We have also been discreet about the randomization element in the consent form and plan to follow all applicants/participants to both increase the generalizability of the findings and attenuate demand characteristics and attrition. Travel and lodging will be provided for Innovation Lab participants.

5.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: Calls for previous Labs have generated 100-200 applications. The ability to distribute recruitment information broadly across the CTSA consortium should ensure that there is no shortage of applications from early career scientists.

6.0 Inclusion and Exclusion Criteria

*6.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Participants in each RCT will be early stage investigators (NIH-defined as "within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent)") who are emerging as independent scholars. For each lab, there will be a "grand challenge" focus. Participants' applications will be reviewed for quality and quantity of academic

productivity, fit with the grand challenge topic, and diversity of perspectives among participants (e.g., biomedical and social/psychological, basic and applied).

Applicants should be faculty at a CTSA hub institution or regional partner, as is clearly stated on the call for applications and in the application itself.

*6.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Anyone who does not meet inclusion criteria.

6.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

*6.4 Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response: In practice, few non-English speakers would be likely to apply, as we are recruiting US CTSA investigators, and we do not know of non-English-speaking individuals within this sample. However, it will be critical that participants speak English, as the focus of the Innovation Labs is to build shared research interests and collaboration, that extend beyond the week-long Lab back

into the home research environment; this would not be possible for an investigator that does not speak English. In addition, all study measures are in English and translation and back-translation work would still not ensure that the measures were valid for non-English-speaking scholars.

7.0 Vulnerable Populations

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

7.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response: This is a minimal-risk study which would not introduce any harm to a pregnant woman. Although they will not be specifically targeted for enrollment, they will not be excluded from participating.

☐ **N/A**: This research does not involve pregnant women.

7.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

7.3 For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

7.4 For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

7.5 For research that involves ***cognitively impaired adults****, safeguards include:*

NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

7.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: N/A

8.0 Eligibility Screening

8.1 Describe ***screening procedures*** *for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response: Participant selection will follow procedures used in previous Labs. As described in our attached "Call for Applications-2017-07-24.doc", participants will submit an an *NIH (or NSF) Biographical Sketch, an NIH (or NSF) Other Support / Current Pending Support form, and answers to each of the following topics/questions:*

- *Provide a brief summary of your professional background (max 250 words). Please note that if you are selected for the Innovation Lab, your answer will be made available to the other attendees to facilitate networking at the workshop.*
- *How do you see your expertise and interests contributing to realizing the goal of this Innovation Lab? (max 250 words)*
- *What do you hope to gain from participating in this Innovation Lab, personally and professionally? (max 150 words)*
- *What is your personal experience with working in teams? What strengths do you bring to a team effort? (max 150 words)*
- *How would you describe your ability to explain your research to non-experts? (max 150 words)*
- *The Innovation Lab environment is especially suited to individuals who are willing to step outside their particular area of interest or expertise, who are positively driven, who enjoy creative activity, who can think innovatively and who can settle in easily in the company of strangers. Please describe an experience you have had in a comparable environment. (max 150 words)*

They will also submit basic demographic and professional characteristics. The application will be submitted via REDCap, and a copy of the complete application is attached as REDCapApplicationFor2017InnovationLabBuffalo-2017-07-25.pdf You can also view the application online at: http://j.mp/2eG4aOp.

Applications will be reviewed for completeness and to ensure they are early stage investigators who are emerging as independent scholars. Applications will then be ranked according to goodness of fit with the topic of the *Innovation Lab,* the quality and quantity of academic productivity and collaboration, and contribution to diversity of perspectives among Lab participants (e.g., biomedical and social/psychological, basic and applied).

Following the application deadline, participants will be sent a link to the REDCap Baseline Assessment. Completion of the Baseline Assessment is required to be considered for the Innovation Lab – but the specific responses will NOT be considered in the applicant review. To encourage honest responses and minimize potential demand characteristics / response bias, the required baseline assessment will be collected separately from the application and will not be accessible to the selection committee.

Once participants have been selected for the Innovation Lab, all remaining participants will be notified by email to a) express appreciation for the application and baseline assessment, b) notify them that they were not selected to attend the lab, and encourage them to remain in the study and complete the follow-up assessments.

☐ **N/A:** There is no screening as part of this protocol.

9.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

9.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response: We will distribute a call for applications from prospective participants throughout the CTSA Program consortium. This will be done by distributing e-mails to the CTSA network PIs and Domain Task Force Leads. E-mails will also be sent to NCATS, NIH, and UB listservs. These e-mails will provide potential candidates with the application guidelines and a link to our study website where they can learn more about the Innovation Lab and apply.

We will post information and updates on Twitter and edgeforscholars.org with a link to the study website (please see attached Twitter/edgeforscholars.org

advertisements). The same "tweets" or blurbs will be used for both Twitter and edgeforscholars.org.

9.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: We will recruit via public advertisements so that interested participants self identify, and we will only contact participants and collect study data by methods to which they have requested/consented.

9.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: Please see the attached Application Guideline, e-mail script, Twitter/edgeforscholars.org advertisements, and study website information (webpages).

10.0 Procedures Involved

*10.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

Additional Pre-Lab Assessment and Randomization. After obtaining informed consent, participants will complete additional Pre-Lab (baseline) assessments via RedCap, at which point the top applicants will be randomized (blind to their responses to baseline assessments) to Innovation Lab or control and all participants will be notified as to whether they were selected to attend. Randomized participants will be considered part of the intent-to-treat (ITT) sample for the RCT aspect of the project.

Innovation Lab. The Innovation Lab methodology was developed to counteract the myriad forces that push for monodisciplinary incremental science by fostering rapid but thoughtful development of innovative transdisciplinary research proposals.

Innovation Labs follow the five stages of the creative problem-solving process: data gathering (Day 1), problem framing (Day 2), idea generation and "stretching" (Day 3), solution/proposal creation with real-time peer-review (Day 4), and action planning – development of detailed proposals (Day 5). Throughout the process, there is a deliberate focus on both expertise identification and the creation of strong social bonds between participants. As part of the process, we have also found it useful to use a psychometric instrument (Puccio, 2002) – FourSight – which was specifically designed to surface problem-solving preferences of the participants. This has shown itself to be useful as a mechanism for helping teams both recognize diversity in their styles, and adapt their working processes accordingly.

All participants will complete 3- (End-of-Lab; EOL), 9- and 15-month assessments similar to the baseline assessment. Participants are notified of the assessments by email generated in REDCap. In June 2018, we saw a marked drop in survey completion rate for RCT 1 – from 92% at 3 months to 58% at 9 months. We became very concerned that a number of factors may have contributed to the decline, including possible email delivery failure and, in at least one confirmed case, failure of the institution to issue requested remuneration to a participant. Therefore, we will follow-up by phone with any participant who has not completed a follow-up assessment within 2 weeks of the email invite, using the "Telephone Check-In Script.doc" submitted to the IRB along with this protocol.

In summary, all participants submit assessments at four timepoints (baseline, 3M, 9M, and 15M). Participants who are not selected to attend the *Innovation Lab* are not asked to complete any additional activities besides the online assessments.

Participants randomized to the *Innovation Lab* group complete the week-long *Lab*. 2017 *Lab* participants completed brief daily program evaluation and feedback forms. 2018 *Lab* participants will be asked to complete daily measures on Mon – Thur of the *Lab*. To avoid potential burden/stress from reporting on the final day of the *Lab*, when participants are also traveling back to their home institutions, overall program evaluation and feedback will be assessed as part of the 3M assessment.

10.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: Participants will be asked to complete surveys and submit their CVs four times over the course of the study. Data collected from participants include all items on the Labs application, CVs, and the baseline and 3M, 9M, and 15M assessments.

10.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: Please see attachments as outlined below.

Application (see above 8.1).

Baseline, 3M, 9M, and 15M follow-up include some or all of the following measures:

Curriculum vitae and social media use

Pending grant information

Measures related to collaboration:

- Motivation Assessment for Team Readiness, Integration, and Collaboration(MATRICx) scale (Mallinson et al., 2016)
- Collaboration Self-Efficacy Scale (teamscience.net behavioral module pre-test, Bonnie Spring and Kevin Wooten, personal communications, Feb 2018)
- Transdisciplinary Integration Scale (Masse et al., 2008)
- Transdisciplinary Orientation Scale (TOS; Misra et al., 2015)

Individual difference measures to characterize the sample and to serve as possible moderators:

- Ten-Item Personality Inventory (TIPI; Gosling et al., 2003)
- Behavioral inhibition and behavioral approach scales (Carver and White, 1994) are designed to measure individual differences in appetitive and aversive motivational systems.
- Foursight (Puccio, 2002) is designed to measure individual differences in creative style.
- PhenX Delayed Reward Discounting Monetary Choice Questionnaire (PhenXDRDMC; Kirby et al., 1999)

* A screenshot of the collaboration self-efficacy scale is included in study documents; a single pdf of all other measures from REDCap is saved as: InnovationLabBuffalo-AllBaselineMeasures-2017-08-14.pdf.

During the *Innovation Lab*, participants will be asked to complete brief daily program evaluation and feedback forms.

* A pdf of the 2017 program evaluation is uploaded in Click: InnovationLabBuffalo – ProgramEvaluation-2017-10-31.pdf.
* A pdf of the updated 2018 program evaluation is uploaded in Click: InnovationLabBuffalo – ProgramEvaluation-2018-04-11.pdf.

10.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: We will review publicly available records regarding grants (e.g., NIH REPORTER), publications (e.g., Google Scholar), and social network activity (i.e., EdgeforScholars.org) for evidence of changes in collaborative activities (number, breadth, depth) and scholarly productivity. As noted in the grant proposal: "New collaborations typically take years to produce funded grants and publications (indeed, quasi-experimental evidence suggests that the benefits of transdisciplinary teams may be preceded by a short-term lag in traditional productivity metrics as teams work to nurture the process; Hall et al., 2012)."

The study sponsor (NCATS) will be asked to indicate whether study participants have been investigators or consultants on proposals submitted in response to NCATS collaboration RFAs at baseline and at 15-month follow-up. From the grant proposal: "In the proposed RCTs, Lab teams will target development of proposals for specific funding targets, the centerpiece of which are grants funded by NCATS to support cross-CTSA collaborations (i.e., PAR-15-172). Importantly, the ability to track submissions to PAR-15-172 yields a narrow but important set of intermediate markers of successful collaboration."

*10.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: N/A. Individual subject results will not be shared with participants or others.

*10.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: We will offer to send all participants the published (de-identified) results of the study following completion of trial follow-up.

11.0 Study Timelines

11.1 Describe the anticipated duration needed to enroll all study subjects.

Response: 15 months

11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Application (~4 hours), Baseline assessment (~1 hour), Innovation Lab (50 hours, for participants randomized to the Lab group), and 3M, 9M, and 15M

assessments (~1 hour each). Total ~58 hours for Innovation Lab attendees; ~8 hours for all other participants.

11.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: 3 years

12.0 Setting

12.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: All consenting and study assessments will take place within the secure online environment of RedCap. Participants will complete study measures on their own computers using the secure REDCap software in settings determined by them (such as their office or home), offering maximal privacy protections.

The Innovation Labs program will take place in a typical conference setting, in a large local hotel with the capacity for hosting such an event safely. Doors to the event will be kept closed and only people who are registered for the Innovation Lab program will be admitted.

12.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response: N/A

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

13.0 Community-Based Participatory Research

13.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

13.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

14.0 Resources and Qualifications

*14.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

Dr. Hawk. As a Professor of Psychology at the University at Buffalo, I have long-standing collaborations with a broad network of scholars beyond my discipline, including neuroscientists, geneticists, physicians, pharmacologists, and epidemiologists. I am driven to contribute to the full spectrum of clinical and translational science, but it did not start that way. Although my doctoral training in clinical health psychology provided me with an excellent background in theory, methods, and interventions for a range of health behaviors, I initially eschewed clinical applications in favor of psychophysiological approaches to studying basic affective and cognitive processes. “Translational” became more than a buzzword in my grant applications and discussion sections as I began collaborating with both more basic and more applied investigators in psychology and other disciplines. Gradually realizing first-hand the value of transdisciplinary work, I have increasingly extended my expertise in basic processes to collaborative evaluation of putative treatment mechanisms in three different areas – anxiety, Attention-Deficit/Hyperactivity Disorder, and cigarette smoking – and harnessing those mechanisms to improve clinical outcome. In preliminary clinical trials that

borrow heavily from preclinical work, we have developed a theory-based but easily delivered approach to improving smoking cessation. Our new large-scale trial (R01 CA206193) will determine whether our approach outperforms the best-in-class treatment, employ pharmacology, lab paradigms, and real-world real-time assessments to test the hypothesized mechanism (and competing alternatives), and gather data to facilitate subsequent dissemination and implementation.

As an early career independent scientist, I was fortunate to obtain unstructured mentorship from more senior scholars. Len Epstein (Co-I) and Caryn Lerman fueled my passion for working with transdisciplinary teams to both understand mechanisms and improve treatment outcomes. Epidemiologist K. Michael Cummings helped me to focus on treatment approaches that can be broadly disseminated and introduced me to the physician epidemiologist who would become my long-standing partner in our smoking cessation work, physician scientist Martin Mahoney. In 2012, I found Len and I and I were both developing a passion for more intentionally generating novel transdisciplinary science. Over the past 5 years, that passion has blossomed in several ways, including our CTSA's Creative Scientist workshop series, which I now lead. Looking ahead, I am excited to conduct translational science to improve CTSA network capacity by developing, assessing, and implementing best practice methods for enhancing collaboration in the developing translational workforce.

Dr. Murphy. As Principal Investigator of the University at Buffalo Clinical and Translational Science Award (CTSA) and Director of the UB Clinical and Translational Research Center, I am committed to supporting clinical and translational research directed toward improving health. This supplement aligns closely with the aims of our CTSA through using novel approaches to workforce development (Aim 2) and enhancing innovation in translational research (Aim 1). This supplement will support CTSA network capacity by engaging early stage investigators at every hub in the consortium (by invitation to apply) to participate in a program to stimulate and nurture consortium-wide collaborations.

My research interests focus on the respiratory tract bacterial pathogens nontypeable Haemophilus influenzae (NTHI) and Moraxella catarrhalis, including the molecular epidemiology of infection, mechanisms of pathogenesis and vaccine development. This work has been continuously funded by the NIH since 1983. My work has also included conducting a 20-year prospective, observational study of bacterial infection in adults with COPD from 1994 to 2014. This study, funded by the Department of Veterans Affairs, has generated an enormously valuable repository of data, bacterial strains, serum and sputum samples that have been the focus of ~50 publications in peer-reviewed journals. My current work focuses on two areas. 1) Prevention of otitis media in children and infection in COPD through vaccine development, and 2) Analysis of the genomes of hundreds of bacterial strains collected in our prospective study of COPD to elucidate mechanisms of infection.

I also oversee a training program that provides research experience to medical students in an effort to attract and train the next generation of physician scientists.

I have had the opportunity to mentor many trainees at the undergraduate, graduate, postdoctoral and junior faculty levels of training in my laboratory.

Coordinator Erin O'Byrne: The Project Coordinator will work with the PIs and Co-I on providing administrative expertise in project timeline management for the logistics of the Innovation Lab.

Graduate Assistant Morgan Jusko: The Project Assistant will work with the PIs and Co-I on the development of measurement plan, data collection, remuneration for participants and provide assistance to the Project Coordinator with logistical needs for the Innovation Labs.

Describe other resources available to conduct the research.

14.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: Dr. Murphy, .36 calendar months (based on a .9 FTE) = 1.3 hours/week; Dr. Hawk, 1.2 academic months = 5.3 hours/week; Project Coordinator, 1.8 calendar months = 6 hours/week; and Graduate Assistant, 3 calendar months = 10 hours/week.

14.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: N/A, there are no anticipated adverse consequences to this research.

14.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: Study investigators will meet/videoconference/teleconference at least monthly, with additional ad hoc meetings as needed, to ensure there is consistency in approach and implementation. All staff will be provided with copies of the grant proposal. Study protocols are provided in binders in the relevant rooms, and training of study staff will include direct observation of mock procedures, followed by supervision in real patient interactions. Duties will be documented in a continuously updated delegation log that will be signed by the staff member whenever there is a change.

15.0 Other Approvals

15.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: Participants will be fully informed of all study data to be collected and these data will only be collected with their consent. Participants will complete study measures on their own computers using the secure REDCap software used throughout the CTSA network, in settings determined by them (such as their office or home), offering maximal privacy protections.

Because the Innovation Labs take place in public places, we cannot ensure that the fact of participant's attendance will be private or confidential. In addition, because the goal of the workshop is to expand networks of connections, a list of Lab participant names and their CTSA affiliation will be shared amongst the participants to facilitate the goal of fostering inter-disciplinary collaborations, and we may share this information with other CTSAs, in our reports to NIH, and in promotional materials. This information is communicated to participants in the informed consent document.

16.2 Indicate how the research team is permitted to access any sources of information about the subjects.

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response: Data will only be collected after obtaining participant consent.

17.0 Data Management and Analysis

17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: Our assessments of immediate/short-term impact will include: 1) self-report indices of collaborative experience and attitudes (motivation, satisfaction, threats, impact; Mallinson et al., 2016; Misra et al., 2015) and 2) composite network metrics (number, breadth, and depth) derived from self-report, bibliographic indices, and unobtrusive measures of science network activity (i.e., EdgeforScholars [Prelim Study 5]). Hierarchical linear models (HLMs) will evaluate changes in collaboration from baseline through 15-month follow-up. HLMs allow us to model the interdependencies in the data (e.g., teams within RCT) and individual differences in change and can accommodate cases with missing data (Raudenbush & Bryk, 2002). We anticipate reliable Group x Time interactions, such that there will be greater improvements in collaboration indices over time among the Innovation Labs group compared to the treatment-as-usual control group. Consideration of potential moderators and covariates will be the focus of scoping activities with NCATS.

We will also conduct a targeted evaluation of the degree to which participants in Innovation Labs are more likely than controls to apply for cross-CTSA collaborative funding (namely via PAR-15-172, which can be tracked by NCATS).

17.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: Power analyses focused on the dichotomous intermediate marker (PI/Co-I on a cross-CTSA collaborative grant during the 15-month follow-up period), because power is lowest for dichotomous outcomes. With n=50/group and alpha=.05, power is ~.8 or greater for detecting a doubling of the percentage submitting such proposals in the Innovation Lab vs. control groups (i.e., 40% vs. 20% or 50% vs. 25%).

17.3 Describe any procedures that will be used for quality control of collected data.

Response: Study data will be collected with REDCap software that will include built-in checks for missing responses and out-of-range responses. The Project Manager will conduct quality control reviews of data on an on-going basis; corrections will be made according to Good Clinical Practice (GCP). Any inconsistencies/deviations will be documented.

18.0 Confidentiality

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: All data will be collected and stored in a secure-access RedCap database.

18.2 A. How long will the data be stored?

Response: Records containing identifying information will be stored for 3 years after completion of the project; they will then be destroyed. De-identified data will be stored indefinitely.

18.3 A. Who will have access to the data?

Response: Access to source documents and identifying information will be limited to project investigators and staff.

18.4 A. Who is responsible for receipt or transmission of the data?

Response: Study investigators and staff.

18.5 A. How will the data be transported?

Response: Data will not be physically transported.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)*

18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

18.7 B. How long will the specimens be stored?

Response:

18.8 B. Who will have access to the specimens?

Response:

18.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

18.10 B. How will the specimens be transported?

Response:

19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: N/A: This is a minimal risk study that does not pose any anticipated harm to participants.

19.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: N/A

19.3 Describe any safety endpoints.

Response: N/A

19.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: N/A

19.5 Describe the frequency of safety data collection.

Response: N/A

19.6 Describe who will review the safety data.

Response: N/A

19.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: N/A

19.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: N/A

19.9 Describe any conditions that trigger an immediate suspension of the research.

Response: N/A

20.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*20.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: The principal investigator of the study can remove participants from the research study without participant approval. Possible reasons for removal include:

1. We discover that a participant provided inaccurate information in the application / recruitment process.

2. A participant has not followed program requirements.

3. The Sponsor, University, or Investigators have decided to stop the program.

20.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: PI or designee will attempt to inform participants (by phone; if unable to contact, then by postal service) of the reason for withdrawal. No additional follow-up is anticipated.

20.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: Already collected data will be retained unless a participant requests destruction of existing records.

21.0 Risks to Subjects

21.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: The only anticipatable risk to subjects in this study is a breach of confidentiality.

21.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: Risks will be mitigated by the data handling procedures described in section 18.0

*21.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: None

21.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: None

21.5 If applicable, describe risks to others who are not subjects.

Response: None

22.0 Potential Benefits to Subjects

22.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: Innovation Lab participants may establish new, productive collaborations as a result of this study. Information that is acquired and analyzed from these controlled studies will be made available to the public in aggregated form, and may contribute to the development of strong "best practices" for developing scientific collaborations among the translational workforce.

23.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*23.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

24.0 Economic Burden to Subjects

24.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: None. See 25.1

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

25.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: The study will pay travel and lodging costs of attending the Innovation Labs. We will follow NIH guidelines in covering lodging, airfare and per diem for the 5-day immersive workshop (see "Innovation Lab Buffalo Travel Lodging.pdf". All participants will be provided modest remuneration in return for completing surveys in a timely fashion: $50 each for 3-M, 9-M, and 15-M follow-ups, with a $50 bonus at 15-M if all 3 assessments were completed within 4 weeks of our request.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

26.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: As this is a minimal risk study, prospective participants will be asked to complete an electronic consent through REDCap at the time of submission of application materials. As part of that consent, participants will be informed that they can contact the PI or project staff with any questions or concerns prior to providing consent; both email and phone contact information will be provided.

26.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: Participants will be given the opportunity to contact the research team with any questions about the research prior to providing consent, as noted above.

26.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: Although we will obtain consent only once in this relatively short term study (each participant is active in the study for ~15 months), participants who raise concerns about continuing participation will always be reminded that they are free to withdraw from the study at any time.

26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response: Yes, we will follow SOP HRP-090, which was most recently reviewed by the PI on 02-15-2017.

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 26.8)*

26.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response:

26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

26.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

26.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

26.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

26.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response:

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response:

*26.12 Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

*26.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response: Given the population of interest are investigators with terminal degrees in their respective fields, all participants will be adults. Children will not be included in this project.

*26.14 **For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review*

your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

Response:

26.15 Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*26.16Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*26.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

26.18 When assent of children is obtained, describe how it will be documented.

Response:

27.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

27.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

27.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

28.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

28.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response: We will present a consent form containing the required Elements of Consent from HRP-314 to prospective participants at the beginning of online application via redcap. Subjects will indicate their consent by electronically entering their initials and date before advancing to the application. We will have implied consent, but no written documentation of consent. We have read CHECKLIST: Waiver of Documentation of Consent (HRP-411) and we believe our research qualifies for a waiver of documented consent. The text of the consent is attached with this submission.

☐ We will be following "SOP: Written Documentation of Consent" (HRP-091).

29.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*29.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

29.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response:

29.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

29.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response:

30.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*30.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the*

data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

30.2 List the data to be stored or associated with each specimen.

Response:

30.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

31.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

31.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

31.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response:

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

31.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

31.4 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response:

32.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

32.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

32.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: