## Supplemental Instructions for Preparation of the Transdisciplinary Tobacco Use Research Centers Grant Application

- 5 These supplemental instructions for preparation of the TTURC application cover aspects of grant preparation that 6 are not addressed by, or that supplant the PHS 398 instructions. Continue to check
- http://tobaccocontrol.cancer.gov/tturc/ for additions or corrections, updates, and Frequently Asked Questions.
- 8
  <u>http://tobaccocontrol.cancer.gov/tturc/</u> for additions or corrections, updates, and Frequently Asked Questions.
- 9 Face Page
- 10 Use the Face Page of the PHS 398 form for the TTURC application as a whole. This is Page 1 of the application. On
- 11 line 2, check "YES", and type Transdisciplinary Tobacco Use Research Centers RFA #CA-04-012. Where human
- and animal subjects approvals are requested, type "see page \_\_\_\_\_ for summary". These instructions are provided
   below.
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## 15 Description, Performance Sites and Personnel Page

- 16 Write a Description that provides the theme and aims of the project as a whole, enumerates and briefly describes the
- 17 individual components, and outlines the interdisciplinary strategy for the TTURC. Performance Sites and Personnel
- 18 (all Sites and all Key Personnel in the TTURC) are to be entered as described in the PHS 398 instructions. Use
- 19 extension pages as necessary.20
- 21 <u>Table of Contents & Title Pages</u>
- 22 Use Attachment 1 for the Table of Contents format for the entire TTURC, which shows the order of all forms and
- 23 subsections. Number pages sequentially through the entire application. Use **Attachment 2** as the Table of Contents
- for individual Research Project Plans, Cores, and Pilot Projects. Attachment 3 provides the Title page format for
- 25 individual Research Project Plans, Cores, and Pilot Projects.
- 26
- 27 <u>Human Subjects protocol summary</u>
- Refer to PHS 398. IRBs are a "Just in Time" item and need not be included in the application. If the application is successful, the applicant will be asked to provide all of the "Just in Time" items during the award process.
- 30
- 31 Animal Subjects protocol summary
- Refer to PHS 398. Provide a list summarizing the IACUC status of all research project plans, cores and pilot projects. You will also need to include IACUC approval at the time of submission of the application or within 60 days.
- 34 35
- 36 Detailed Summary Budget for Initial Budget Period (DD)
- 37 Include this page in the front section of the TTURC application. This page is a summation of all project costs in the
- 38 first year of funding. The TTURC P.I. should show his or her percent effort and salary information where
- 39 appropriate in the individual research project plans, cores, and pilot projects. Total effort should be listed on this
- 40 form as well.41
- 42 <u>Summary Budget for Entire Proposed Project Period (EE)</u>
- 43 Provide aggregate figures that encompass all Research Project Plans, Cores, and Pilot Projects across all project
- 44 years. Also, provide budget Justification information here if it relates to the TTURC as a whole. This form should
- 45 also be used in the Individual Research Project Plans, Cores and Pilot Projects.
- 46
- 47 <u>Consolidated Direct Costs for First Year of Requested Support</u> Use Attachment 4 for the overall TTURC budget,
- 48 across all Research Project Plans, Cores and Pilot Projects. Note that standard 398 budget pages and justifications
   49 of budget items and personnel should be embedded within the individual sections, as outlined in the PHS 398
- 50 application packet.
- 51 <u>Percent Distribution of Professional effort on this application</u> Use Attachment 5.
- 52 <u>Percent Distribution of Core Resources</u> Use Attachment 6.
- 53 <u>Gender and Minority Inclusion</u> Use targeted plan enrollment table from PHS 398 form.
- 54
- 55 <u>Biographical Sketch</u> as described in the PHS 398. Include only the Principal Investigator's Biosketch here; do not
- 56 exceed two pages. Other Biographical Sketches (each not to exceed two pages) for all other P.I.s and key personnel

57 should be embedded later in the application as part of the individual projects, Cores, and pilot projects, as described 58 below. 59 60 Other Support 61 Information on Other Support is "Just in Time" and need NOT be submitted with the application. This information is required, however, for all applications that are to receive grant awards. NIH will request complete and up to date 62 "Other Support" information from applicants at an appropriate time after peer review. The Institute's scientific 63 64 program and grants management staff will review this information prior to award. 65 66 Resources 67 This page relates to the TTURC as a whole, including off-site collaborative facilities. Use extension pages if 68 necessary. 69 70 Introduction and overview of the entire TTURC application. 71 This section should not exceed five pages, exclusive of literature references. 72 Sub-sections of the overview should include: 73  $\geq$ Specific Aims of the TTURC, including a brief description of each Center component (including 74 Core(s)). Include here a brief overview of the transdisciplinary strategy with regard to interactions and collaborations 75 76  $\triangleright$ Setting and Facilities, including a statement of institutional commitment (this does not supplant 77 the Resources form). Describe here how the institution will make the TTURC an area of high 78 priority. If the TTURC is being submitted from an institution already designated as an NCI 79 clinical or comprehensive center, clearly delineate the relationship of the TTURC (P50) to the 80 cancer center (P30).  $\geq$ Proposed animal models and species, and/or proposed use of human volunteers (e.g., patient 81 82 populations, epidemiological samples) TTURC organization and administration, including a brief description of the Principal Investigator 83 84 and other Scientific Leadership. 85  $\geq$ Renewal applications should provide a succinct overview of the center's accomplishments. For 86 individual (continuing) projects, this may be expanded in the "research project" section, below. 87 New directions and/or departures from original aims or objectives should be clearly presented and 88 justified. 89 90 Applications are strongly discouraged from naming individual members of "advisory committees" or "scientific 91 boards" until the time the application has been funded. 92 93 Detailed Description of the Transdisciplinary Collaboration. Explain how the all projects fit together across 94 disciplines to promote synergy and syntheses. This section also should identify creative strategies to foster intra-95 and inter-center collaborations of a formal and informal nature to identify and address overarching scientific and 96 methodological issues. The NIH is especially interested in opportunities to engage arts and sciences university 97 faculties and schools of public health in collaboration with medical schools, drug abuse research centers or cancer 98 center faculty. Budget pages and other 398 forms should be included in this section if relevant. Five page limit, 99 exclusive of forms and literature references. 100 101 Individual Research Projects and Cores 102 There is required at minimum three research projects concurrently active in any given year of the TTURC. It is not necessary, however, for all projects in the TTURC to span the 5-year period. An application can, for example, 103 104 propose an initial project to begin and end in 2 years followed by a different 3-year project, while two other projects 105 concurrently span the entire 5-year period. Across all projects, different aspects of tobacco use should be addressed; 106 ideally, these should include research, from basic to applied, oriented toward critically needed areas, and should 107 stimulate and sustain novel collaborations and test novel ideas. Although a detailed description of the 108 transdisciplinary collaboration (above) will describe the overall collaboration across all of the TTURC's projects and cores, it would be helpful within each Project Plan, Core and Pilot Project to describe its integration with the 109 whole TTURC. For renewal of ongoing projects, delineate the scientific progress over the past term of the grant, 110 111 and, if applicable, why the project has not completed its proposed objectives in the five-year period. 112

113 Each Research Project Plan of the TTURC should be written as a separate and contained PHS 398 application. Do

114 not, however, use the face page of the 398 package for the title page of the individual Research Project Plans or 115

- Cores. Use the table of contents and title page formats provided in Attachments 2 and 3. Otherwise, use all of the
- 116 required 398 budget and other forms and sections for each individual research project plan. Each Research Project
- Plan is limited to **25 pages.** The page limit refers to the Specific Aims, Background and Significance, Preliminary 117 Studies, and Research Design and Methods sections. Refer to the PHS 398 instructions for guidance regarding 118
- 119 inclusion of children in research protocols.
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121 Similarly, each Core of shared administrative, clinical, statistical, training or other resources and activities (e.g.,

122 Administrative Core, Scientific Core, Clinical Core) should be written as a separate 398 application, using the title 123 page format provided in Attachment 3, followed by the 398 forms and sections as appropriate. The Core sections

124 need not conform exactly to the layout of the Research Project Plans (for example, a research design and methods

125 section may be inappropriate for a Core description). Try to follow the table of contents outline, but if a section

126 category is not applicable, type a dash "-" in the page number column in the table of contents page. Each Core

127 description is limited to 10 pages, exclusive of forms and literature references.

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129 As described in the RFA, a Career Development Plan must be included that will target either new investigators or

- 130 established investigators who wish to expand their research skills. Recruitment must include qualified women and
- 131 minorities. To this end, propose a clear policy and plan for recruitment of career development candidates. State the
- 132 number of career development candidates proposed, the criteria for eligibility and for selection of candidates, and
- 133 describe the selection process. Also indicate potential mentors who are already in place at the proposed TTURC,
- briefly describe their research programs, and describe complementary activities that contribute to the 134 135 transdisciplinary environment for career development (e.g., existing training grants, other career development
- 136 mechanisms and relevant programs). Competing renewal applications should present data that demonstrate how the

TTURC contributed to participant career enhancement in tobacco use research. Do not exceed 10 pages. 137

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- 139 Pilot Research Proposals:
- 140 A TTURC should use pilot funds to stimulate projects that take maximum advantage of new research opportunities
- 141 by carrying out developmental research that will facilitate new collaborations and the opportunity to pursue
- 142 challenging ideas. Such projects may be collaborative among scientists within one or more TTURCs, or with
- 143 scientists outside the TTURC environment. There is no limit to the number of pilot projects that can be proposed,
- 144 nor is there a budgetary cap for each or all of the pilots, apart from the budgetary cap for the entire TTURC. The
- 145 TTURC application should propose an institutional review process (do not exceed two pages) for future pilot 146 projects (i.e., those that are not included in the initial TTURC review) which represent the most innovative and
- 147 transdisciplinary ideas, and which are likely to have the greatest impact on reducing the burden of tobacco use and

its consequences. Future Pilot projects should be able to be submitted by investigators both inside and outside of the 148

- 149 TTURC team. The application may also include examples of up to two pilot projects. Each example should not
- 150 exceed 2 pages. Renewal applications may provide an overview of the completed projects, outcomes and
- 151 accomplishments.
- 152
- 153 Checklist – Use one for the entire TTURC application. This is the last page of the application.
- 154
- 155 Appendix 156

157 Do not include appendix material with the TTURC application; they will not be accepted. Following submission of

158 the proposal, the Scientific Review Administrator may allow a P.I. to send original glossy photographs or other

159 color images. If such permission is granted (and only if) by the SRA, these photos are to be sent directly to the 160 SRA.

- 161
- Attachments 162
- 163 Attachment 1: Table of Contents for TTURC application as a whole
- 164 Attachment 2: Table of Contents for individual Research Project Plans, Cores, and Pilot Projects.
- 165 Attachment 3: Title page format for individual Research Project Plans, Cores, and Pilot Projects.
- 166 Attachments 4 - 6: Formats for consolidating budget and demographic information across TTURC components
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