**Application Guidelines for Gillings Innovation Labs, Round 4**

**Mission and Purpose**

A major goal of the Gillings Innovation Laboratory initiative is the development of research and teaching capacity within the UNC Gillings School of Global Public Health. This round of competitive Gillings Innovation Labs is open to faculty members with a *primary* appointment in one of the degree-granting units of the School. If you have questions regarding your eligibility to apply as the principal investigator in this round, please contact Research and Innovation Solutions (accelerate@unc.edu).

The Gillings School of Global Public Health at the University of North Carolina at Chapel Hill [“the School”] is pleased to offer support for Gillings Innovation Labs (GILs). GILs will engage in high-impact research, demonstration projects, or teaching innovations which *anticipate* future public health challenges and *accelerate* solutions.

Proposals must include a **global and local innovation**; alternatively, a convincing case that project done in one setting (global or local) will have relevance to the other. We encourage proposals to contain a specific innovation, clearly defined.

We strongly encourage proposals in the following areas:

* Implementation Science
* Aging/lifecourse
* Big data and data visualization
* Health inequities and health disparities
* Methods to evaluate Affordable Care Act

However, the School will accept letters of intent for truly groundbreaking work, even if the work of the proposal is in a different subject area.

In addition to promoting major improvements in public health, Gillings Innovation Labs will engage interdisciplinary teams, train future public health leaders, and encourage connections among academic investigators, communities, governments, and public and private institutions committed to stemming public health threats. Initial funding for Gillings Innovation Labs is intended to stimulate rapid gains toward solving material public health problems. Many goals will not be reached within the period of initial funding, and it will be important for awardees to sustain efforts after an initial funding period. GILs may provide initial support for a promising line of research and demonstration, enabling an awardee to acquire ongoing support after the award period. We also will accept proposals that seek support for transformative user-centered curricular innovations that meet the needs of 21st century learners.

Challenges to public health occur at local, state, regional, national and international levels. Solutions at any of those levels may be proposed, though solutions that cross (or potentially cross) barriers of geography, environment, culture, income, and education have benefit beyond the populations in which they are demonstrated. An Innovation Lab effort should speed solutions to significant public health challenges through groundbreaking science, through effective translation of interventions to high-impact settings, and through innovative approaches to teaching and training.

GIL proposals may span the entire range of discovery to implementation, including *but not limited to* proposals that represent a) pilot investigations of promising interventions or the basic science underlying such potential interventions, b) highly innovative interventions which represent major potential leaps forward but carry non-trivial risk, c) taking well-established interventions to scale or sustaining such interventions, d) the building of important public health capacity through training and education, technology, or coalition building, and e) the development and testing of important methodological advances which in turn enable appropriate evaluation of public health interventions.

The GIL program is funded by a personal gift from Dennis Gillings and Joan Gillings. The donors are not involved in the evaluation of proposals or the administration of the program.

**Award information – competitive funding cycle 4**
*Key dates*
Updated Guidelines Posted: 23 July 2014

Deadline for non-binding Letter of Intent: September 2, at 5:00 pm ET
Deadline for proposals: 1 October 2014, at 5:00 pm ET

Earliest notification of awards: late November 2014

Earliest start date: 1 January 2015

*Funds available*

The School expects to award up to 4 projects, from a pool of $400,000 for this funding cycle. Applicants may request support for up to two years (24-months), and a total of $100,000 for the entire period.

**Eligible principal investigators/organizations**

*Principal investigators*

Round 4 of competitive Gillings Innovation Labs is open only to faculty members with a *primary* appointment in one of the degree-granting units of the School. The PI or Co-PI *must* be a member of the faculty of the UNC Gillings School of Global Public Health.

*Investigators/collaborators*
Gillings Innovation Labs should be comprised of investigators and collaborators appropriate to the proposed activity. In some instances, members of a single discipline may collaborate to develop well-defined technology; in most, the make-up of the Innovation Lab will cross disciplines, schools, and institutions, and often will benefit from partnerships with other academic and government institutions, communities, non-government organizations, and businesses. Participation of each collaborator and consortium member must be carefully described and justified in the proposal. Though not required, it is highly desirable that students be given opportunities to participate as members of Innovation Lab teams.

## Conflicts of interest

All real and apparent conflicts of interest, with any GIL participant, whether investigator or organization, *must* be disclosed and a plan for mitigation proposed. This plan must be approved by both the School and Research and Innovation Solutions (RIS) prior to the start of any award. Conflict of interest will be defined in a manner consistent with UNC-Chapel Hill policies (policy.sites.unc.edu/files/2013/04/Individual-COI-Policy.pdf). Principal investigators must disclose to RIS any significant financial interests (and those of family members) which are or might appear to be affected by the activities of the proposed GIL. RIS, in consultation with other UNC-CH offices, will review the disclosures to determine whether they could influence the design, conduct, or reporting of the project. If so, methods for eliminating or mitigating the potential conflict must be developed and approved by RIS. RIS recognizes that partnerships with both for-profit and not-for-profit organizations are crucial in developing scalable public health solutions, but it is crucial that financial considerations of individuals or organizations not influence the conduct and reporting of GIL activities. *Failure to disclose real or potential conflicts of interest may disqualify applications.*

**Applications for Gillings Innovation Labs**
Basic elements of Innovation Lab proposals are similar to those for other research or program proposals: state major aims of the proposal, demonstrate need for the work, describe specific activities required to implement the activity, demonstrate that the team has skills and experience to perform and evaluate the activity, present clear metrics for assessing the success of the project, and show that adequate measures have been taken to assure the ethical conduct of the activity. Though details will vary across proposals, successful Innovation Lab proposals often will be characterized by:

* Clear connection to demonstrable, high-impact improvements in public health or in measurable steps on the pathway to improved public health; that is, the proposal provides evidence that the activity will solve an important problem and that the solution is likely to be obtained—by the team proposed, in the time allocated, and within the budget requested;
* Use of a logic model to show how this activity could affect public health (see description of logic models and logic model resources at the bottom of these guidelines);
* Novel, innovative approaches to address important public health problems;
* Interdisciplinary, multi-institutional teams (as appropriate) to create and implement solutions;
* Technology, products, or programs that are replicable, scalable and are being developed with potential users in mind;
* Opportunity for rapid dissemination of findings, rapid improvements in public health; and,
* Clear outcome metrics to demonstrate impact.

Applications will be completed in two phases: 1) non-binding letters of intent to submit a proposal, and 2) full proposals. Submission of a proposal does not depend on having the letter of intent “approved”—there is no review of letters of intent; they are only to assist RIS staff in estimating the number of likely proposals and identifying potential reviewers.

***Non-binding Letter of Intent***
Investigators applying for Gillings Innovation Labs first will submit a one-page, non-binding letter of intent (via email attachment to accelerate@unc.edu no later than 2 September 2014 by 5PM ET) providing:

* the name of the principal investigator,
* working title of the project,
* any strategic area(s) addressed (i.e. implementation science, aging/lifecourse,big data and data visualization, health inequities and health disparities, or methods to evaluate Affordable Care Act). Projects on all public health topics are welcome, and are not limited to the School’s strategic areas
* intended list of collaborators.

Letters should also recommend a minimum of two UNC-CH content or methods experts *not in conflict* with the proposal who would be appropriate reviewers for the anticipated proposal, along with their affiliations and contact information. Department chairs are involved in the selection of proposals and are not eligible to review individual proposals. They are, however, able to provide informal feedback to PIs while the proposal is under development.

***Proposals***

The sections under *Activity of the Innovation Lab* may not exceed 5 single-spaced pages (using 11-point Arial, with one-inch margins), including text, figures and tables. Though appendices may be used to present technical or supporting material (e.g., technical descriptions of equipment or questionnaires), appendices may not be used to circumvent page limitations. The following sections are required elements in a proposal:

* Abstract and logic model (1 page maximum)
* Activity of the Innovation Lab (5 page maximum)
	+ Project Aims
	+ Connection to Public Health
	+ Project Design and Methods
	+ Assessment and Evaluation
	+ Plan for Dissemination of Findings and Sustained Effort
	+ Project Milestones and Deliverables
* Appendices
	+ Letters of support from collaborators and consultants (if applicable)
	+ Data use agreements (if applicable)
	+ Protection of Human Subjects, Care and Use of Vertebrate Animals, and Biohazards
	+ Department chair’s letter of support
	+ Qualifications of investigators and organizations
	+ Current and pending other support
	+ Budget
	+ Budget justification
	+ Subcontract details including budget & budget justification.

Abstract and Logic Model
A half page *description* of the important elements of the project, including summaries of the sections detailed in the “*Activity of the Innovation Lab”* sections, and a half page *logic model* providing an overview of the proposed project and its anticipated downstream impact on public health. See examples of logic models at the end of this document.

Activity of the Innovation Lab

*Project Aims*
Project aims should be specific, quantifiable and clearly related to achievement of a high-impact gain in public health or the development of technology or techniques that will enable important improvements in public health. Aims should not address incremental improvements in existing approaches or technology but rather should propose public health solutions that 1) make substantial progress in technology application, 2) develop novel methods for intervention delivery, 3) translate effective interventions into practice or make the interventions available to previously underserved populations, or 4) develop or disseminate novel, high impact approaches to teaching and training. While important gains (e.g., reduction in morbidity or mortality) in public health may be beyond the scope of the project, the connection of project aims to ultimate goals of improved public health must be made clear. Proposal writers should use the logic model to illustrate connections.

*Connection to Public Health*
The public health challenge underlying the proposed project should be described succinctly, including the burden of disease or disability, geographic distribution of the condition, populations susceptible to the condition, implications of the condition for societal function and quality of life, current attempts to ameliorate the condition, and barriers to successfully overcome the challenge. The proposed project should be placed in the context of current knowledge on the topic. Progress toward meeting the public health challenge that can be expected if project aims are met should be specified. If the project will yield publicly available materials or products (e.g. software, data sets, methodological tools) this should be noted.

*Project Design and Methods*
Plans, methods and procedures for carrying out the proposed activity should be described. In particular, describe the setting in which the activity will take place, populations from which participants (if there are human participants) will be drawn and plans for identifying a sufficient and representative sample, any new technology to be developed as part of the project, methods to be used to implement any interventional activity or development plan, and the methods by which important processes and outcomes will be assessed. Particular attention should be given to any methods or procedures that are novel or that constitute an important outcome of the study in their own right (e.g., a project in which development and testing of methods is central to the specific aims). If there are important technological challenges or methodological barriers, these should be discussed, along with a plan for overcoming potential barriers. If it is possible that a patent or other intellectual property will emerge from the project, please indicate.

*Assessment and Evaluation*
The assessment plan should describe crucial outcome variables, justify outcome variables as most appropriate for the proposed activity, explain relationship of outcome variables to more distal improvements in public health (e.g., how development of a novel technology will decrease morbidity or mortality), and specify means by which outcomes will be collected with maximal accuracy and minimal bias. The analysis plan should describe how project aims will be evaluated, and the *a priori* criteria for judging relative success in meeting project aims. Important process or intermediate outcome variables should also be described, including the purpose for collecting such variables, methods for measurement, means for assuring timely collection of data (particularly if they are to be used for mid-course modifications in protocol), and specific approaches to analysis. Process and outcome measures should be linked explicitly to one or more specific aims of the overall project.

*Plan for Dissemination of Findings*
Dissemination *includes* traditional dissemination of findings in academic settings, but goes well beyond that. In many cases, the most important dissemination will occur in non-academic areas. Plans for expanding reach of interventions, further development or distribution of technology, or applying novel methods developed in the initial award period must be made clear. In particular, if there are activities crucial to the broad fielding of interventions or technology, a plan for conducting those activities must be included, even if the plan does not involve the original members of the Innovation Lab. (As an example, if a community-based intervention is to be expanded to other communities, the means by which dissemination will be promoted should be detailed, even if dissemination is to be conducted by a government agency or philanthropic concern.)

*Project Milestones and Deliverables*
The project milestones should reflect the key points in time that represents an important intermediate event or decision in the life of the project. A milestone should be capable of validation (e.g., seminar completed, device field tested). The deliverables enumerated are the outputs of the project.

Additional required sections

*Letters of support*

Letters of support from proposed collaborators, particularly those outside the School, may be included.

*Data use agreements*

If the proposed project makes use of either existing data or data to be collected, which are controlled by a collaborator or other third party (e.g. medical claims data), the agreement under which access to the data is to be obtained should be included.

*Protection of Human Subjects, Care and Use of Vertebrate Animals, and Biohazards*
If a proposed Innovation Lab involves human participation, whether as part of an intervention or otherwise, adequate measures must be taken to protect personal information and assure safety. At a minimum, a human subjects plan must meet criteria for a data and safety monitoring plan set forth by the applicable UNC Institutional Review Board (IRB). Similarly, projects involving vertebrate animals must propose safeguards sufficient to meet the criteria set forth by the UNC Institutional Animal Care and Use Committee (IACUC). In either case, the proposal must make clear that involvement of humans or non-human vertebrates is crucial to the success of the study and that every reasonable effort has been made to minimize risk or injury associated with participation. If biohazards are involved in project activities, their use and handling must be justified and must be in accordance with all UNC regulations. Projects that take place outside UNC (e.g., in collaboration with county health departments, foreign health districts) must get approval not only from relevant UNC authorities but from appropriate local authorities. Any projects involving human subjects, invertebrate animals, or biohazards must get approval from relevant UNC authorities. Approval may be pending at the time of application but must be obtained prior to any funded activities. Inclusion of IRB/IACUC application details can be included in an appendix.

# Qualifications of investigators and organizations. Each individual named investigator/key person should provide an NIH-style biographical sketch or equivalent brief resume, not to exceed four pages each. Participating/partnering organizations may provide similar information regarding their skills and capabilities, not to exceed four pages.

*Current and pending other support*. Principal investigators must provide, at the time of submission, a listing of all current or pending support for research activities, whether related to the proposed project or not. Applicants should follow the NIH format for providing such information, which can be found at http://grants1.nih.gov/grants/funding/phs398/phs398.html.

*Departmental letter of support*

A one-page letter of support from the principal investigator’s department chair is required. It should be placed in the proposal immediately after the human subjects section, and before the biographical sketches.

**Budget and allowable costs**
Budgets for Innovation Lab proposals may include salary support (including fringe benefits) for investigators and study staff, costs of study-specific intervention or assessment materials (e.g., medications, blood collection materials, air sampling equipment), procurement or conduct of crucial assessments (e.g., lab assays, environmental measurements), or study-specific travel or transportation. In general, costs *directly* related to conducting the proposed work are allowed. Costs for infrastructure or other activities that are spread beyond the efforts of the Innovation Lab (e.g., buildings, general lab equipment and computers) generally are not allowed.

Though we expect some *conceptual* overlap of GIL aims with projects either underway or proposed by Principal Investigators, GIL support is intended only for the conduct of the proposed activities, and if other funding is obtained to support some or all of the activities in the proposed GIL, this must be disclosed and a plan implemented to assure that GIL support is used only for its intended purposes, and that there is no duplicate funding of effort. In the event that investigators obtain supplemental funding from other sources for a GIL project, it must be made clear how the supplemental funding enables activities that would otherwise not have been able to be conducted, or enables the achievement of new aims consistent with but extending or expanding the existing GIL aims.

Because Innovation Labs will be administered by UNC, F&A (indirect) costs are disallowed. Innovation Lab funds may not be used to support training programs or training grants, but individual students may be supported through Innovation Labs for work specific to the Lab. Budgets should be drawn up in accordance with regulations in place at the UNC-CH Office of Sponsored Research. The proposal budget must be submitted using this Excel budget template, accompanied by a detailed budget justification – see the GIL Round 4 page for templates and guidance (tinyurl.com/innovation\_labs).

The program does not require cost sharing, but if there are important resources or funding available which will complement the Innovation Lab funding, these should be identified and corresponding documentation of cost sharing should be included with the budget justification. Such funds or resources should be specific to the activities of the Innovation Lab, and not general support (e.g., buildings, lab infrastructure, salaries for administrative support) that crosses projects.

Projects may be proposed for up to two years (24-months). Budgets which exceed $100,000 total cost for the *entire* two year period will be returned without review.

**Review and selection**
All proposal materials will be submitted electronically to accelerate@unc.edu. Gillings Innovation Lab applications will be reviewed by a panel of methodology and content experts. These experts will be drawn from among UNC-Chapel Hill faculty and leaders. While a number of reviewers will represent broad methodological expertise or transdisciplinary approaches to public health challenges, others will be chosen because of their expertise in content areas and methods represented in the Innovation Lab proposals submitted in any given round. *Proposals, therefore, must be written in a manner that addresses the concerns of field-specific content experts, while making the larger potential public health impact clear to reviewers who may not share the same technical expertise as the principal investigator.*

Reviewers will be asked to comment on every aspect of the proposal but will focus on the following questions.

*Investigators/consortium*

* Is the principal investigator qualified by experience and training to lead the proposed work?
* Will appropriate collaborating investigators and organizations support the work, and is the effort proposed sufficient to carry out proposed activities?
* If multiple organizations are involved, is there a clear delineation of tasks, plan for coordination of work, and evidence of either previous/ongoing collaboration or the development of a working relationship?

*Budget*

* Are the budget and budget allocation in line with the funding guidelines, proposed project activities, and personnel effort?
* Are all budget items clearly identified, described and justified, using the required budget template, and consistent with budget guidelines?
* Is the overall budget proportionate to the funds available during the current round (i.e., does the proposed budget support RIS’s ability to fund multiple awards)?

*Innovation Lab activities*

* Are there specific, quantifiable aims related to improving public health, either directly or by addressing an important intermediate step?
* Is there a sound, evidence-based justification for addressing the proposed public health challenge, even if the study aims themselves are ambitious or highly innovative?
* If study aims are successfully achieved, will they result in direct improvement in public health, in substantial ability to achieve public health improvements through application of results, or in achievement of measurable and crucial steps on the path to public health improvement?
* *For projects specifically focused on innovative curricula and training in public health*, does the proposal represent a substantial innovation beyond current instructional methods or settings, does the content and audience for the proposed program address an important public health topic, do the methods make maximal use of modern instructional approaches including distance learning and other appropriate applications of technology, is the proposed audience appropriate, and do the aims and approach foster academic scholarship?
* If study aims are achieved, will results apply to broad population groups, particularly those at greatest risk, those who are traditionally underserved and/or those economically or otherwise disadvantaged? That is, does the work, even if conducted in a relatively restricted setting or on a small scale, have the potential (not necessarily as part of the GIL) to generalize to broader settings and larger populations, particularly those in greatest need?
* Will the project advance scientific and methodological knowledge?
* Is the study population (when applicable) appropriate for the proposed work? Is there an acceptable method to recruit and retain participants or organizations, consistent with ethical conduct of the proposed activities? If the project involves existing data sets or data controlled by third parties, are data use agreements in place?
* Are the methods likely to achieve specific aims?
* Does the study protocol describe appropriate and feasible methods for project implementation and activities and for measurement of important outcomes?
* Does the assessment and analysis plan specifically address each specific aim, with clear metrics for determining success?
* Is there a plan for dissemination -- not only of results but of products or inventions -- to broad and appropriate audiences?

*Other review considerations*
Because Gillings Innovation Labs will support a wide range of projects, from technology to development to teaching; to partnerships with local health districts; to international public-private collaborations; some additional review criteria will be considered:

* Will the project create or sustain interdisciplinary teams?
* Does the project involve both local and global facets?
* Will the project foster collaborations among schools at UNC-Chapel Hill, community organizations, governmental and non-governmental organizations, and businesses?
* Does the proposed activity involve students, particularly in leadership roles or roles that demonstrably promote their training and career development?

A group of SPH leaders, including department chairs and several other members of the Dean’s Council, will consider the results of the merit review in light of available funds and programmatic goals, and will recommend applications to the Dean for funding. Investigators will be notified of the award decisions, and all proposals will receive summarized feedback on their merit reviews.

**Reporting**

Project reporting will include a brief, impact focused progress update at the end of the 6th month. An annual report will be required at 12 months and a final project report is due at the end of the project period. Details of project reporting, publication acknowledgement, provision of deliverables, and other engagement requirements will be contained in the award documentation.

For awards of greater than one year’s duration, annual and end of project financial reporting is required. The annual financial report is due within 30 days of the anniversary date. The final financial report is due within 90 days of the project/budget end date.

**Sharing Information and Tools**
One of the goals of GILs is to accelerate the translation of scientific discoveries into practice. To facilitate this process, we encourage the use of open source technologies that permit broadest access to research methods, results and outcomes across geographic, disciplinary and other boundaries. We also encourage investigators to share tools and findings through Web-based and other methods.

## Resources for Applicants

## *Use of logic models in proposals*

## Among their many uses, logic models can be used to help describe the ultimate impact of a program or intervention, even if the activities or aims of a specific proposal are not sufficient to achieve those final goals. A logic model allows an investigator to estimate the *eventual* impact of the proposed project on public health, while specifying the intermediate steps along that path to impact which will be specifically addressed by the proposed project (see figure below). It is likely that many successful GILs will address what are described below as initial or intermediate outcomes. Nevertheless, the potential for impact on longer-term goals *must* be made explicit, along with the connection of the proposed GIL activities to achieving those goals.

## An example of a logic model for reducing environmental tobacco smoke (ETS) (below) specifies long-term goals of reduced exposure to ETS, reductions in morbidity and mortality, and reductions in disparities. However, a GIL proposal to reduce ETS using high-impact or novel behavior change methods or implementing policy changes, could focus on initial or intermediate endpoints, while estimating their ultimate impact on the long-term goals.

## http://www.sph.unc.edu/images/stories/centers_institutes/accelerate/images/logic_model3.gifFigure. Logic model. ( Source: CDC)

## The following two links provide excellent resources available for the development of logic models

## <http://www.yourunitedway.org/outcome-measurements>

## <http://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide>