Conditions Affecting Neurocognitive Development and Learning in Early Childhood: CANDLE Collaboration Guidelines

(Version 2.0, Revised 8/3/2012)

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A) Goals

1) To encourage high quality publications and presentations produced in a timely fashion.
2) To encourage broad participation by CANDLE investigators in publications and presentations.
3) To provide a consistent process for requesting data and biological specimens.

B) Scope of the Guidelines

1) These guidelines apply to investigators affiliated with CANDLE and to those without an affiliation with CANDLE who are proposing any form of analysis, publication, or report that describes CANDLE methodology or utilizes core or ancillary study data collected in the course of the study.
2) These guidelines apply to papers (including methodology and validation papers), abstracts/extended abstracts, oral and poster presentations, letters to the editor, and meeting proceedings that use data collected as part of the core CANDLE study or ancillary study data.

C) CANDLE Collaboration

1) The CANDLE Emerging Science Coordinator will review requests for use of data for all collaboration with CANDLE, including abstracts, presentations, manuscripts and preliminary data for grant applications. The purpose of this review is to:
    A) Make sure the request does not overlap with already approved plans.
    B) To ensure the organization and oversight of all CANDLE collaboration and data use.

D) Publication Committee

Three members of the CANDLE Publication Committee, assigned by the Principal Investigator, will review and make recommendations concerning approval for all collaboration applications. In the event that the analysis proposal covers subject areas outside scientific expertise of the Publication Committee members, an external reviewer will be secured. All members of the Publication Committee will be given the opportunity to be added as a co-author to the project under review.

E) Types of Publications

1) These guidelines broadly cover any form of analysis, publication, or report that describes CANDLE methodology or utilizes core or ancillary study data.
2) The guidelines encompass four different types of publications:
    A) Manuscripts relating outcomes associated with the CANDLE Study data.
    B) Methodology/validation papers.
    C) Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster) submitted to meetings.
    D) Letters to the editor reporting CANDLE data.

F) Analysis Plans

1) Submitting an Analysis Plan
    A) All investigators planning projects or publications utilizing CANDLE core or ancillary study data must submit an Analysis Plan form and accompanying document.
    B) Analysis Plan forms and accompanying documents should be submitted to the CANDLE Emerging Science Coordinator. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
    C) The Analysis Plan must include:
        i. The name of the first author. If the first author is not a CANDLE investigator, then the sponsoring CANDLE investigator (or designee) must also be listed.
        ii. A provisional list of potential co-authors
        iii. Statement of the research question(s) or hypothesis
        iv. Brief background and rationale for addressing the research question or hypothesis in CANDLE
        v. Variables to be used in the analysis (the control, main predictor, and outcome variables should be identified) using variables listed in the CANDLE Data Dictionary (for more information, please contact the Emerging Science Coordinator)
        vi. A mock-up of key tables
        vii. A timeline for completion and submission of the project
        viii. Deadlines for submission of abstracts or dates of presentation and meeting (if applicable)
        ix. The CANDLE biostatistician that will be responsible for directing the analysis of the data (Note: If you have not identified a CANDLE biostatistician, one will be assigned to you upon approval of your Analysis Plan.)
    D) Analysis Plans must be submitted to the Emerging Science Coordinator a minimum of 6 weeks prior to proposed submission deadline to allow time for review and possible revision of the plan and/or abstract. There will be no expedited reviews of Analysis Plans.
2) Review of Analysis Plans
    A) Once an Analysis Plan is received by the Emerging Science Coordinator, the Analysis Plan will be initially reviewed by the Emerging Science Coordinator to check for potential overlap with other plans, a complete/accurate variable list, and overall feasibility. Initial preliminary revisions

may be requested by the Emerging Science Coordinator prior to dissemination to the Publication Committee.

B) If there is no overlap and the analysis packet is complete, then the plan will be transmitted electronically to the Publication Committee for their review and approval. Any member of the Publication Committee can designate a representative who can submit comments and a recommendation to accept or revise the Analysis Plan. All other members of the CANDLE Publication Committee may submit comments on the proposal.

C) Reviewers and the Publication Committee will have 10 working days (2 weeks) to review the submitted Analysis Plan and forward comments to the Emerging Science Coordinator. There will be no expedited reviews of Analysis Plans.

D) After review by the Publication Committee, the Emerging Science Coordinator will send a letter to the first author indicating:

i. The Analysis Plan has been approved.

ii. The Analysis Plan has been approved, pending suggested changes by the Publication Committee.

iii. The Analysis Plan has not been approved; the author must revise and resubmit. If an assigned reviewer or member of the Publication Committee does not approve the plan, the first author must consider revisions and then resubmit the Analysis Plan.

3) Obtaining data

A) Upon approval of an Analysis Plan, the first author will be directed to contact the CANDLE biostatistician/ data analyst to discuss the data set to be analyzed. All data analysis will be done by a CANDLE biostatistician/ data analyst.

B) No raw data sets will be provided to an investigator. Only in the following scenarios will data be provided for analysis by an investigator:

i. If the project requires special software that CANDLE does not possess, the first author may be granted permission to do analysis on their own. Circumstances such as this will be reviewed by the CANDLE Principal Investigator on a case-by-case basis. If access to data is granted, the investigator is responsible for conducting an Exit Consultation with the CANDLE Emerging Science Coordinator upon completion of the project. (See Section S)

ii. Students, under the direction of a CANDLE biostatistician, may be granted access to do analysis on their own. (See Section N)

4) Expiration of Analysis Plans

A) Analysis Plans remain current for 9 months from the date of approval. If the Emerging Science Coordinator has not received an abstract or manuscript draft within 9 months, the Analysis Plan will be pronounced expired. At this time, the project may be reassigned to a new investigator or claimed by another investigator. If no new investigator has shown interest in the area of focus, the initial investigator must submit an Analysis Plan Amendment in order to proceed with the project (See Section M).

B) Analysis Plans may also expire and authorship potentially reassigned if a manuscript has not been submitted for publication within 18 months from the date of approval. If no new investigator has shown interest in the area of focus, the initial investigator must submit an Analysis Plan Amendment in order to proceed with the project (See Section M).

5) Once an Analysis Plan is approved, the first author may be subject to signing a confidentiality agreement. Contact the Emerging Science Coordinator for more details.

6) Miscellaneous

A) In general, each Analysis Plan should be designed to result in at least one manuscript. If more than one manuscript will result from the Analysis Plan, the research question(s) or hypothesis of each manuscript must be described. The Publication Committee may determine that an Analysis Plan is too broad and request that the scope be narrowed.

B) If the objectives of an Analysis Plan devolve and deviate substantially from the original plan, the first author is responsible for submitting an Analysis Plan Amendment. (See Section M)
C) The Emerging Science Coordinator and Publication Committee will depend on the first author to provide updates regarding members of the writing group.
D) The Emerging Science Coordinator will depend on the first author to provide updates regarding the status and progression of the project.
E) Any investigator wishing to join the writing group must contact the first author.
F) Because of our common interest in the quality of articles involving CANDLE, the need to avoid duplicate publication of data, all Analysis Plans will be reviewed for conflict with previous publications/Analysis Plans or with UT faculty by the members of the Publication Committee. If there are conflicts that cannot be resolved, the PI will arbitrate among working groups.
G) The primary investigator is responsible for checking with their IRB on the need for the proposal to be approved by their home institution. If the home institution will accept UTHSC's IRB decision, please contact the Emerging Science Coordinator for necessary documentation.

G) Analysis Plan ID Number Assignment

1) Upon submission, each Analysis Plan will be given an AP ID#.
2) The first author will be informed of this ID# via the Emerging Science Coordinator. The first author is to use this AP ID# as the main frame of reference for all discussion related to the associated Analysis Plan.
3) If at any time the first author forgets their assigned AP ID#, they can request the information from the Emerging Science Coordinator.

H) Specimen Requests

1) Biological specimens from the CANDLE study are stored in the Tissue Core Services, 956 Court, Ave Memphis, TN 38163. These specimens and/or accompanying data are de-identified and made available to investigators upon special written request following the procedures outlined below. All requests for biological specimens require approval of a UTHSC IRB application prior to distribution of specimens.
2) Analysis Plans that require the use of specimens must submit a supplementary Specimen Request form. This form must be sent to the Emerging Science Coordinator at the time of the Analysis Plan submission.
3) Upon completing the Specimen Request form, please include the following information:
    A) Sample subset: criteria which participants must meet to be included in the sample requested (e.g., male vs. female)
    B) Desired number of specimens (sample size): the number of samples the investigator hopes to run. NOTE: sample size depends on availability of samples based on requested subset criteria.
4) The use of specimens will be approved by the assigned Publication Committee at the same time as the concurrent Analysis Plan.
5) The UTHSC Department of Preventive Medicine will charge an administrative fee to requestors for specimens (cost of processing specimens + shipping fees).
6) Please allow adequate time from date of Analysis Plan approval to have the specimens processed for investigator use. Please note that specimen processing time is subject to change based on:
    A) The size of the request.
    B) The processing involved with request.
7) If more samples are needed, a new Specimen Request form must be submitted to address the additional samples. Additional Specimen Request forms will be reviewed for potential overlap or deviating substantially from the original Analysis Plan by the Emerging Science Coordinator. If the addition of these new samples causes the approved Analysis Plan to evolve and deviate from the original plan, the investigator must follow the guidelines proposed for an Analysis Plan Amendment.
8) Investigators or institutions that request these isolates to use for human subjects research will need to seek local IRB approval as appropriate.

9) Any samples left over after analysis must be returned to the CANDLE Tissue Core Services or destroyed upon approval of the CANDLE Principal Investigator.

I) Review and Approval of Abstracts and Presentations

1) Abstracts may only be produced from an approved Analysis Plan and present analysis that has been reviewed by a CANDLE biostatistician. (NOTE: Analysis plans must be submitted to the Emerging Science Coordinator a minimum of 6 weeks prior to an abstract deadline to allow time for review and possible revision of the plan. There will be no expedited reviews of Analysis Plans.)
2) Prior to submitting the abstract to a meeting, the first author is responsible for completing an Abstract/Presentation Approval form.
    A) Abstracts must be reviewed and approved by all co-authors prior to submission.
    B) The first author must complete the Abstract/Presentation Approval form, confirming that all co-authors have had an opportunity to review the abstract, offer feedback, and approve its submission.
    H) A copy of the final abstract, along with the completed Abstract/Presentation Approval form must be sent to the Emerging Science Coordinator before the abstract is submitted to the meeting. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
    C) The first author is responsible for informing the Emerging Science Coordinator of the status of the submission in a timely fashion.
3) If the abstract is accepted, the first author is responsible for completing a 2nd Abstract/Presentation Approval form prior to presentation.
    A) Poster/Presentation must be reviewed and approved by all co-authors prior to display.
    B) The first author must complete the Abstract/Presentation Approval form, confirming that all co-authors have had an opportunity to review the final poster/presentation, offer feedback, and approve its display.
    C) A copy of the final poster/presentation, along with the completed Abstract/Presentation Approval form must be sent to the Emerging Science Coordinator prior to display. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).

J) Manuscript Approval

1) Manuscripts may only be produced from an approved Analysis Plan and present analysis that has been reviewed by a CANDLE biostatistician..
2) Prior to submission, the first author is responsible for completing a Manuscript Approval Form, confirming that all co-authors have had an opportunity to review the manuscript, offer feedback, and approve its submission.
3) All manuscripts must be reviewed by an outside reviewer prior to submission for publication. The Emerging Science Coordinator will transmit the manuscript draft to a reviewer, who will then offer feedback to the first author.
4) The first author must submit the completed Manuscript Approval form along with a copy of the final manuscript to the Emerging Science Coordinator prior to submission to the journal. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
5) The first author is responsible for notifying the Emerging Science Coordinator of the status of the manuscript, and if/when the manuscript is accepted for publication. The first author must include a PDF (or paper copy) of the final published article.

K) Archives

The Emerging Science Coordinator will maintain an electronic archive of all CANDLE publications, posters, presentations, etc. Electronic copies of the final version of all manuscripts will be available via the CANDLE

website (See Section R). Electronic copies of abstracts and presentations are available upon request, and only with approval of the first author.

L) Additional Data Request

1) If, after an Analysis Plan has been approved, the investigator wishes to update their existing data set, an Additional Data Request form must be completed. Additional data sets can fall into one of three categories:
    A) Refresh existing data set with no additions.
    B) Refresh existing data set, and request additional variables to be added to the data set.
    C) Request additional variables to merge with the current data set.
2) Additional Data Requests must be submitted to the Emerging Science Coordinator a minimum of 2 weeks prior to desired date of obtaining the data. There will be no expedited Additional Data Requests. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
3) Once the request is received by the Emerging Science Coordinator, it will be reviewed by the Emerging Science Coordinator to check for:
    A) Potential overlap with other plans
    B) A deviation from the primary Analysis Plan that is substantial enough to require a separate analysis plan to be submitted.
4) If there is no overlap and the amendment is within the acceptable parameters of the primary Analysis Plan, the Additional Data Request will be approved and fulfilled via the CANDLE data analyst and assigned biostatistician.
5) If, with the addition of the new variables, the objectives of the previously approved Analysis Plan evolve and deviate substantially from the original plan, the first author is responsible for submitting an Analysis Plan Amendment (See Section M) or new Analysis Plan (See Section F).

M) Analysis Plan Amendments

1) If the objectives of the previously approved Analysis Plan evolve and deviate from the original plan, the first author is responsible for submitting an Analysis Plan Amendment.
2) In the amendment, the author is responsible for updating their previously approved Analysis Plan to include all new information (background, rationale, hypothesis, variables, mock tables). Also, an Analysis Plan Amendment form must be completed. This form may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
3) Once the amendment is received by the Emerging Science Coordinator, it will be reviewed by the Emerging Science Coordinator to check for:
    A) Potential overlap with other plans.
    B) A deviation from the primary Analysis Plan that is substantial enough to require a separate Analysis Plan to be submitted.
4) If there is no overlap and the amendment is within the acceptable parameters of the primary Analysis Plan, the amendment will be transmitted electronically to the Publication Committee for their review and approval. Any member of the Publication Committee can designate a representative who can submit comments and a recommendation to accept or revise the Analysis Plan. All other members of the CANDLE Publication Committee may submit comments on the proposal. Reviewers and the Publication Committee will have 5 working days to review the amendment and forward comments to the Emerging Science Coordinator. There will be no expedited reviews of amendments.
5) After review by the Publication Committee, the Emerging Science Coordinator will send a letter to the first author indicating:
    A) The amendment has been approved.
    B) The amendment has been approved, pending suggested changes by the Publication Committee.

C) The amendment has not been approved; the author must revise and resubmit. If an assigned reviewer or member of the Publication Committee does not approve the amendment, the first author must consider revisions and then resubmit the amendment.
D) The amendment deviate too far from the primary Analysis Plan, and a new Analysis Plan must be submitted.

6) If new data will be needed, an Additional Data Request form must be submitted simultaneously. (See Section L)
7) If new specimens will be needed, a Specimen Request form must be submitted simultaneously. (See Section H)

N) Student Request for Data Analysis

1) All Analysis Plans submitted to the CANDLE Study will have data analysis done by an assigned CANDLE Biostatistician. However, in the instance that a student desires access to a raw data set to analyze themselves, the student may submit a Student Request for Data Analysis form.
2) The student must first submit an Analysis Plan for approval (See Section F). This form and accompanying document may be submitted via email, fax, or electronically through the CANDLE website (See Section R).
3) Upon approval of the Analysis Plan, the student may then submit the Student Request for Data Analysis form. This form and accompanying documents may be submitted via email, fax, or electronically through the CANDLE website (See Section R).The application must include the following:
    A) Personal Statement
        i. Explain capability and proficiency in area
        ii. Previous experience with data analysis
        iii. What programs the student has used in the past
        iv. What type of projects the student has worked on
        v. What type of analysis the student plans on using
        vi. What the student hopes to gain from the process (how is this a learning experience for the student)
        vii. How will this contribute to the student's education and career path
    B) Letter of support from a supporting faculty member involved in student's project
        i. Explain the student's role in the project
        ii. The faculty member's role in the project
        iii. Why the faculty member feels it is important for the student to do the analysis
    C) Letter of approval from a CANDLE biostatistician, offering support and guidance throughout the analysis process. (Note: For assistance in contacting a CANDLE biostatistician, contact the Emerging Science Coordinator.)
4) The student is responsible for sending all documents to the Emerging Science Coordinator. Decisions regarding the data set will be made by the CANDLE PI.
5) After review by the CANDLE PI, the Emerging Science Coordinator will send a letter to the first author indicating:
    A) The request has been approved.
    B) The request has been approved, pending suggested changes by the CANDLE PI.
    C) The request has not been approved; the author must revise and resubmit.
6) Data will be provided to the student and CANDLE biostatistician. All analysis must be done under the guidance of the CANDLE biostatistician.
7) Upon completion of the project, the student is responsible for conducting an Exit Consultation with the CANDLE Emerging Science Coordinator. (See Section S)

O) Money for Travel

If an investigator wishes to use CANDLE funds to pay for travel costs to scientific meetings and/or conferences to present CANDLE data, the investigator must be in the process of completing a manuscript for publication with the related data. The manuscript must be complete and ready for submission to the intended journal. All co-authors must have provided their approval on the manuscript.

P) Electronic Signature

1) All forms involved in the collaboration process require a signature from the author. As forms may be submitted electronically, an electronic signature (typed) is used. By agreeing electronically, the investigator acknowledges that they have both read and understand all information presented as part of the collaboration process, all information submitted is truthful and original, and they are responsible for all information submitted.
2) If the investigator has access to programs able to include a digital signature (i.e. Adobe), it is advised that they use this method of electronic signature as well.

Q) Authorship Guidelines for CANDLE Abstracts and Manuscripts

1) General Principles
    a. A co-author should contribute to (1) conception and design, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) approve the final version of the manuscript or abstract.
    b. On abstracts or publications, each putative co-author must be given the time and opportunity to contribute substantially to the elements listed above. If more than one author is proposed by a CANDLE investigator or more than one CANDLE co-investigator author is proposed by the CANDLE Publication Committee, each coauthor and/or co-investigator coauthor must meet the ICMJE authorship criteria. If necessary, the Principal Investigator (PI) will be the arbiter of the final authors list for a manuscript. Acknowledgements on manuscript may include more than one person associated with the CANDLE Study. It is recommended that the following individuals who helped with the start-up and ongoing conduct of CANDLE be acknowledged in all publications if they do not meet the criteria for authorship.

Department of Preventive Medicine, University of Tennessee Health Science Center (UTHSC):
Frances A Tylavsky, Dr.P.H.
Marion Hare, M.D.
Pamela Connor, Ph.D,

Boiling Center for Developmental Disabilities, UTHSC:
Fred B. Palmer, M.D[1]., Laura D. Murphy, Ed.D. [2], J. Carolyn Graff, Ph.D. [3]
Cognitive Examiners: C. Butzon, C. Warner-Metzger, B. Keisling
([1]Department of Pediatrics, [2] Department of Psychiatry, [3] College of Nursing)

Tissue Core Services, UTHSC:
Anand Kulkarni, M.D.

School of Urban Affairs and Public Policy, University of Memphis:
Phyllis Betts, Ph.D.

CANDLE Staff:
Maureen Sorrells, M.P.H., Study Coordinator
Amy Mary Scheck, M.A., Emerging Science Coordinator

   c. Authorship priority will be given to participating CANDLE Investigators for the first year after the data is locked and preliminary analysis is complete. Non-CANDLE investigators will have the opportunity to propose their projects and publish on those that are approved.

2) Levels of authorship
   a. Reporting on fundamental objectives of CANDLE: participating investigators will be given the opportunity to participate as a co-author.
   b. Using essential CANDLE data for secondary analyses: The "CANDLE Team" will be listed as co-author, with members listed at the end of the article.
   c. Using CANDLE data or specimens for analyses, the primary purposes of which are not fundamental to the CANDLE mission: CANDLE should be acknowledged as the source of the data or specimens. Such analyses may include cost-effectiveness analyses, development of new laboratory tests, etc.
   d. The CANDLE PI will be the final arbiter of the category into which a given analysis falls.
3) Abstracts: In general, the same principles for authorship on journal articles apply to abstracts submitted for presentation at meetings. However, given the preliminary nature of data contained in abstracts and the seemingly inevitable rush to meet deadlines, some flexibility is appropriate. In particular, lead authors may need to limit the abstract author list because of space restrictions. Submission of an abstract should be considered a "sentinel event" that a manuscript on the topic will be prepared, and those interested in co-authoring the manuscript should communicate with the principal author of the manuscript. Co-authors for an abstract should generally be co-authors of any corresponding manuscript; it is understood, however, that, because of personnel turnover and other reasons, this may not always be possible.
4) Laboratory analyses: When laboratorians at UTHSC or elsewhere undertake analyses using CANDLE data, CANDLE should be acknowledged as the source of the specimens. The CANDLE PI and Emerging Science Coordinator should also be made aware of these manuscripts prior to publication and non-laboratory authors included if so warranted. Studies using CANDLE specimens should use the methodology publications as the citation source.
5) Authorship criteria: Criteria for authorship on a CANDLE article should follow the uniform requirements published by the International Committee of Medical Journal Editors (ICMJE) (see www.icmje.org).

The following is taken from ICMJE, Uniform Requirements for Manuscripts Submitted to Biomedical Journals. N Engl J Med 1997;336:309-315.

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

Editors may ask authors to describe what each contributed; this information may be published.

Increasingly, multicenter trials are attributed to a corporate author. All members of the group, who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the Acknowledgments section in an appendix.

6) Grantsmanship Criteria: Criteria for authorship on any grant applications from CANDLE data will follow the Authorship Guidelines for CANDLE Abstracts and Manuscripts as listed above.

R) CANDLE Website

1) All researchers (anyone interested in learning more about CANDLE) will have the ability to:
    a. Review a list of all measures used by CANDLE
    b. Submit Analysis Plans electronically
    c. View a list of all CANDLE manuscripts
2) Approved collaborators (those with an approved Analysis Plan) may create a CANDLE Web Account by going to "Create Account" on the CANDLE Research Website (http://candlestudy.com/user/register) and creating a username and password. All CANDLE Web Accounts will be monitored by the Emerging Science Coordinator; for questions regarding your account, please contact the Emerging Science Coordinator. Once you have created your account, you may log in on the CANDLE Research Website "Log In" page (http://candlestudy.com/user). Approved collaborators will have the ability to:
    a. Review a list of all measures used by CANDLE
    b. Submit Analysis Plans electronically
    c. View a list of all CANDLE manuscripts
    d. Submit Abstract/Presentation Approvals electronically
    e. Submit Additional Data Requests electronically
    f. Submit Analysis Plan Amendments electronically
    g. Submit Manuscript Approvals electronically
    h. Submit Student Requests For Data Analysis electronically
3) Any misuse of the CANDLE Research Website will result in termination of your user account.

S) Exit Consultation

Upon expiration or completion of an approved Analysis Plan, any investigator that has had access to CANDLE data must complete the CANDLE Exit Consultation Form. This form cannot be submitted electronically; a hard copy of the signed document must be submitted to the Emerging Science Coordinator.

T) Pilot Studies

1) Any investigator wishing to add new measures to the CANDLE battery for the purpose of a pilot study must first submit an Analysis Plan for approval (See Section F). Emphasis on the timeline and resulting action (manuscript, grant submission, etc.) should be provided in the Analysis Plan submission.
2) The following items must be discussed in depth and finalized with the CANDLE Principal Investigator prior to submission:
    a. Data: collection, entry, database
    b. Forms: creation, format
    c. Funding: Based on the magnitude of the pilot study, the investigator may be required to supply additional funding to support the implementation of their pilot study (creation of forms, effort put forth by Research Assistants, etc.).
    d. An IRB must be submitted to The University of Tennessee Health Science Center to cover the addition of data.

U) Ancillary Studies

1) An ancillary study is a study that requires access to CANDLE participants, whether based on specific

recruitment criteria or the cohort as a whole, to collect measurements or data directly from CANDLE participants using procedures or instruments that are not included in the already funded core protocol.

2) Any investigator wishing to recruit currently enrolled CANDLE participants for the purpose of an ancillary study must first submit an Analysis Plan for approval (See Section F). Emphasis on the timeline and resulting action (manuscript, grant submission, etc.) should be provided in the Analysis Plan submission.
3) The following items must be discussed in depth and finalized with the CANDLE Principal Investigator prior to submission:
    a. Data: collection, entry, database
    b. Forms: creation, format
    c. Funding: The principal investigator of the ancillary study is responsible for funding the study.
    d. An IRB must be submitted to The University of Tennessee Health Science Center.

V) Grant Submissions

1) Grant submissions fall into one of three categories:
    a. Use CANDLE information for preliminary data, and will contribute money directly to CANDLE for the continuation of the CANDLE Study as a whole.
        i. Need Analysis Plan to obtain preliminary data (See Section F). All data analysis will be done by a CANDLE biostatistician.
    b. Use CANDLE information for preliminary data to fund an ancillary study. This grant will contribute money to the collection of new information in a separate area of study not related to the currently funded CANDLE protocol.
        i. Follow guidelines outlined for Ancillary Study (See Section U).
    c. Use CANDLE information for preliminary data, but will not produce any new data for CANDLE and will not contribute any money to CANDLE.
        i. Need Analysis Plan to obtain preliminary data (See Section F). All data analysis will be done by a CANDLE biostatistician.
2) The first author is responsible for notifying the Emerging Science Coordinator of the status of the grant submission, and if/when the submission is scored and/or funded.