DEVELOPMENTAL PROGRAM ON PERSONALITY AND PSYCHOPATHOLOGY
POLICIES AND PROCEDURES FOR DATA-SHARING RESEARCH
May 2018

We are pleased to share data with you! This document is intended to help standardize the conduct of research among our research group, students and collaborators in the interest of smooth communication. Its contents are drawn from the guidelines of the APA, AMA, ASA, and the Dunedin Study. Please consider this checklist as you conduct data-sharing research with us. We ask that you follow each of the policies and procedures listed below. In some cases, exceptions may be negotiated in advance if you have special circumstances.

Thank you...

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GETTING STARTED...

* Discuss your idea with Temi or Avshalom to ascertain its general feasibility.
* Familiarize yourself with the Dunedin "Policy & Procedures Handbook".
* Prepare a brief concept paper for your study. A boilerplate for this is at end of file. A concept paper should contain:
    a. Your name and affiliation, the name of the PI sponsoring your work with the data set, the date, a working title for the paper.
    b. Brief statement of the hypothesis or topic and its significance.
    c. Which sample and which variables at which ages you will need.
    d. What analyses you will perform.
    e. Confidentiality & data security agreement
    f. A "response sheet" that any data caretakers or potential collaborators can fill out. This sheet has a place they can sign for permission to use their data. It also offers options that they can check off to signify what sort of role they would like to play (authorship roles: contribute to design & data, help with analyses, help with writing, critique drafts; or non-authorship role with acknowledgement only). Include 2 copies, one they can keep and one to return to you, via Temi.

* Have Temi or Avshalom send your concept paper to all concerned individuals.
* When response sheets are returned, you have a project, and the research may proceed.
* Neither the Dunedin nor E-risk Studies are public domain data sets. **You may not share your data file with others, and by signing the concept paper you agree to this restriction**.
*All papers require an approved concept paper on file, including papers by the active collaborating investigators.

In addition, many researchers use the Newcastle-Ottawa scale to rate the quality of a paper for inclusion in meta-analyses. Why wait to be rated by others? It's a great idea to use this scale in advance to rate your own paper, perhaps at the time of the Concept Paper. Have you included the right measures and analyses to get a high score?

You can find an explanatory page here:
http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp

And the actual questions here (see page 2 for questions related to cohorts):
http://www.ohri.ca/programs/clinical_epidemiology/nosgen.pdf

STEP ONE:

Researchers not employed by the University of Otago who will physically access and analyse Dunedin data must be appointed as Associated Investigators of the Dunedin Unit, as required for ethical reasons explained in the Unit Handbook. Temi and Avshalom must nominate you for this formal appointment, submitting an application to the Director and Scientific Advisory Group of the Unit for review. It is not automatically granted to everyone. The nominating PI takes responsibility for all activities of the A.I. with respect to the Study, and this is quite a serious responsibility. Thus, one consideration in granting this status is the number of Associated Investigators we are already responsible for. Discuss with Temi and Avshalom whether they can nominate you for A.I. status. If not, then your collaboration must include a PI or AI who agrees to take ethical responsibility for the project and to physically analyse the data base for your paper. If you are not an A.I., you must follow the steps in the rest of this document with the help of a person who holds an appointment at the Dunedin Unit.

STEP TWO:

For research funded in any way by the US NIH (which includes all Dunedin-based projects) it is a requirement that all investigators have completed the NIMH research ethics training course in human subjects protection, or equivalent training from their own country. Even if research is not actively funded by NIH, knowledge of human subjects protection is still a requirement of the ethics committees who approve and monitor our Dunedin study. Increasingly journals are also asking for this documentation. Therefore, by accepting data from us to analyse, the researcher should understand they are attesting to us that they have completed research ethics training. If you have not yet taken a course, it is easy to take by going to: http://www.citiprogram.org/default.asp?language=english

STEP THREE:

* Consult electronic data dictionary and read previously published papers from the study to get information about the data you plan to use.

*Think carefully about which statistical analyses you will perform. Consult with our statistical expert (currently Renate Houts). Suggested reading;

Thomas & Peterson (2012). The Value of Statistical Analysis Plans in Observational Research: Defining High-Quality Research From the Start. JAMA 308, 773-774. (below).

* When you place your request for data, take the time to carefully consider which variables you will need and discuss this with Temi, and Avshalom. Collaborators who continuously contact us for “just one more variable” wear their welcome out fast. At the same time, asking for too many variables without a good justification is not advised. The best proposals are those that carefully outline a set of well justified research questions and request the appropriate number and types of variables required to test the research questions. Requests that do not meet these expectations will be returned for a more careful consideration.
* When merging computer files, always match by subject number and always ‘select if’ the subject number falls within the true range of assigned numbers.
* Look at the frequency distribution of a variable before you use it.
* Report any bug in a file in writing to the data manager (DM).
* Use “comments” in your command files for data analysis, so that others can retrace your steps later.
* Save all your printouts in a labeled notebook (electronic or paper). These must be saved for 5 years.

IF YOU CREATE NEW VARIABLES FROM THE BASIC DATA

* We ask that you provide to us any new variables that are published in your paper.
* When you create a new variable give it the following features:

- **variable name** ending with a number indicating the assessment age wave
- **variable label** with data source for the original constituent data
  e.g. Mother or teacher report, DSM4 based diagnosis, Average of …, Sum of…
- **value labels** for the coded numeric values (e.g. 0 = no, 1 = yes).

Examples:

mde1115 dx mde at 11, 13 or 15
totMDE1538 count of episodes with MDE 15 to 38
dxmde38 Major depressive episode, dsm4, p38

It used to be that Variable names were limited to 8 characters and variable labels were only 40 but statistical software is more flexible now. Please assign names & labels that clearly communicate what the variable is. That said, it is helpful to put the most important information at the beginning of the variable label.

A suffix of “1838” can refer to the Sum of whatever at those 5 phases or the Average or Any. You need to use the label to make clear what the phase notation refers to.

* Prepare a system file and documentation for all new variables you created for the study. Include the variable labels and value labels. Documentation includes how you made the variable and its frequency distributions, including the derivation code used to create each variable from the base-data variables themselves (i.e. before any re-codes etc) - this makes it easier to see what exactly was done.

* Send the file and documentation to the data manager.

WRITING IT UP...

* Don't re-create the wheel; use our existing boilerplates for the "methods" section for consistency across publications. Look at recent submissions for bits to copy.

*STROBE checklist (below). We have begun to get requests from editors of journals to include a completed STROBE checklist when manuscripts are submitted for review. Note, it is not enough to just tick off the items on the checklist, for example, BMJ is requiring that the checklist report the page number where each item has been fulfilled.

* Access our reference system if you like, to help construct your reference list.
* Include the date and the electronic file name, as well as page numbers, on every printed version of the manuscript.
* Acknowledge all appropriate individuals, agencies and grants on your manuscript. This is not an option, it is required by our funding agencies.

SAMPLE TEMPLATE FOR ACKNOWLEDGEMENTS SECTION (DUNEDIN STUDY)

Updated as of **May 2018**

The Dunedin Multidisciplinary Health and Development Research Unit is supported by the New Zealand Health Research Council and New Zealand Ministry of Business, Innovation and Employment (MBIE).

This research received support from

The US-National Institute of Aging grant R01AG032282 (current funding for 45; please cite in all papers), and

The UK Medical Research Council grant MR/P005918/1 (current funding for phase 45, please cite in all papers),

Grants you might also acknowledge, depending on the nature of the paper:

US NIA 1R01AG049789: the brain imaging grant “Neural signatures of healthy and unhealthy aging” (please cite in any papers using IQ, neuropsych test measures, or on brain-related topics).
If using MRI data add; "We thank the members of the Dunedin Neuroimaging Study Advisory Board"

For papers that use sequence/methylation/expression data: This work used a high-performance computing facility partially supported by grant 2016-IDG-1013 (HARDAC+: Reproducible HPC for Next-generation Genomics") from the North Carolina Biotechnology Center.

The New Zealand Health Research Council Programme Grant (16-604)

The New Zealand Health Research Council Project Grant 15-265 when using dental data from Phase 45.

The Jacobs Foundation (bec of donation to our research for the period 2011-2019)

The Avielle Foundation (if crime is in the paper)

We thank the Dunedin Study members, their [parents], [teachers], [partners], [children] and [peer informants], Dunedin Unit Director Richie Poulton [if not a coauthor), Unit research staff, [names of principal investigators who shared data with you, if they are not co-authors], and Study founder Phil Silva.

Research assistance was provided by [name, name].

Helpful comments on earlier drafts were provided by [name, name].

For official crime data: we thank the Dunedin Police [if you use police data].

For "Benefits" data: the authors wish to thank The Ministry of Social Development for provision of and assistance with Benefit data. [if you used benefit data]

For "ACC" data: the authors wish to acknowledge the help and support of the ACC in identifying and gathering the accident data for Dunedin Study members. [if you used ACC (accident) data]

Author X was supported by [name, name, your own funding sources here, if you don't know ask somebody],

The study protocol was approved by the institutional ethical review boards of the participating universities. Study members gave informed consent before participating.

* Institutions have become really strict about the way their names appear on publications so they get credit for papers when electronic search engines allocate products to universities and departments. For the Dunedin main investigators, the affiliations are:

Avshalom Caspi: MRC Social, Genetic, and Developmental Psychiatry Centre, Institute of Psychiatry, King's College London, London SE5 8AF, United Kingdom; Departments of Psychology and Neuroscience, Psychiatry and Behavioral Sciences, and Institute for Genome Sciences and Policy, Duke University, Durham, North Carolina, USA.

Terrie E. Moffitt: MRC Social, Genetic, and Developmental Psychiatry Centre, Institute of Psychiatry, King's College London, London SE5 8AF, United Kingdom; Departments of Psychology and Neuroscience, Psychiatry and Behavioral Sciences, and Institute for Genome Sciences and Policy, Duke University, Durham, North Carolina, USA.

BEFORE YOU SUBMIT FOR PUBLICATION...

* all primary authors need to lodge the annotated script of their data analysis with HonaLee **BEFORE** submitting the final draft of the paper. We will then review the script and check all analyses.

Specifically, here is what we would like to ask all authors to provide:

1. Script for new variables you've created.
2. Script for final analyses (in SPSS, STATA, SAS or Mplus preferred, but whatever you have used is fine), with documentation included in the script. It would be especially helpful if you could orient us in the script to the manuscript (e.g., analyses for Fig. 1, etc.).

Example:

```
* Testing cortisol profiles as a function of victimisation status (Result section, paragraph 1).

GLM
  meancort2_3 lgcort4cor lgcort5cor lgcort6cor BY victims  WITH
  cont7 Medclass13
  /WSFACTOR = time 4 Helmert
  /METHOD = SSTYPE(3)
  /PLOT = PROFILE( time*victims )
  /CRITERIA = ALPHA(.05)
  /WSDESIGN = time
  /DESIGN = cont7 Medclass13 victims .
```

Checking will be carried out using an original data set, separate from the data set with which you have been working.

***** Temi or Avshalom must approve the penultimate draft before it is circulated among collaborators.
* Send a copy to all collaborating co-authors for review and approval.
* Send a copy to the original PI of the study; their approval and release of every paper is a condition of our data-sharing agreements.
* Specify the target journal.
* Ask collaborators to send written permission to submit the paper if journal requires it.
* Allow PI's and collaborators 3 weeks from the date of receipt to review the paper.

SUBMITTING FOR PUBLICATION REVIEW...

* Lodge a copy of the submitted paper and letter to the editor with Temi, both dated with the electronic file name on the document.

DOING REVISIONS...

* Send a copy of the editor's letter and reviews to all co-authors.
* Invite them to comment or contribute to the revision process.
***** Temi or Avshalom must approve the revised draft before it is sent back to the editor.

WHEN THE PAPER IS ACCEPTED FOR PUBLICATION...

* Celebrate!
* Give Temi the Word file for the final version for filing in the electronic reprint system.
* Temi or Avshalom are to be listed as the corresponding author for each published paper, i.e. the source from which reprints may be ordered.
* Send a copy of the paper to all collaborators with the citation for their vitae.
* You need to deposit the final version of your analysis file, scripts and new variable descriptions with the data manager. Upon confirmation of receipt, you agree to delete the data file (s). Collaborators and graduates of DPPP may not take a data file away from the DPPP office. The data remain the property of the Study and cannot be used for further analyses without express, written permission.

VERY IMPORTANT – you must apply for PMCID.

Since 2008 NIH has required that all published papers that are (a) peer-reviewed, and (b) credited to the support of a NIH grant, must be lodged in PubMed Central for public access. You must have the PMCID for any paper that reported as a new in the annual progress report of a grant. The next year of grant funds that supports our work will not be released unless the progress report includes PMCIDs for every paper. Additionally, you must have the PMCID as part of the reference citation for any paper that is shown on your NIH biosketch which is submitted with proposals. So, you cannot be named as an applicant or a co-investigator on a grant application if you do not do this to get the PMCIDs. This is also true for UNC-CDS and Duke Aging and TPRC, all training grants supported by NIH funds.

As soon as your paper is IN PRESS, you must go to the website and upload a WORD PDF copy, along with entering the grant number(s). This will get you the PMCID. You do not wait for the publication or page proofs to come out. Learn more here: http://publicaccess.nih.gov/index.htm

DURING THE PROCESS TOWARD PUBLICATION...

* Notify Temi or Avshalom when you get the copy-edited version and the page-proof version. One of us will help you check each of them.
* DPPP sends an end-of-year thank-you note to all editors who have accepted our work. Be sure your editor's address gets on Temi's list.

ONCE PUBLISHED….

* Notify Temi and send a PDF.
* Send PDF to all co-authors.

IF THERE IS MEDIA COVERAGE OF THE PROJECT.

* Consult with Temi about drafting a fact sheet for journalists.
* Deliver copies of all media articles, or websites, to Temi.

IF YOU GIVE A LECTURE OR POSTER PRESENTATION ON YOUR WORK

* Notify Temi of the title, date, and context of the presentation. We need to report these for our progress reports to funding agencies.
* Oral presentations do not require a concept paper.

Thank you for reading this document.

We share data with a large number of collaborators, who live in many countries, and who work at many different levels of training and expertise. This memo is intended to instruct students who are embarking on their first research project, and to remind senior professors who are embarking on their thousandth research project. We have listed here the practices that help to keep our working relationships comfortable and productive. We hope they work for you too.

Avshalom and Temi (*Concept template follows.)*

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results			
Participants	13*		(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
			(b) Give reasons for non-participation at each stage
			(c) Consider use of a flow diagram
Descriptive data	14*		(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
			(b) Indicate number of participants with missing data for each variable of interest
			(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*		*Cohort study*—Report numbers of outcome events or summary measures over time
			Case-control study—Report numbers in each exposure category, or summary measures of exposure
			Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16		(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
			(*b*) Report category boundaries when continuous variables were categorized
			(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion			
Key results	18		Summarise key results with reference to study objectives
Limitations	19		Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20		Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21		Discuss the generalisability (external validity) of the study results
Other information			
Funding	22		Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

The Value of Statistical Analysis Plans in Observational Research

Defining High-Quality Research From the Start

Laine Thomas, PhD
Eric D. Peterson, MD, MPH

THE INCREASING AVAILABILITY OF ELECTRONIC HEALTH data combined with federal investment has stimulated an expansion in observational clinical research.[1] Observational studies can complement clinical trials and provide important information about comparative safety and effectiveness in populations not well studied in clinical trials. However, there are numerous examples in which the findings from observational studies have failed to be replicated.[2] These failures may be due to several factors, including the exploratory nature of observational questions, failure to fully account for treatment selection bias, known publication biases, and the tendency to pursue post hoc hypotheses. This later problem, termed *data dredging*, is facilitated by the lack of fidelity to a prespecified hypothesis and inadequate reporting of the actual analytic process.

In contrast to observational research, clinical trials ordinarily operate under strict standards at every step of study planning and data analysis. A detailed protocol, including the definition of end points, hypotheses, and all analytical procedures, is submitted to the US Food and Drug Administration and registered in various data repositories, such as clinicaltrials.gov, prior to enrollment of patients. Trial registration helps ensure that both positive and negative findings are publicly known. Prespecification of trial protocols creates an incentive to understand the biological function of the intervention, carefully define the population of interest, target the most appropriate end points, and achieve certainty about the statistical approach. Prespecification of hypotheses and minimal testing means that standard errors and *P* values are accurate measures of uncertainty and statistical evidence is rigorous. Trial protocols can also be referred to and reviewed to understand the questions, end points, and subgroup analyses that were defined ahead of time and those that were post hoc and in need of replication for validation.

See also p 771.

A natural question arises as to whether elements of this rigorous process should be applied to observational research. While select observational studies are already registered in clinicaltrials.gov,[3] some argue that observational research is, by its nature, exploratory and requires substantial flexibility to investigate novel findings and unexpected signals in the data.[4,5] Yet interpretation of statistical evidence (*P* values and confidence intervals) can be made potentially meaningless when multiple hypotheses are generated by exploring the available data. Hence, a balance must be achieved to promote some flexibility but also encourage a rigorous, efficient analytical process that minimizes unnecessary data dredging.

Aside from considering the advantages of preregistration, substantial progress has been made to define standards for reporting observational research.[6,7] The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations provide a checklist of items to include in reporting of cohort, case-control, and cross-sectional studies.[6] Good Research for Comparative Effectiveness (GRACE) principles similarly reflect a consensus on good practice for design and evaluation in comparative effectiveness research.[7] Despite these standards for high-quality observational research and reporting, such guidelines are not consistently adopted, in part because of their complexity and the difficulty of including all components in published articles.

The concepts for improving observational research can be operationalized via use of a formal, prospectively defined statistical analysis plan (SAP). The SAP should include enough detail that another statistician familiar with the data set (or their own independent data) could replicate the analysis. This implies that the SAP should delineate populations (exclusion criteria); end points; descriptive objectives; testable hypotheses; modifications or derivations of standard variables; statistical methods, including handling of missing data, correlated data, bias, and confounding; subgroups; interactions; and sensitivity analy-

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sis. While the SAP should be finalized prior to data analysis, authors may make changes to the analytic plan in response to subsequent findings. These changes to methods, hypotheses, or both should be noted in the SAP to capture when and why components were modified during analysis. Once created, the SAP should be cited in the methods, submitted along with the manuscript for review, and potentially made available as an online appendix to a published article.

The benefits of this process are numerous. First, it promotes good planning rather than haphazard data analysis and communicates this distinction to reviewers and readers. Second, it optimizes statistical resources to focus the best methods on good questions, those with the potential for important findings, either negative or positive. When key hypothesis are defined at the outset, they can be carefully addressed. Third, it facilitates transparency. The existing STROBE recommendations for reporting are quite comprehensive but almost impossible to address in the limited space that is afforded to a published methods section, particularly if the statistical methods are to be replicable. The submission of an SAP provides reviewers with a complete description of what was done, not limited by space. Fourth, this approach may increase efficiency by avoiding distracting messages, maintaining focus on the a priori hypotheses with room for post hoc and sensitivity analysis to be reported.

This suggested process for the SAP in observational research is feasible for real-world adoption. For instance, the Duke Clinical Research Institute, an analytical center for the American College of Cardiology National Cardiac Data Registries, has implemented such an SAP process within their ACTION and Cath/PCI registries. A formal proposal is submitted by clinical researchers, including detailed background and hypotheses, and prioritized by a publications committee. From the proposal, a primary statistician works with the clinical researcher to develop the SAP, translating the clinical questions into descriptive objectives and testable hypotheses. Statistical methods are proposed to address each major objective, including the details mentioned above, table shells for intended output, and the corresponding potential conclusions or takeaway message. A senior statistician and coauthors review the SAP, and it is revised iteratively until all parties support the aims and approach. The review of table shells and cross-checking of potential conclusions with technically stated hypotheses help avoid misunderstandings between the clinician and statistician. These details allow the authors to visualize the project and anticipate issues. While developing the SAP, the statistician may investigate the data availability, extent of missingness, colinearity, and other issues. However, the analysis begins once the SAP is finalized and a single report containing all information is provided to the primary author. Some revisions are nearly always necessary; unforeseen issues with the data may indicate alternative statistical methods or unexpected results may require new analysis. Both the SAP and report are revised to reflect changes.

The process of writing and submitting an SAP captures many of the attributes of clinical trials, without excessive rigidity that would inhibit exploratory research. It requires extra work on the front end but greater efficiency and clarity in producing and reporting results. Current practice may be augmented by making the SAP publicly available as online ancillary material.[8] This would allow readers to confirm and, if desired, replicate the methods used in the study. Some authors have expressed concerns that readers of observational research may become too rigid and dismiss an important finding just because it was not prespecified.[5] However, this can be mitigated if authors make a strong biological case to support post hoc findings and readers may, appropriately, require more confirmatory evidence. The gains in public and academic trust associated with transparency outweigh this concern.[9] Thus, investigators conducting observational research should develop and use prespecified SAPs and should submit these to journals, along with their manuscripts, for review and ultimate online publication.

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

REFERENCES

1. Patient-Centered Outcomes Research Institute. http://www.pcori.org/what-we-do/. Accessed July 27, 2012.
2. Lauer MS. Will academia embrace comparative effectiveness research? *Acad Med*. 2011;86(6):671-673.
3. Williams RJ, Tse T, Harlan WR, Zarin DA. Registration of observational studies: is it time? *CMAJ*. 2010;182(15):1638-1642.
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6. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ*. 2007;335(7624):806-808.
7. Dreyer NA, Schneeweiss S, McNeil BJ, et al; GRACE Initiative. GRACE principles: recognizing high-quality observational studies of comparative effectiveness. *Am J Manag Care*. 2010;16(6):467-471.
8. Sox HC, Helfand M, Grimshaw J, et al; PLoS Medicine Editors. Comparative effectiveness research: challenges for medical journals. *PLoS Med*. 2010;7(4):e1000269.
9. Ioannidis JPA. The importance of potential studies that have not existed and registration of observational data sets. *JAMA*. 2012;308(6):575-576.

Concept Paper Template

Provisional Paper Title:

Proposing Author:

Author's Email:

P.I. Sponsor:
(if the proposing author is a student or colleague of an original PI)

Today's Date:

Please describe your proposal in 2-3 pages with sufficient detail for helpful review.

Objective of the study:

Data analysis methods:

Variables needed at which ages:

Significance of the Study (for theory, research methods or clinical practice):

References cited:

Data Security Agreement

Provisional Paper Title	
Proposing Author	
Today's Date	

Please keep one copy for your records and return one to the PI Sponsor

Please initial your agreement

	I am current on Human Subjects Training (CITI (www.citiprogram.org) or equivalent)
	My project is covered by Duke or Otago ethics committee OR I have /will obtain ethical approval from my home institution.
	I will treat all data as "restricted" and store in a secure fashion. My computer or laptop is: a) encrypted (recommended programs are FileVault2 for Macs, and Bitlocker for Windows machines) b) password-protected c) configured to lock-out after 15 minutes of inactivity AND d) has an antivirus client installed as well as being patched regularly.
	I will not "sync" the data to a mobile device.
	In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact Professor Moffitt or Caspi. (919-684-6758, tem11@duke.edu, ac115@duke.edu)
	I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper.
	I will not post data online or submit the data file to a journal for them to post. *Some journals are now requesting the data file as part of the manuscript submission process. The Dunedin Study Members have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to Terrie or Avshalom for strategies for achieving compliance with data-sharing policies of journals.*
	I will delete all data files from my computer after the project is complete. Collaborators and trainees may not take a data file away from the office. The data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.

Signature: _____

CONCEPT PAPER RESPONSE FORM

A

Provisional Paper Title	
Proposing Author	
Other Contributors	
Potential Journals	
Today's Date	
Intended Submission Date	

Please keep one copy for your records and return one to the proposing author

B. To be completed by potential co-authors:

	Approved
	Not Approved
	Let's discuss, I have concerns

Comments:

Please check your contribution(s) for authorship:

	Conceptualizing and designing the longitudinal study
	Conceptualizing and collecting one or more variables
	Data collection
	Conceptualizing and designing this specific paper project
	Statistical analyses
	Writing
	Reviewing manuscript drafts
	Final approval before submission for publication
	Acknowledgment only, I will not be a co-author

Signature:

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