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To: <u>List NIH1102-L</u>

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Subject: Workform Update

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The workforms have been updated to incorporate the changes required by the following:

- NOT-OD-12-150, "Revision of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) to Include Synthetic Nucleic Acids and to Clarify Criteria for Section III-A-a Experiments,"
- NOT-OD-13-119: "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies,"
- NOT-OD-13-099 "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data,"
- NOT-OD-14-052 "Notice of Salary Limitation on Grant, Cooperative Agreements, and Contracts,"
- NOT-OD-14-053 "Notice of Legislative Mandates in Effect for FY 2014,"
- NOT-OD-14-062 "Notice of Additional Legislative Mandate in Effect for FY 2014 Restricting Pornography on Computer Networks," and
- The Consolidated Appropriations Act of FY 2014 (Public Law 113-76)

This update also fixes various broken links and other housekeeping changes. The updated files are dated 5/07/2014 and can be found on the NIH OAMP Internet at http://oamp.od.nih.gov/DGS/DGS-workform-information. The Document Generation System (DGS) can be accessed at: http://oamp.od.nih.gov/DGS explanation of the changes made to each workform.

I. CONTRACT

II. RFP

EXPLANATION OF CHANGES MADE TO THE CONTRACT:

- 1. Item 96, Page 41, Article B.15.b.3., is updated PRESCRIPTION ONLY to clarify the location of the list of exempted Nonprofit Organizations formally under Attachment III of OMB Circular A-122. This circular has been superseded by Title 2 of Code of Federal Regulations (CFR) Part 200.
- **2. Item 97, Page 42,** <u>Article B.15.b.3.</u> is updated to add Title 2 of the CFR, Part 220 which supersedes OMB Circular A-21, "Cost Principles for Educational Institutions."
- **3. Item 98, Page 42,** <u>Article B.15.b.3.</u>, is updated to add Title 2 of the CFR, Part 230 which supersedes "Cost Principles for Non-Profit Organizations (OMB Circular A-122)."
- **4. Item 116**, **Page 47**, Article C.2.a.5. Annual Technical Progress Report for Clinical Research Study Populations, is revised to update the title of required deliverable to Cumulative Inclusion Enrollment Report.
- 5. OLD Item 191, Page 80, Article G.6. Recipients Reimbursement Procedures, is deleted as it is no longer applicable. (*Note*: No New contracts can be awarded involving the offset of contract cost based upon the sale of research substances, living organisms, or research data.)
- 6. OLD Items 204-216, Pages 90-97, Article G.9. Letter of Credit Payment information, has been removed as it is no longer applicable. (*Note*: No new awards will use Letter of Credit (LOC) invoicing procedures. In order to process a payment through the payment management system (PMS) a sub-account must be associated with the award which is no longer supported by NBS. This does not impact previously awarded contracts.)
- 7. Item 245, Page 110, Article H.14. Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research), is revised in accordance with NIH Guide Notice: NOT-OD-12-150, "Revision of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) to Include Synthetic Nucleic Acids and to Clarify Criteria for Section III-A-a Experiments," dated September 11, 2012.
- 8. **NEW Item 249, Page 112,** Article H.18. Data Sharing in Genome-Wide Association Studies (GWAS), is added in accordance with NIH Guide Notice NOT-OD-13-119: "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies," dated January 25, 2008.
- 9. NEW Item 250, Page 112, Article H.19. Sharing HeLa Cell Whole Genome Sequence Data and Family Acknowledgement, is added in accordance with NIH Guide Notice NOT-OD-13-099 "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data," dated August 14, 2013.

10. NEW Item 268, Page 119, <u>Article H.37.</u> <u>Restriction on Pornography</u>, is added in accordance with the NIH Guide Notice: NOT-OD-14-062 "Notice of Additional Legislative Mandate in Effect for FY 2014, dated February 27, 2014 and the FY 2014 Consolidated Appropriations Act (P.L. 113-76).

- **11. Items 269 and 270, Page 119**, Article H.38. Gun Control and Article H.39. Certification of Filing and Payment of Taxes, are added in accordance with the NIH Guide Notice: NOT-OD-14-053 "Notice of Legislative Mandates in Effect for FY 2014," dated February 10, 2014 and the FY 2014 Consolidated Appropriations Act (P.L. 113-76).
- **12. OLD Item 312, Page 161**, Article H.57. Wage Rates (ORF ONLY), is deleted to remove duplicate information.
- **13. OLD Item 349, Page 191**, Article H.61.14. Grounds, Roads and Walkways (ORF ONLY), is deleted to remove duplicate information.
- **14. OLD Item 353, Page 194**, Article H.61.18. Release of Information (ORF ONLY), is deleted to remove duplicate information.
- **15. OLD Item 363, Page 198**, Article H.64.3. Product and Service Guarantee (ORF ONLY), is deleted to remove duplicate information.
- **16. Item 402, Page 259,** Article I.2.d. Alternate II of FAR Clause 52.215-2 Audit and Records-Negotiation, is updated PRESCRIPTION ONLY to include educational institutions or other non-profit organizations, in accordance with FAR 15.209.
- **17. Item 409, Page 260,** Article I.2.k. Alternate IV of FAR Clause 52.216-7 Allowable Cost and Payment, is updated PRESCRIPTION ONLY to clarify the location of the list of exempted Nonprofit Organizations under Attachment III of OMB Circular A-122. This circular has been superseded by Title 2 of CFR Part 200.
- **18. Item 432, Page 266,** Article I.2.hh. Alternate I of FAR Clause 52.232-25 Prompt Payment, is updated PRESCRIPTION ONLY to clarify instructions for use of this item.
- **19. Item 589, Page 297,** Article I.3.b.4. HHSAR Clause 352.231-70, Salary Rate Limitation, has been updated to include Public Law 113-76 and effective date in accordance with NIH Guide Notice: NOT-OD-14-052 "Notice of Salary Limitation on Grant, Cooperative Agreements, and Contracts," dated February 10, 2014.
- 20. OLD Item 669, Page 360, Section J-List of Attachments 3. Monthly Summary Sheet of

<u>Sales</u>, is deleted as it is no longer applicable. (**Note:** No New contracts can be awarded involving the offset of contract cost based upon the sale of research substances, living organisms, or research data.)

- 21. Item 662, Page 350, Section J-List of Attachments, Item 9: Cumulative Inclusion

 Enrollment Report PHS 398/2590 (Rev. 08/12), is updated to replace the Inclusion

 Enrollment Report, PHS 398/2590 (Rev 6/09). Note: The updated form is effective and must be used no later than October 1, 2014. Existing awards must incorporate use of this form. The former Inclusion Enrollment Report, PHS 398/2590 (Rev 6/09) will not be acceptable for use after September 30, 2014.
- **22. OLD Item 677**, **Page 361**, <u>Section J-List of Attachments, Item 11: Inclusion Table (Formerly Annual Technical Progress Report Format for Each Study), April 1998</u>, is removed as this form is no longer applicable.

Manual Maintenance: It is recommended that you print and replace the entire "Contract Handbook" file under DGS Handbook Files from the NIH OAMP Internet. (Please note that this document has been formatted for a XEROX Work Centre 7775. If using another printer definition, the page numbers listed above may differ on your document. However, the ITEM NUMBERS will always be the same.)

EXPLANATION OF CHANGES MADE TO THE RFP:

- 1. Item 70, Page 36, Article C.2.a.3. Annual Technical Progress Report for Clinical Research Study Populations, is revised to update the title of required deliverable to Cumulative Inclusion Enrollment Report.
- 2. **OLD Item 135, Page 69**, Article G.6. Recipients Reimbursement Procedures, is deleted as it is no longer applicable. (*Note*: No New contracts can be awarded involving the offset of contract cost based upon the sale of research substances, living organisms, or research data.)
- 3. OLD Items 148-160, Pages 75-82, Article G.9. Letter of Credit Payment information, has been removed as it is no longer applicable. (*Note*: No new awards will use Letter of Credit (LOC) invoicing procedures. In order to process a payment through the payment management system (PMS) a sub-account must be associated with the award which is no longer supported by NBS. This does not impact previously awarded contracts.)
- **4. Item 177, Page 92,** <u>Article H.13. Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research)</u>, is revised in accordance with NIH

Guide Notice: NOT-OD-12-150, "Revision of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) to Include Synthetic Nucleic Acids and to Clarify Criteria for Section III-A-a Experiments," dated September 11, 2012.

- 5. **NEW Item 182, Page 94,** Article H.17. Data Sharing in Genome-Wide Association Studies (GWAS), is added in accordance with NIH Guide Notice NOT-OD-13-119: "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies," dated January 25, 2008.
- 6. **NEW Item 183, Page 95,** Article H.18. Sharing HeLa Cell Whole Genome Sequence Data and Family Acknowledgement, is added in accordance with NIH Guide Notice NOT-OD-13-099 "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data," dated August 14, 2013.
- 7. **NEW Item 199, Page 100,** Article H.35. Restriction on Pornography, is added in accordance with the NIH Guide Notice: NOT-OD-14-062 "Notice of Additional Legislative Mandate in Effect for FY 2014," dated February 27, 2014 and the FY 2014 Consolidated Appropriations Act (P.L. 113-76).
- 8. NEW Items 200 and 201, Page 101, Article H.39. Gun Control and Article H.40.

 Certification of Filing and Payment of Taxes, are added in accordance with the NIH Guide Notice: NOT-OD-14-053 "Notice of Legislative Mandate in Effect for FY 2014," dated February 10, 2014 and the FY 2014 Consolidated Appropriations Act (P.L. 113-76).
- **9. OLD Item 243, Page 143**, <u>Article H.55. Wage Rates (ORF ONLY)</u>, is deleted to remove duplicate information.
- **10. OLD Item 280, Page 174**, Article H.59.14. Grounds, Roads and Walkways (ORF ONLY), is deleted to remove duplicate information.
- **11. OLD Item 284, Page 177**, Article H.59.18. Release of Information (ORF ONLY), is deleted to remove duplicate information.
- **12. OLD Item 294, Page 181**, Article H.62.3. Product and Service Guarantee (ORF ONLY), is deleted to remove duplicate information.
- **13. Item 334, Page 194,** Article I.2.d. Alternate II of FAR Clause 52.215-2 Audit and Records-Negotiation, is updated PRESCRIPTION ONLY to include educational institutions or other non-profit organization, in accordance with FAR 15.209.
- 14. Item 358, Page 200, Article I.2.bb. Alternate I of FAR Clause 52.232-25 Prompt Payment, is

- updated PRESCRIPTION ONLY to clarify instructions for use of this item.
- **15. Item 511, Page 231,** Article I.3.b.4. HHSAR Clause 352.231-70, Salary Rate Limitation, has been updated to include Public Law 113-76 and effective date in accordance with NIH Guide Notice: NOT-OD-14-052 "Notice of Salary Limitation on Grant, Cooperative Agreements, and Contracts," dated February 10, 2014.
- **16. Item 574.1, Page 284,** <u>Section J- Solicitation Attachments, Item 4: Proposal Intent Response Sheet (NCI ONLY)</u>, is updated to revise the link to the response sheet.
- 17. Item 574.2, Page 286, Section J-Technical Proposal Attachments, Attachment 11: Planned Enrollment Report, (PHS 398/2590, Rev 08/12), is updated to replace the Targeted/Planned Enrollment Table, (PHS 398/2590 Rev 06/09).
- **18. OLD Item 587.2, Page 294,** <u>Section J-Technical Proposal Attachments, Attachment 12:</u> <u>Inclusion Table (Formerly Annual Technical Progress Report Format for Each Study</u>, is removed as it is no longer applicable.
- **19. NEW Item 625, Page 321**, Article L.2.a.18.Certification of Filing and Payment of Taxes, is added in accordance with NIH Gide notice: NOT-OD-14-053 "Notice of Legislative Mandates in Effect for FY 2014," dated February 10, 2014 and the FY 2014 Consolidated Appropriations Act (Public Law 113-76).
- 20. Item 693, Page 370, Article L.2.b.4.h. Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research), is revised in accordance with NIH Guide Notice: NOT-OD-12-150, "Revision of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) to Include Synthetic Nucleic Acids and to Clarify Criteria for Section III-A-a Experiments," dated September 11, 2012.
- 21. NEW Item 705, Page 387, Article L.2.b.8.c. Data Sharing Policy for Genome-Wide

 Association Studies, is added in accordance with NIH Guide Notice: NOT-OD-07088 "Policy
 for sharing Data Obtained in NIH Supported or Conducted Genome-Wide Association
 Studies (GWAS)," dated January 25, 2008.
- 22. NEW Item 706, Page 388, Article L.2.b.8.d. Sharing HeLa Cell Whole Genome Sequence

 Data and Family Acknowledgement, is added in accordance with NIH Guide Notice: NOTOD-13-099 "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell
 Whole Genome Sequence Data," dated August 14, 2013.
- **23. Item 718, Page 401,** Article L.2.c.6 Salary Rate Limitation in Fiscal Year 2014, has been updated to revise the title from 2013 to 2014 add Public Law 113-76 and effective date in

accordance with NIH Guide Notice: NOT-OD-14-052 "Notice of Salary Limitation on Grant, Cooperative Agreements, and Contracts," dated February 10, 2014.

24. NEW Item 768, Page 433, Section M.13. Evaluation of Plan for Submission of Genome-Wide Association Study (GWAS) Data, is added in accordance with NIH Guide Notice: NOT-OD-07088 "Policy for Sharing Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)," dated January 25, 2008.

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