

VOLUNTARY EXCLUSION AND SETTLEMENT AGREEMENT

This Voluntary Exclusion and Settlement Agreement (Agreement) is entered into by and between the United States Department of Health and Human Services (HHS), through the Public Health Service (PHS) and Eric T. Poehlman, Ph.D. (Respondent).

The purpose of this Agreement is to settle HHS' scientific misconduct findings against Respondent made this day by the PHS. Based on the report of an investigation conducted by the University of Vermont (Report) (Attachment A), admissions made by Respondent, and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the PHS finds that Respondent engaged in scientific misconduct in research. The research was supported by National Institutes of Health (NIH) grants from the National Institute of Aging (NIA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Center for Research Resources (NCRR) as set forth in Attachment B and made part of this Agreement.

The PHS finds that Respondent is responsible for scientific misconduct by engaging in the misleading and deceptive practices set forth herein below:

Group 1: Longitudinal study of aging; Protocol 678 and associated Excel spreadsheets

Proposing Research (Report pp. 22-25)

1. That Respondent falsified preliminary data purportedly obtained in a longitudinal study of aging in NIH grant application 1 R01 AG17906-01, submitted May 27, 1999; specifically, the claim of 130 subjects at visit one (T1) and 70 subjects at visit two (T2), mean values for total energy expenditure (TEE) obtained with a doubly-labeled water technique were falsified; additional parameters such as physical activity energy expenditure (PAEE), resting metabolic rate (RMR), fat-free mass, appendicular skeletal muscle mass, and percent body fat were falsified to show significant trends during the aging process that were not reflective of the actual data (Abstract, and pp. 19, 21, 22, 23, 27, 29, 34, 41, 42).
2. That Respondent falsified preliminary data purportedly obtained in a longitudinal study of aging in NIH grant application 1 R01 AG17906-01A1, submitted February 2000, specifically, the claim of 130 subjects at visit one (T1) and 70 subjects at visit two (T2), mean values for total energy expenditure (TEE) obtained with a doubly-labeled water technique were falsified; additional parameters such as physical activity energy expenditure (PAEE), resting metabolic rate (RMR), fat-free mass, appendicular skeletal muscle mass, and percent body fat were falsified to show significant trends during the aging process that were not reflective of the actual data (Abstract, and pp. 32, 34, 38, 39, 45, 46).

Conducting Research

3. That Respondent systematically falsified a number of metabolic and physical measures of subjects in the longitudinal study of aging; these falsifications of specific types of data in the Protocol 678 spreadsheet commenced immediately after he assigned responsibility for maintenance of the data to a young technician and simultaneously arranged to have personal access to the data; his widespread alteration of data in specific fields has been detected in a number of different versions, often with cumulative effect, and several were transmitted to different co-workers for specific reasons, as detailed in the following sub issues:
 - a. that in the spreadsheet labeled "678data3.xls," produced during the late spring/early summer of 2000, Respondent falsified and fabricated numerous values in the fields called underwater fat mass (UWFM), underwater fat-free mass (UWFFM), leisure time activity (LTA), and maximum oxygen consumption (VO₂ Max);
 - b. that on July 16, 2000, Respondent transmitted a subset of the Protocol 678 spreadsheet to a witness (TB) entitled "RevisedTEE_s.xls;" that had 135 values each for T1 and T2 for TEE; many values were fabricated and most of the remaining values had been falsified by reversing the original T1 and T2 values (Report pp. 6-8);
 - c. that Respondent falsified additional data fields in the version of the 678 data set called "Excellongitudinal2.xls," on or about August 17, 2000; specifically values for total cholesterol, insulin, resting metabolic rate (RMR), and glucose values of the subjects with names in the second half of the alphabet were falsified (often by reversing T1 and T2) or fabricated (Report p. 10);
 - d. that Respondent gave falsified data to another witness (MT) in August 2000 to provide him with data for a presentation to be given in September 2000 to UVM staff (initially postponed until February 2001); the spreadsheet given to MT contained the falsified and fabricated TEE and underwater body composition values of RevisedTEE_s.xls; the spreadsheet, when subsequently obtained by ORI, was labeled "LongitudinalBodyComp[REDACTED].xls";
 - e. that Respondent falsified additional data in another version of "Excellongitudinal2.xls" that he sent to another witness (AT) on or about August 22, 2000; specifically, this version contained the falsifications already described above (Issues 3a through 3c) and, in addition, the remainder of the glucose values, and individual lipid components (triglycerides, HDL, and LDL) were extensively falsified and fabricated; this spreadsheet was transmitted to AT with the

expectation that he would write a paper describing the effect of aging on lipid metabolism (Report pp. 8-10);

- f. that Respondent provided a falsified version of the Protocol 678 spreadsheet to a witness, (ER) in the fall of 2000 so that ER could write a review article;
- g. that Respondent, in late September/early October 2000, extensively falsified body composition data (a number of parameters including but not limited to fat mass and fat-free mass) obtained with the DEXA method in a spreadsheet transmitted to a witness (CG) so that CG could write a paper using the DEXA method to demonstrate body composition changes with age (Report pp. 5 and 39);

Reporting Research

- h. that Respondent reported falsified data from the longitudinal study of aging at the annual North American Association for the Study of Obesity (NAASO) meeting in October 2000, and to the Vermont community; the falsifications on his slides included falsified values for both the number of subjects tested at T1 and T2 for TEE and the claim of a significant difference between the means for TEE at T1 versus T2; values for RMR, PAEE, and body composition (fat mass and fat-free mass) were also falsely reported (Report p. 34);
- i. From the falsified data set that Respondent provided [REDACTED] [REDACTED] ("Resting Metabolic Rate and Aging") Rawson, E. And Poehlman, E., "Resting Metabolic Rate and Aging", IN: Recent Research Developments in Aging, Research Signpost Group, India, 2000, co-authored by Respondent, that included falsified yet unpublished results about the decline in RMR upon aging. (p. R1792). These results, ORI determined, are very similar to the falsified results that Respondent presented at NAASO, based on the falsified Protocol 678 data set;

Conducting Research

- j. That on October 16, 2000, Respondent provided a witness (WD) a version of the Protocol 678 data set entitled "ExcelLongitudinal4.xls" that included falsified cholesterol and individual lipid component data (as well as falsified parameters such as insulin, glucose (all subjects), TEE, RMR, PAEE, and underwater body composition data) so that WD could write a paper on the effect of aging on lipid composition (Report pp. 8-10);

Other

- k. That Respondent falsely testified to the University of Vermont Investigation Committee that he had never used data from the longitudinal study of aging in grant applications or in public presentations (Report, pp. 34 and 36).

Group 2: Muscle biopsy results

Proposing Research

4. That Respondent reported fabricated muscle biopsy data in NIH grant application 1 R01 AG17906-01A1 (p. 27), submitted in February 2000; specifically, he falsely claimed to have successfully tested five individuals on two occasions (1994 and 1999) when he had not (Report pp. 25-26).

Group 3: Protocol 467, including the “longitudinal menopause study” and other falsifications/fabrications

Reporting Research

5. That Respondent published falsified thyroid hormone results for women entered in a cross-sectional study (Protocol 467) (Figures 3A and 3B and related text and the portion of Table 2 related to T3 and free T3) in a paper entitled “Determinants of decline in resting metabolic rate in aging females,” Poehlman, E.T. Goran, M.L. Gardner, A.W., Ades, P.A., Arciero, P.J., Katsman-Rooks, S.M., Montgomery, S.M., Toth, M.J., and Sutherland, P.T., *American Journal of Physiology, Endocrinology and Metabolism*, 264:E450-E455, 1993 (Correction required);
6. That Respondent published in November 1995 falsified and fabricated data from a longitudinal study of menopause in women in a paper entitled “Changes in energy balance and body composition at menopause: A controlled longitudinal study” (Poehlman, E.T., Toth, M.J., and Gardner, A.W., *Annals of Internal Medicine*, 123:673-675, 1995); Respondent has admitted that this longitudinal study was never conducted (the number of women seen at T1 was falsified, and there were at most 3, rather than 35, women seen at T2). (Report pp 27-32) (Retracted by editor; letter from Respondent required);

Proposing Research

7. That Respondent repeatedly reported this non-existent longitudinal menopause study and cited the 1995 *Annals of Internal Medicine* paper in NIH grant applications as proof that Respondent could conduct such longitudinal studies, and the falsified and fabricated data supported his proposed hypotheses:
- a. Respondent provided for the annual report for the University of Vermont General Clinical Research Center (GCRC) grant (M01 RR00109) for the period 12/1/94-11/30/95, information about the falsified longitudinal menopause study, and the *Annals of Internal Medicine* paper was cited as having utilized the University of Vermont GCRC facilities;
 - b. in application 5 K04 AG00564-05, submitted July 18, 1995, Respondent reported the results of a seven (7) year¹ followup study of pre- and post-menopausal women, noting an article was in press in the *Annals of Internal Medicine* 1995 (unnumbered page 3);
 - c. in application R01 AG13978-01, submitted in September 1995, Respondent reported falsified and fabricated data on menopause related changes in metabolism, body composition, and other variables in Preliminary Data (pp. 35, 41 and 42), and cited the published *Annals of Int. Med* 1995 paper;
 - d. in application R01 AG13978-01A1, submitted in July 1996, Respondent reported falsified and fabricated data on menopause related changes in metabolism, body composition, and other variables in Preliminary Data (p. 33) and cited the published 1995 paper in the *Annals of Int. Med.* and a submitted manuscript on the same topic (pp. 25, 29, 33, 40, 44, 49);
 - e. in Project 1 of application P01 AG16782-01, submitted in June 1998, Respondent reported (p. 233) fabricated data showing that menopause led to significant changes in body composition, (pp. 229, 230, 231, 232, 233, 246, 256) (Report p. 32);
 - f. in application 1 R01 AG 18238-01, submitted in April 1999, Respondent reported falsified and fabricated data from his longitudinal menopause study (RMR, leisure time physical activity, fat-free mass, fat mass, waist to hip ratio, and insulin (pp. 9, 18, 19, 20, 22, 23, 33, 37, 44);

¹ All other reports of the “longitudinal menopause study” claimed an average of six (6) years of follow-up.

- g. in application 1 R01 AG17906-01, submitted in May 1999, Respondent reported falsified and fabricated data in the description of his longitudinal menopause study (RMR, leisure time physical activity, and fat-free mass, p. 25);
- h. in Project 1 of application P01 AG16782-01A1, submitted in January 2000, Respondent reported the falsified and fabricated longitudinal menopause study (pp. 214, 220, 221, 228, 250) (Report p. 32);
- i. in application 1 R01 AG17906-01A1, submitted in February 2000, Respondent reported the falsified and fabricated longitudinal menopause study (pp. 31 and 59);
- j. in application 1R01 AG19800-01, submitted in September 2000, Respondent reported the falsified and fabricated longitudinal menopause study (pp. 18 and 43).

Reporting Research

- 8. That Respondent continued to publish papers on the fictitious longitudinal menopause study, referring to the same cohort of 35 women, 18 of whom purportedly went through the menopause transition during the six year followup period; all of parts of the following additional papers² reported this non-existent study and require correction or retraction:
 - a. Poehlman, E., Toth, M, Ades, P., and Rosen, C., “Menopause-specific changes in plasma lipids, insulin-like growth factor I, and blood pressure: a longitudinal study,” *European Journal of Clinical Investigation* 27:322-327, 1997 (Report p. 30) (Retraction required);
 - b. Tchernof, A., and Poehlman, E., “Effects of the menopause transition on body fatness and body fat distribution,” *Obesity Research* 6(3):246-254, 1998 (pp. 249-251) (Correction required);
 - c. Tchernof, A., Poehlman, E., and Despres, J., “Body fat distribution, the menopause transition, and hormone replacement therapy,” *Diabetes and Metabolism* 26:12-20, 2000 (Report p. 31) (p. 17 Correction required);
 - d. Rawson, E. and Poehlman, E., “Resting metabolic rate and aging,” IN: Recent Research Developments in Aging, Research Signpost Group, India, 2000 (pp. R1791 and R1804) (Correction required);

² The first paper describing the longitudinal menopause study, the 1995 *Annals of Internal Medicine* paper, was the subject of PHS Issue 6.

- e. Poehlman, E. T., "Menopause, energy expenditure, and body composition," *Acta Obstet. Gynecol. Scand.* 81:603-623, 2002 (Retraction required).
 - f. Poehlman, E., and Tchernof, A. "Traversing the menopause: changes in energy expenditure and body composition," *Coronary Artery Disease* 9: 799-803, 1998 (Correction/retraction required).
9. That Respondent reported falsified and fabricated longitudinal menopause data in a talk presented in October 2000 at the annual NAASO meeting and to the Vermont community; specifically he reported to the NAASO falsified RMR and fat mass data on 40 women followed over six years (17 pre-menopausal, 18 post-menopausal, and 5-peri-menopausal) and RMR, FM, F-FM, PAEE, WHR, and insulin (Vermont Community) (Report, pp. 33-34).

Other

10. That Respondent falsely wrote to the University of Vermont Investigation Committee that the subjects in the longitudinal menopause study had not stayed overnight in the GCRC for the second visit. In fact, no women were seen a second time at the GCRC on an in-patient or outpatient basis. (Report p. 29).

Group 4: Protocol 646 - Hormone replacement therapy and visceral fat and weight loss; the genetics of an obesity gene.

Proposing Research

11. That Respondent included Protocol 646 in grant application 2 M01 RR00109-33 (funding for the University of Vermont, GCRC), submitted in February-March 1996, in which he provided falsified and fabricated data on 40 women with and without the variant gene Trp64Arg; falsified parameters included body weight, body mass index, and percent body fat that were falsely claimed to be significantly different between the two groups.
12. That Respondent reported falsified and fabricated preliminary data and results in application 1 R01 AG18238 on HRT and its preferential effect on abdominal fat content:
- a. that Respondent, in grant application 1 R01 AG18238-01 (p. 24), submitted in April 1999, presented falsified data in Table 1, on a study of women who had reported to be on, or not on, hormone replacement therapy (HRT); specifically, he claimed that women on HRT had significantly lower intra-abdominal fat than non-users and that there was a significant difference in PAEE between the two groups;

- b. Respondent also falsely claimed to have evaluated the effect of HRT on intra-abdominal fat loss in a double blind placebo controlled study of 27 weeks duration (Figure 4); the actual study was not unblinded until 2002;
 - c. Respondent also falsely claimed (pp. 36-37) to have completed a six month pilot study on the effect of exercise weight loss on postmenopausal women administered HRT, compared to women not on HRT.
13. That Respondent, in grant application 1 P01 AG16782-01A1, submitted in January 2000, presented (p. 230) falsified data:
- a. on a study of women reported to be on, or not on, HRT; specifically the number of subjects in Table 4 was 25 for HRT users and 23 for non-users, while seven of eight values for PAEE and intra-abdominal fat (3 means and 4 standard deviations) were unchanged from Table 1 of Application 1 R01 AG18328-01, where the number of subjects was 13 for each group;
 - b. Respondent repeated the false claim in the April 1999 application to have evaluated the effect of HRT on intra-abdominal fat in a double blind placebo controlled study of 27 weeks duration; the actual study was not unblinded until 2002; Respondent admitted to falsifying the figure in this application relative to the version in the 1 R01 AG18328-01 application;
 - c. Respondent falsely claimed (p. 231) to have studied 8 post-menopausal women on HRT and 7 women not on HRT in a six month weight loss program, when the average ages, standard deviations and certain mean values were unchanged from the smaller and purportedly different, groups described in the April 1999 application (*see* PHS Issue 12c above).
14. That Respondent, in grant application 2 R01 DK052752-05, submitted in June 2000:
- a. falsified the number of subjects carrying or not carrying the Trp64Arg genotype in Tables 4, 5, and 6 (pp. 30-31); specifically in the application, he falsely claimed to have tested 40 in each group; Respondent admitted that the actual number tested varied from 8-13, depending on the group and parameter being measured;
 - b. Respondent also falsely claimed that the number of women recruited to his funded grant on the menopause transition was 85 (p. 49).
15. That Respondent, in grant application 1 R01 AG19800-01, submitted in September 2000:
- a.-c. made the same three false claims with respect to HRT as in application 1 P01 AG16782-01A1 (Findings 13 a-c); in addition, Respondent falsely claimed in

Table 5 that the number of subjects with and without HRT participating in the six-month weight loss program (see PHS Issue 13 c. above) was now 10 in each group rather than the group sizes of 8 and 7 claimed in Table 5 of the 1 P01 AG16782-01A1 application; many of the means and standard deviations in these two tables match the values obtained in a 6 month weight loss pilot study described on pp. 36-37 of application 1 R01 AG18238-01, where the two groups were comprised of 3 and 4 individuals; (pp. 13, 15, 17, 20, 21 and Tables 4 and 5 and Figure 6);

- d. falsely claimed (Table 3, p. 19) to have weight-reduced 70 obese women in the genetic study.

Reporting Research

16. That in public presentations or material prepared for these fora, Respondent falsified or fabricated data and results of the effects of HRT and of the effects of the Trp64Arg genotype:
 - a. that Respondent, at talks given at the annual NAASO meeting in October 2000, and to the Vermont Community (October 17, 2000), presented false information on the effects of HRT on visceral fat loss and glucose disposal when the HRT users and non-users were on a six-month weight loss program;
 - b. that Respondent, in both the NAASO and Vermont Community talks, falsely claimed that Trp64Arg carriers have significantly lower rates of glucose disposal than non-carriers.

Other

17. that Respondent falsely testified to the University of Vermont Investigation Committee that the slide shown at NAASO regarding the loss of visceral fat in women on or not on HRT during a six-month weight loss program (Issue 16a) had been labeled “hypothesized.” Respondent falsely labeled the NAASO slide “hypothesized” and submitted it to the University of Vermont Investigation Committee with the intention of misleading the committee. (Report pp. 34, 37)

Group 5: Alzheimer’s disease

18. that Respondent, in applications 2 R01 AG07857-06 and 7 R01 AG07857-07, submitted June 26, 1992, and March 28, 1994, respectively, falsified certain preliminary data (average ages, height, and fat-free weight values) to show that the Alzheimer’s and control patients were more closely matched for age than shown in the original data;

19. that Respondent, in application 5 R01 AG07857-09, submitted May 18, 1995, falsified preliminary data; specifically, compared to data in the preceding 5 R01 AG07857-08 application, where the number of Alzheimer's and control subjects was 7 and 13 respectively, the number of Alzheimer's and control subjects was doubled to 14 and 26 respectively, while many of the data values and standard deviations remained unchanged; in the latter application however, Respondent claimed that Alzheimer's patients had significantly lower fat-free mass and significantly higher fat mass than controls patients, while no claim of significant differences had been made in the earlier application.

Group 6: Effect of endurance training on metabolism

20. Respondent admitted to falsifying norepinephrine data (a measure of sympathetic nervous system activity) in two papers published in 1992 and 1994 and agreed to retraction of the papers.³ Specifically:
- a. Respondent falsified norepinephrine data in Table 2 and Figure 4 of Poehlman, E.T., Gardner, A.W., and Goran, M.J., "Influence of endurance training on energy intake, norepinephrine kinetics, and metabolic rate in older individuals," *Metabolism* 4:941-948, 1992, in order to strengthen the relationship between endurance training and increased norepinephrine levels and rate of appearance (paper to be retracted);
 - b. Respondent falsified norepinephrine data in Table 2 and associated text of Poehlman E.T., Gardner, A.W., Arciero, P.J., Goran, M.I., and Calles-Escandon, J., "Effects of endurance training on total fat oxidation in elderly persons," *J. Appl. Physiol.*, 76(646):2281-2287, 1994, in order to make the claims that norepinephrine concentration and norepinephrine appearance were significantly enhanced following endurance training (paper to be retracted).

³ Both the 1992 and 1994 papers were designed to reproduce, under more controlled conditions, an earlier result, published in Poehlman, E., and Danforth, E., "Endurance training increases metabolic rate and norepinephrine appearance rate in older individuals," *Am. J. Physiol.* 261:E233-E239, 1991, claiming that plasma levels of norepinephrine increased significantly in older individuals following endurance training. Because the norepinephrine results in the two carefully controlled studies conducted to verify this finding were falsified, it is apparent that this original report cannot be relied upon.


The terms of the Agreement are as follows:

1. Respondent accepts the findings of scientific misconduct as set forth above and in the Report,⁴ which is attached as Attachment A and made a part of this Agreement, and agrees not to appeal the jurisdiction of the PHS or its findings set forth herein.
2. Beginning the effective date of this Agreement, Respondent agrees to exclude himself permanently from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in, nonprocurement programs of the United States Government defined as “covered transactions” in the debarment regulations at 45 C.F.R. Part 76. Respondent agrees that he will not petition HHS to reverse or reduce the scope the permanent voluntary exclusion or administrative actions that are the subject of this Agreement.
3. Respondent certifies that he is not currently engaged in, nor receiving Federal funding under any covered transactions with the United States Government, as discussed in the debarment regulations at 45 C.F.R. Part 76.
4. Beginning the effective date of this Agreement and to implement the terms contained in Paragraphs 1, 2, and 3 above, Respondent agrees that henceforth he will neither apply for, nor permit his name to be used on any application, proposal, or other request for funds, to the United States Government or any of its agencies, as defined in the debarment regulations.
5. Beginning the effective date of this Agreement and to implement the terms contained in Paragraphs 1, 2, 3, and 4 above, Respondent will ensure that henceforth he will not receive funds of the United States Government and its agencies made available through grants, subgrants, cooperative agreements, contracts, or subcontracts, as discussed in the debarment regulations at 45 C.F.R. Part 76.
6. Beginning the effective date of this Agreement, Respondent agrees to exclude himself permanently from serving in any advisory capacity to the PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS.
7. Respondent agrees that on or before the effective date of this Agreement, he will execute and deliver the letters annexed hereto in Attachment D requesting retraction or correction, to the United States Attorney’s Office for the District of Vermont. Respondent understands and agrees that, in order to implement this term, he will sign the letters to the editors requesting the retraction or correction prepared for his signature by ORI without alteration or modification in any way.

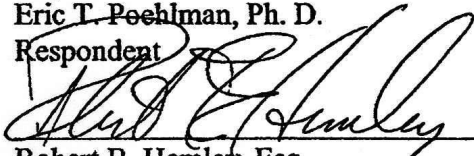
⁴ Except page 34, paragraph 4 and Finding of Fact 128 (Report).

8. Paragraphs 1 through 7 are material provisions of this Agreement. Respondent understands and agrees that a violation of any of these material provisions by Respondent, as determined by HHS, shall entitle HHS to seek enforcement of the Agreement in the United States District Court for the District of Vermont, which court shall maintain jurisdiction over this Agreement.
9. This agreement contains a complete description of the agreement between the PHS and the Respondent. All material representations, understandings, and promises between PHS and the Respondent are contained in this Agreement. Any modifications must be set forth in writing and signed by the PHS representative and respondent or his authorized representative. Respondent represents that this Agreement is entered into voluntarily with knowledge of the events described and following consultation with legal counsel. The parties recognize that the Respondent has also entered into written agreements with the Department of Justice pertaining to his civil and criminal liability for his scientific misconduct and other matters which will be filed in United States District Court for the District of Vermont.
10. In accordance with its normal procedures, ORI shall provide public notice of this Agreement and its terms, and notify Respondent's current employer.
11. This Agreement shall become binding and effective only when it is signed by the PHS representative and by Respondent and his counsel.

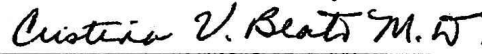
March 1, 2005
Date


Eric T. Poehlman, Ph. D.
Respondent

March 3, 2005
Date


Robert B. Hemley, Esq.
Reviewed by Counsel for Respondent

March 9, 2005
Date


Cristina V. Beato, M.D.
Acting Assistant Secretary for Health
for the Public Health Service
U.S. Department of Health and Human Services

- Attachments:
- A- Vermont Report
 - B- Grant Applications and Awards
 - C- Schedule of Publications for Retraction/Correction
 - D- Retraction letters