



# **DEPARTMENTAL CONTRACTS INFORMATION SYSTEM**

## **NATIONAL INSTITUTES OF HEALTH**

### **DATA ELEMENT USER MANUAL**

**October 2016**



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# I: NIH DCIS ITEM DEFINITIONS

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## ITEM 100 - TYPE OF PROCUREMENT ACTION Updated 04/2015

Coverage: N01, N02, N03, N43, N44

Definition: A code indicating the type of action reported.

Code	Definition
1	<b>New DEFINITIVE Contract</b> - Document covering new work; defining specifications, conditions, and negotiated clauses pertaining to a contractual agreement between the government and a non-government contractor. A new contract will obligate funds and specify the period of performance covered by the funds. "C" type Contract action.
2	<b>MAJOR Modification</b> - Contract modification, excluding options and incremental funding actions, and provides for additional supplies, equipment, or services. It obligates additional funds and may extend the period of performance.
3	<b>MINOR Modification</b> - A Contract modification that does not meet the tests for coding as Type of Procurement - 2 (Major Modification) or Type of Procurement - 7 (Exercise of Option). In general, actions such as cost overruns, change orders, no cost time extensions, administrative changes, changes to delivery schedules, etc., will be code 3 – Minor Modification. Actions that obligate funds may be coded 3 – Minor Modification, if no "new work" is involved. If Type of Procurement 2, 5, or 7 is met, use that particular type of Procurement code.
6	<b>Not Applicable</b> - Action does not fall in to any category listed.
7	<b>EXERCISE OF OPTION</b> - Action taken to implement the Government's rights to require the contractor to accomplish additional work under the contract as negotiated in the original contract.
8	<b>New Contract resulting from BASIC ORDERING AGREEMENT</b>
9	<b>New - SINGLE AWARD Indefinite Delivery Contract (IDC)</b> <b>New - MULTIPLE AWARD Indefinite Delivery Contract (IDC)</b> - Refers to multiple award Indefinite Delivery Contracts "delivery/task order contracts" under one solicitation.

<b>Code</b>	<b>Definition</b>
<b>B</b>	<b>Blanket Purchase Agreement (BPA)</b>
<b>G</b>	<b>Delivery/Task order (DO/TO)</b> - Awarded against a Federal Supply Contract (FSS) GSA - (External DO/TO); NIH wide Indefinite Delivery Contract Vehicle (IDC/IDV) (Internal DO/TO); COAC specific IDC/IDV (Internal DO/TO); or Government Wide Acquisition Contract (GWAC) (External DO/TO).
<b>P</b>	<b>Purchase Order</b> -Award placed on the Open Market (“P” type award).
<b>R</b>	<b>BPA call</b> – Award placed against an NIH BPA.

*Retired codes on any base or modification will be carried forward for historical purposes.*

## **ITEM 101 - ACTIVITY CODE - Updated 04/2015**

*Coverage: N01, N02, N03, N43, N44*

Definition: Codes established to identify NIH extramural activities supported by contracts.

<b>Code</b>	<b>Definition</b>
<b>N01</b>	<b>R&amp;D Contracts and contracts in direct support of R&amp;D</b> - to develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community. <i>(All contracts awarded by R&amp;D contracting components.)</i>
<b>N02</b>	<b>Station support contracts awarded by authorized Station Support IC</b> – (Non-R&D awards) contracting offices - to contract for intramural and extramural station support needs and provide resources to the intramural biomedical research programs within the NIH through negotiated contracts or sealed bids.
<b>N03</b>	<b>The Office of Logistics and Acquisition Operation and IC Delegated Offices-</b> to contract for a myriad of goods and services for the NIH such as NIH Blanket Purchase Agreements (BPAs), NIH Indefinitely Delivery Contracts (IDCs), NIHCATS, PICS, LTAS; Purchase Orders written by a Delegated Office; and BPA Calls; etc.
<b>N43</b>	<b>SBIR (Phase I)</b> - to support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product or service. These contracts may be awarded only to small business concerns.

<b>Code</b>	<b>Definition</b>
<b>N44</b>	<b>SBIR (Phase II)</b> - to support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be awarded only to small business concerns that were previously awarded a Phase I SBIR award (N43).

## ITEM 115 - HUMAN SUBJECTS INVOLVEMENT – Updated 01/2016

*Coverage: N01, N02, N03, N43, N44*

Definition: Codes to identify **involvement of human subjects** in research. Item 115 may not be blank.

<b>Code</b>	<b>Definition</b>
<b>10</b>	<b>Human Subjects Not Involved</b> - A final code applicable to contracts with activities that do not involve human subjects.
<b>30</b>	<b>Human Subjects Involved, Not Exempt from Regulations, No Concerns</b> - A final code applicable to contracts where human subjects are involved; none of the human subjects' protections exemptions apply; and no concerns were identified in the review evaluation of human subjects' involvement.
<b>44</b>	<b>Human Subjects Involved, Concerns</b> - An interim code applicable to contracts that involve human subjects, for which human subjects protections concerns were identified in the review evaluation process. Prior to making any award, proposals with a code 44 must be resolved through the Office of Extramural Programs (OEP), Office of Extramural Research, as mandated by NIH policy for grants and contracts (see: <a href="https://oer-sharepoint.nih.gov/hspas/HS%20Contracts/SitePages/Home.aspx">https://oer-sharepoint.nih.gov/hspas/HS%20Contracts/SitePages/Home.aspx</a> ). OEP will review the proposed resolution and will determine the appropriate human subjects' code. After resolution, code 54 indicates that the proposal has plans that meet the definition of non-exempt human subjects' research and that identified concerns (code 44) have been resolved. If appropriate to the proposal, human subjects codes of 10 or E1-7 may be designated if the resolution determines that human subjects are not involved (10) or are involved, but exempt from regulation (E1 – E7 choices). In no case is a code 30 appropriate to indicate resolution of a code 44. No award should be made without following this resolution process.

<b>Code</b>	<b>Definition</b>
<b>48</b>	<b>Human Subjects Involved, Concerns, Restricted Award</b> - An interim code that can be assigned only for contracts with a prior code of 44 but which must be awarded before concerns can be resolved (typically used at the end of the fiscal year). Such awards must be issued with terms and conditions that specifically instruct the awardee or sub-awardees not to conduct any activities supported by NIH funds that involve human subjects until the concerns have been resolved. Per NIH policy for grants and contracts, the award restrictions can be lifted by adhering to the resolution process described under the Code 44 definition.
<b>54</b>	<b>Human Subjects Involved, Not Exempt from Regulations, Concerns Resolved</b> - A final code that applies to contracts previously coded 44. Code 54 indicates that prior concerns have been resolved adhering to the process described under the code 44 definition.
<b>E1 – E7</b>	<b>Human Subjects Involved, Exempt from Regulations, No Concerns or Concerns Resolved.</b> A final code that meets the definition of human subjects' research; applicable only to human subjects involvement in research activities that are exempt from the regulations as described by the codes below. A claim of exemption must be justified in the proposal or prior to making an award. In general, most NIH supported human subjects research is not exempt. However, exemptions that are used for NIH research typically include Exemptions 1, 2, or 4; use exemption 7 only if more than one exemption applies. See list below for details on each of the exemptions. <i>None of the exemptions apply to research involving prisoners.</i>
<b>E1</b>	<b>Exemption 1</b> - Research conducted in an educational setting involving normal educational practice.
<b>E2</b>	<b>Exemption 2</b> - Research using educational tests, survey procedures; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. <i>This exemption for parts involving educational tests is applicable to children. However, this exemption for parts involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.</i>
<b>E3</b>	<b>Exemption 3</b> - Research using educational tests, survey procedures; interviews; or observations of public behavior, if the subjects are public officials or candidates for public office or federal law requires that confidentiality be maintained. <i>Not typically used in NIH research projects.</i>

<b>Code</b>	<b>Definition</b>
<b>E4</b>	<b>Exemption 4</b> - Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens; if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified. <i>Since 2008 guidance from OHRP, E4 is seldom applicable; most research with existing data or specimens is either non-exempt human subjects research (code 30) or not human subjects research (code 10).</i>
<b>E5</b>	<b>Exemption 5</b> - Research and demonstration projects that evaluate public benefit or service programs. <i>Not typically applicable to NIH research projects.</i>
<b>E6</b>	<b>Exemption 6</b> - Research that evaluates taste and food quality; or consumer acceptance of foods. <i>Not typically applicable to NIH research projects.</i>
<b>E7</b>	<b>Exemption 7</b> - NIH administrative designation for exemptions claims that involve two or more exemptions.

**NOTES:**

**Human subjects' research is defined** as research involving a living individual about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. There are six categories of human subjects' research activities that are considered very low risk for human subjects and are therefore exempt from the federal regulations. The codes for involvement and exemptions are explained above. Codes must be consistent with the scientific objectives of the project(s). For more information see <http://nih-extramural-intranet.od.nih.gov/d/nih/policies/hs/index.htm>.

**Involvement:** According to NIH [Manual Chapter 7410](#), proposals with plans to conduct non-exempt human subjects' research are instructed to include a human subjects section in the proposal that considers and discusses risks to human subjects, protections against risks, potential benefits of the research, and the importance of the knowledge to be gained. Additionally, proposals involving clinical trials must include a data and safety monitoring plan, and in some cases, describe a data and safety monitoring board.

**Exempt:** Proposals with plans to conduct exempt human subjects' research should indicate the applicable exemption category/categories and provide a justification for exemption that includes a description of human subjects' involvement and characteristics and sources of materials.

**No Involvement:** Proposals with plans that do not meet the definition of human subjects research but will make use of human materials and/or data, must clearly indicate why the proposed research does not involve human subjects; refer to definition for human subjects provided above.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

## **ITEM 115A - HUMAN EMBRYONIC STEM CELL (hESC) Use - New 01/2016**

*Coverage: N01, N02, N03, N43, N44*

Definition: Within the context of the NIH Guidelines, human embryonic stem cells (hESCs) are cells derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. NIH awardees may use only those hESCs that are posted on the [NIH Human Embryonic Stem Cell Registry](#). Any use of hESCs must be in accord with these guidelines prior to the obligation of NIH funds. This item must not be blank.

<b>Code</b>	<b>Definition</b>
-------------	-------------------

- |          |                                                               |
|----------|---------------------------------------------------------------|
| <b>Y</b> | Yes – Human Embryonic Stem Cells are proposed to be used.     |
| <b>N</b> | No – Human Embryonic Stem Cells are not part of the proposal. |

### **NOTES:**

When endorsing applications or proposals and progress reports submitted to NIH for projects, applicants and awardees must provide the following assurances:  
The hESC line(s) must be listed on the [NIH Registry](#). Any use must be consistent with the restrictions specified on the Registry.

If a specific hESC line from the NIH Registry cannot be identified at the time of submission, the applicant/awardee must provide a strong justification why a line cannot be identified at that time and a certification that a line from the NIH Registry will be used for projects supported with NIH funds. No NIH funds in an award may be used for any research involving human embryonic stem cells (hESCs) until the awardee has submitted to NIH information on the specific, approved hESC line(s) that will be used from the [NIH Human Embryonic Stem Cell Registry](#).

If proposing a line that is not on the NIH Registry, eligibility of specific cell lines for NIH funding must be established prior to NIH funding, which is initiated by submitting a [Request for Human Embryonic Stem Cell Line to be approved for Use in NIH Funded Research](#) (NIH Form 2890).

### Prohibitions

- If a line proposed for use is not on the NIH Registry, the line may not be used in NIH-funded research.
- For lines on the NIH Registry, the restrictions for use of each line used must be followed.



- Two specific types of research are prohibited: (1) hESCs or human induced pluripotent stem cells may not be introduced into non-human primate blastocysts and (2) research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.
- Derivation of stem cells from human embryos is not allowed by annual appropriations ban termed Dickey Wicker Amendment.

Guidance Resources -

NIH Grants Policy Statement, Sections 4.1.13 and 4.1.13.1,

[http://grants.nih.gov/grants/policy/nihgps\\_2013/nihgps\\_ch4.htm#human\\_stem\\_cell\\_research](http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch4.htm#human_stem_cell_research)

NIH Stem Cell information page, <http://stemcells.nih.gov/Pages/Default.aspx>

Grants resources include: Grants Management Staff, [http://nih-extramural-intranet.od.nih.gov/nih/how-to/hs\\_stem\\_cell\\_awards\\_hesc.html](http://nih-extramural-intranet.od.nih.gov/nih/how-to/hs_stem_cell_awards_hesc.html) and Program Staff, [http://nih-extramural-intranet.od.nih.gov/d/nih/topics/stemcells\\_special.html](http://nih-extramural-intranet.od.nih.gov/d/nih/topics/stemcells_special.html)  
[OEP-hs@mail.nih.gov](mailto:OEP-hs@mail.nih.gov)

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH hESC guidelines.**

## **ITEM 121 - AIDS AFFILIATED DOLLARS**

*Coverage: N01, N02, N03, N43, N44*

Definition: Reports the actual dollar amount for AIDS affiliated action(s) with an obligation. If dollars are reported in this field, then NIH Item 122 AIDS Affiliated Contract must be coded 'Y.'

## **ITEM 122 - AIDS AFFILIATED CONTRACT**

*Coverage: N01, N02, N03, N43, N44*

Definition: This code identifies whether or not the contract action is affiliated with AIDS research. If this action is coded 'Y,' then NIH Item 121 AIDS Affiliated Dollars must be completed.

<b>Code</b>	<b>Definition</b>
<b>Y</b>	Yes
<b>N</b>	No

## **ITEM 123 - PRIVACY ACT APPLICABLE**

*Coverage: N01, N02, N03, N43, N44*

Definition: Indicates whether a contract award is subject to the Privacy Act (P.L. 93-579).

Code	Definition
Y	Yes
N	No

## ITEM 126 – CLINICAL RESEARCH - CHILDREN (Formerly Children Representation) - Updated 01/2016

Coverage: N01, N02, N03, N43, and N44

Definition: Codes to identify the representation of children in clinical research studies as appropriate to the scientific objectives of the project(s). Applies to awards that are clinical research and meet the definition of human subjects' research (see Item 115 for definition). If Item 115 is 10 or E4, then leave Item 126 blank. For any other Item 115 code, Item 126 must not be blank.

### Code Definition

#### Block 1 Representation Proposed in Project:

- 1 Both Children and Adults
- 2 Only Children
- 3 No Children included
- 4 Representation of Children is unknown

#### Block 2 Scientific Acceptability/Unacceptability of Representation of Children:

- A** Acceptable: Representation of children is scientifically acceptable and recruitment has been realistically addressed, or a scientifically acceptable justification for exclusion has been provided.
- U** Unacceptable: Representation of children is unacceptable. Application fails to conform to NIH policy guidelines in relation to the scientific purpose of the study or fails to provide sufficient information; or does not adequately justify that certain groups are not included; or does not realistically address recruitment. Code U constitutes a bar to funding unless or until resolved by NIH staff.
- R** Resolved: Representation of children in the original proposal was of unacceptable but has been subsequently resolved.

#### NOTES:

“Children” is defined as an individual under the age of 18. For further policy guidance, see <http://grants.nih.gov/grants/policy/hs/children.htm>. Clinical research is defined as research with human subjects that are: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly

interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

## **ITEM 127 - CLINICAL RESEARCH – MINORITY - Updated 01/2016**

*Coverage: N01, N02, N03, N43, N44*

Definition: Codes to identify the representation of minority populations in clinical research studies as appropriate to the scientific objectives of the project(s). Applies to awards that are clinical research and meet the definition of human subjects' research (see Item 115 for definition). If Item 115 is 10 or E4, then leave Item 127 blank. For any other Item 115 code, Item 127 must not be blank.

<b>Code</b>	<b>Definition</b>
-------------	-------------------

Block 1 Representation Proposed in Project:

- |          |                                        |
|----------|----------------------------------------|
| <b>1</b> | Includes minorities and non-minorities |
| <b>2</b> | Includes only minorities               |
| <b>3</b> | Includes only non-minorities           |
| <b>4</b> | Minority representation unknown        |

Block 2 Scientific Acceptability/Unacceptability of Representation of Minority Populations:

- |          |                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>A</b> | Acceptable: Representation of race/ethnicity is scientifically acceptable and recruitment has been realistically addressed, or a scientifically acceptable justification for exclusion has been provided.                                                                                                                                                                                                             |
| <b>U</b> | Unacceptable: Representation for race/ethnicity is unacceptable. Application fails to conform to NIH policy guidelines in relation to the scientific purpose of the study, or fails to provide sufficient information; or does not adequately justify that certain groups are not included; or does not realistically address recruitment. Code U constitutes a bar to funding unless or until resolved by NIH staff. |
| <b>R</b> | Resolved: Representation for race/ethnicity in original proposal was unacceptable but has been subsequently resolved.                                                                                                                                                                                                                                                                                                 |

**NOTES:**

**Race and ethnicity guidance**, see

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

For policy guidance on other related issues see [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm).

**Clinical research is defined** as research with human subjects that are: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

## **ITEM 128 - CLINICAL RESEARCH – GENDER - Updated 01/2016**

*Coverage: N01, N02, N03, N43, N44*

Definition: Codes to identify the representation of gender in clinical research studies as appropriate to the scientific objectives of the project(s). Applies to awards that are clinical research and meet the definition of human subjects' research (see Item 115 for definition). If Item 115 is 10 or E4, then leave Item 128 blank. For any other Item 115 code, Item 128 must not be blank

<b>Code</b>	<b>Definition</b>
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Block 1 Representation Proposed in Project:

- 1 Includes both men and women
- 2 Includes only women
- 3 Includes only men
- 4 Gender representation unknown

Block 2 Scientific Acceptability/Unacceptability of Representation of Children:

- A** Acceptable: Representation for sex/gender is scientifically acceptable and recruitment has been realistically addressed, or a scientifically acceptable justification for exclusion has been provided.
- U** Unacceptable: Representation for sex/gender is unacceptable. Application fails to conform to NIH policy guidelines in relation to the scientific purpose of the study, or fails to provide sufficient information; or does not adequately justify that certain groups are not included; or does not realistically address recruitment. Code U constitutes a bar to funding unless or until resolved by NIH staff.

**Code      Definition**

**R** Resolved: Representation for sex/gender in original proposal was unacceptable but has been subsequently resolved.

**NOTES:**

**Gender representation** in research guidance, see [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

For policy guidance on other related issues see [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm).

**Clinical research is defined** as research with human subjects that are: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

**ITEM 129 - NIH-DEFINED PHASE III CLINICAL TRIAL – Updated 01/2016**

*Coverage: N01, N02, N03, N43, N44*

Definition: Indicates if the research is a Phase III clinical trial or if it is Clinical Research, but not a Phase III trial. Item 129 must be filled in if the research involves a Phase III clinical trial (Y) or is Clinical Research (N). If NIH Item 115 = 10 then Item 129 must be blank.

**Code      Definition**

**Block 1:**

**Y**      NIH-defined Phase III Clinical Trial  
**N**      Clinical Research - not an NIH-defined Phase III Clinical Trial

**NOTES:**

As of 2015, the option of “X” code definition is removed as of 2015. Data from prior years for this code definition option will be carried forward for historical purposes.

**A Phase II clinical trial, as defined** by NIH, is a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease

prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included.

**Clinical research is defined** as research involving human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

## **ITEM 136 – VERTEBRATE ANIMAL INVOLVEMENT (Formerly Animals in Research) – Updated 01/2016**

*Coverage: N01, N02, N03, N43, N44*

Definition: Code to indicate **involvement of vertebrate animals in research** as appropriate to the scientific objectives of the project(s). Item 136 may not be blank.

<b>Code</b>	<b>Definition</b>
<b>10</b>	<b>Vertebrate Animals Not Involved</b> - A final code applicable to contracts with activities that do not involve vertebrate animals.
<b>30</b>	<b>Vertebrate Animals Involved, No Concerns</b> - A final code that indicates that no concerns were identified in the review evaluation of vertebrate animal involvement.
<b>44</b>	<b>Vertebrate Animals Involved, Concerns</b> - An interim code applicable to contracts that involve vertebrate animals for which vertebrate animals involvement concerns were identified in the review evaluation process. Prior to making any award, proposals with a code 44 must be resolved through the Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research. OLAW will review the proposed resolution and will determine the appropriate vertebrate animal code. After resolution, code 54 indicates that identified concerns (code 44) have been resolved. If appropriate to the proposal, vertebrate animal codes of 10 may be designated if the resolution determines that vertebrate animals are not involved. In no case is a code 30 appropriate to indicate resolution of a code 44. No award should be made without resolving the code 44 to an appropriate code.
<b>48</b>	<b>Vertebrate Animals Involved, Concerns, Restricted Award</b> - An interim code is used in cases for which there are timing issues related to

<b>Code</b>	<b>Definition</b>
	obtaining the Animal Welfare Assurance and/or the IACUC Approval Verification at the end of the fiscal year. Such awards must be issued with terms and conditions that specifically instruct the awardee or sub-awardees not to conduct any activities that involve vertebrate animals until the proper documentation has been received. <b>This code may not be used if there are concerns as indicated by a code 44 for Item 136</b> ; in those cases, the concern must be resolved prior to making an award and then a code 48 may be used.
<b>54</b>	<b>Vertebrate Animals Involved, Concerns Resolved</b> - A final code that applies to contracts previously coded 44. Code 54 indicates that prior concerns have been resolved using the process described under the code 44 definition.

**NOTES:**

Definition of vertebrate animal: Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes (PHS policy definition). This includes use in generating custom antibodies; obtaining tissue from live vertebrate animals; and holding animals, which includes housing animals that currently are not participating in research but are maintained for potential research purposes or maintaining animal breeding colonies intended to be used in research. For further policy guidance, see <http://grants.nih.gov/grants/olaw/olaw.htm>.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

**ITEM 136A CHIMPANZEE INVOLVEMENT - New 01/2016**

Coverage: N01, N02, N03, N43, N44

Definition: This guidance applies to the chimpanzee species, *Pan Troglodytes*, and to chimpanzee biomaterials, which includes biological specimens that may have been obtained directly from a chimpanzee or collected indirectly during post-mortem procedures, habitat cleanup, or some other circumstance. A few examples of biomaterials include tissue, blood, bone marrow, urine, feces, saliva, hair, and other biological material. If any of these uses apply, then Item 136A must be checked “Yes” and the guidelines for special review as described below in the NOTES section must be followed for proposals in the competitive range. This item must not be blank.

<b>Code</b>	<b>Definition</b>
<b>Y</b>	Yes – Chimpanzees are involved
<b>N</b>	No – Chimpanzees are not involved



**NOTES:**

**Chimpanzee Research Use Form:** The form is designed to obtain information that allows the NIH to assess whether the proposed chimpanzee use meets the definition of “research exempt from CRUP consideration” or whether the proposed use of chimpanzees is “research subject to CRUP consideration” and therefore will be considered by the CRUP (see below). Completion of this form is a mandatory step for research involving chimpanzees. Failure to complete this form will prevent the agency from taking funding action on a research project involving chimpanzees or otherwise allowing the research to proceed.

**Review Advisory Bodies:** After the technical peer review and before award, for proposals involving use of chimpanzees or chimpanzee biomaterials that are 1) non-exempt from CRUP consideration and 2) and in the competitive range, two additional advisory bodies are required to provide a recommendation, the Chimpanzee Research Use Panel (CRUP) and the Council of Councils (CoC). The recommendation will be forwarded to the NIH Director of the awarding IC. The CRUP meets 3x per year in a set schedule; meetings are closed to the public to protect confidential and commercially sensitive information; the CoC review follows, they meet 3x per year as well. The recommendations from these bodies are considered by the appropriate IC Director who is responsible for making the final decision as to whether this project can proceed.

**References:** The NIH guide notice contains additional details on definitions, the basis for exempting certain chimpanzee research, and approximate dates the CRUP and CoC meet. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html> for more information.

**COs should consult with the technical representative to ensure the answer to this item is scientifically sound and in accordance with the NIH guidelines.**

**NOTES:**

For additional information go to: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-097.html>

**ITEM 144 – EMERGENCY MANAGEMENT OPERATIONS**

*Coverage: N01, N02, N03, N43, N44*

Definition: This code is **REQUIRED**. This code identifies contractors that can be used to maintain NIH mission essential functions during and immediately following natural disasters or human-caused hazards that have an adverse impact on NIH operations such as: earthquakes, hurricanes, tornadoes and floods, or biological, chemical, and explosive attacks affecting the NIH Bethesda Campus, the National Capital Region and other locations associated with NIH.

<b>Code</b>	<b>Definition</b>
Y	Yes – this is for emergency management operations



<b>Code</b>	<b>Definition</b>
<b>N</b>	No – this is NOT for emergency management operations

## **ITEM 145 – PAST PERFORMANCE REPORTING – 04/2015**

*Coverage: N01, N02, N03, N43, N44*

Definition: This code is **REQUIRED**. This code identifies any contract action (for goods or services) that fall at or above the dollar thresholds established per FAR Subpart 42.15 Contractor Performance Information, with regards to reporting past performance evaluations. Contractor Performance Assessment Reporting System (CPARS) collects and manages past performance evaluation as required by FAR 42.1502 Policy.

Contractor past performance thresholds:

- All contracts/orders for systems and non-systems (good and services) at or exceeding the simplified acquisition threshold - \$150,000.00 and greater;
- Architect-Engineering contracts/orders at or exceeding \$30,000.00 and all contracts/orders terminated for default;
- Construction contracts/orders at or exceeding \$650,000.00 and all contracts/orders terminated for default.

<b>Code</b>	<b>Definition</b>
<b>Y</b>	Yes – Past performance reporting is required per FAR 42.15.
<b>N</b>	No –Past performance reporting is not required.

**[NOTE: All contract modifications resulting in a Termination for Cause (T4C) or a Termination for Default (T4D) must be reported in FAPIIS via the CPARS website at [www.cpars.gov](http://www.cpars.gov). To gain access to FAPIIS for reporting terminations, please contact the Contract Data Management Program (CDMP) Help Desk at [cdmphelpdesk@mail.nih.gov](mailto:cdmphelpdesk@mail.nih.gov). IC Delegated offices shall not modify contract actions for termination. These types of issues/actions are handled by the Office of Acquisition within the COAC.]**

## II: NIH DCIS ITEM REQUIREMENTS – Activity Code Applicable to Items

ITEM	DESCRIPTION	SIZE	FORMAT	ACTIVITY CODE
100	Type of Procurement action	1	Alphanumeric	N01/N02/N03/N43/N44
101	Activity Code	3	Alphanumeric	N01/N02/N03/N43/N44
115	Human Subjects Involvement	2	Alphanumeric	N01/N02/N03/N43/N44
115A	Human Embryonic Stem Cell (hESC) Use	2	Alphanumeric	N01/N02/N03/N43/N44
121	AIDS Affiliated Dollars	10	Numeric	If Applicable
122	AIDS Affiliated Contract	1	Alphanumeric	If Applicable
123	Privacy Act Applicable	1	Alphanumeric	If Applicable
126	Clinical Research – Children (Formerly Children Representation)	2	Alphanumeric	N01/N02/N03/N43/N44
127	Clinical Research – Minority	2	Alphanumeric	N01/N02/N03/N43/N44
128	Clinical Research – Gender	2	Alphanumeric	N01/N02/N03/N43/N44
129	NIH-Defined Phase III Clinical Trial	2	Alphanumeric	N01/N02/N03/N43/N44
136	Vertebrate Animal Involvement (Formerly Animals in Research)	2	Alphanumeric	N01/N02/N03/N43/N44
136A	Chimpanzee Involvement	1	Alphanumeric	N01/N02/N03/N43/N44
144	Emergency Management Operations	1	Alpha Y/N	N01/N02/N03/N43/N44
145	Past Performance Reporting	1	Alpha Y/N	N01/N02/N03/N43/N44

## III: NIH DCIS ITEM REQUIREMENTS – Carried Forward Items

ITEM	DESCRIPTION	NEW AWARD	MODIFICATION
100	Type of Procurement action	Y	Y
101	Activity Code	Y	Carried forward from base
115	Human Subjects	Y	Carried forward from base
115A	Human Embryonic Stem Cell (hESC) Use	Y	Carried forward from base
121	AIDS Affiliated Dollars	If Applicable	If Applicable
122	AIDS Affiliated Contract	If Applicable	If Applicable
123	Privacy Act Applicable	Y	Carried forward from base
126	Clinical Research – Children (Formerly Children Representation)	Y	Carried forward from base
127	Clinical Research – Minority	Y	Carried forward from base
128	Clinical Research – Gender	Y	Carried forward from base
129	NIH-Defined Phase III Clinical Trial	Y	Carried forward from base
136	Vertebrate Animal Involvement	Y	Carried forward from base

<b>ITEM</b>	<b>DESCRIPTION</b>	<b>NEW AWARD</b>	<b>MODIFICATION</b>
136A	Chimpanzee Involvement	Y	Carried forward from base
144	Emergency Management Operations	Y	Carried forward from base
145	Past Performance Reporting	Y	Carried forward from base

#### IV: NIH DCIS ITEM REQUIREMENTS – Number of Characters per Item

<b>ITEM</b>	<b>ITEM NAME</b>	<b>MAX NUMBER OF CHARACTERS</b>
100	Type of Procurement Action	1
101	Activity Code	2
115	Human Subjects	2
115A	Human Embryonic Stem Cell (hESC) Use	1
121	AIDS Affiliated Dollars	10
122	AIDS Affiliated Contract	1
123	Privacy Act Applicable	1
126	Clinical Research – Children (Formerly Children Representation)	2
127	Clinical Research – Minority	2
128	Clinical Research – Gender	2
129	NIH-Defined Phase III Clinical Trial	2
136	Vertebrate Animal Involvement (Formerly Animals in Research)	2
136A	Chimpanzee Involvement	1
144	Emergency Management Operations	1
145	Past Performance Reporting	1

## V: NIH DCIS ITEM EDITS

<b>ITEM</b>	<b>EDIT</b>
<b>100</b>	Required on all actions; N01, N02, N03, N43, N44. Field may not be blank. Changes with Modification.
<b>101</b>	Required on all actions; N01, N02, N03, N43, and N44. Field may not be blank. Field carried forward and editable on all modifications.
<b>115</b>	Required on all actions; N01, N02, N03, N43, and N44. Field may not be blank. Field Carried forward and editable on all modifications.
<b>115A</b>	Required on all actions; N01, N02, N03, N43, and N44. Field carried forward and editable on all modifications.
<b>121</b>	Required on all actions; N01, N02, N03, N43, and N44 if NIH Item 122 AIDS Affiliated Contract = 'Y.'
<b>122</b>	Required on all actions; N01, N02, N03, N43, and N44 if NIH Item 121 AIDS Affiliated Dollars is > \$0.
<b>123</b>	Required on all actions; N01, N02, N03, N43, and N44. Field may not be blank. Field carried forward on all modifications.
<b>126</b>	Required for N01, N02, N03, N43, and N44 base awards only. Field carried forward and editable on all modifications. If NIH Item 115 Human Subjects = '10' or 'E4' then NIH Item 126 Clinical Research – Children must be blank.
<b>127</b>	Required for N01, N02, N03, N43, and N44 base awards only. Field carried forward and editable on all modifications. If NIH Item 115 Human Subjects = '10' or 'E4' then NIH Item 127 Clinical Research – Minority must be blank.
<b>128</b>	Required for N01, N02, N03, N43, and N44 base awards only. Field carried forward and editable on all modifications. If NIH Item 115 Human Subjects = '10' or 'E4' then NIH Item 128 Clinical Research – Gender must be blank.
<b>129</b>	Required for N01, N43, and N44 base awards only awards. Field carried forward and editable on all modifications. Blank for N02 and N03 awards.
<b>136</b>	Required on all actions; N01, N02, N03, N43, and N44. Field carried forward and editable on all modifications.
<b>136A</b>	Required on all actions; N01, N02, N03, N43, and N44. Field carried forward and editable on all modifications.
<b>144</b>	Required on all actions; N01, N02, N03, N43, and N44. Field carried forward and editable on all modifications.

**ITEM    EDIT**

**145**      Required on all actions; N01, N02, N03, N43, and N44. Field carried forward and editable on all modifications.

**VI: DISABLED NIH DCIS ITEMS – Effective April 2015**

**ITEM    ITEM NAME**

- 102**      ADMINISTERING IC, SERIAL NUMBER, and SUFFIX
- 103**      FORMER NUMBER
- 104**      ADB CONTRACT NUMBER
- 105**      DATE - ACTION EFFECTIVE
- 106**      FISCAL YEAR
- 107**      DOLLARS FUNDED TO DATE
- 108**      DOLLARS - TOTAL IN SUBCONTRACTING PLAN
- 109**      DOLLARS - SUBCONTRACTING PLAN, SMALL BUSINESS GOAL
- 110**      DOLLARS - SUBCONTRACTING PLAN, DISADVANTAGED BUSINESS GOAL
- 111**      DOLLARS - SUBCONTRACTING PLAN, WOMAN-OWNED BUSINESS GOAL
- 112**      DOLLARS - SUBCONTRACTING PLAN, HUBZONE GOAL
- 113**      DOLLARS - SUBCONTRACTING PLAN, VETERAN'S GOAL
- 114**      DOLLARS - SUBCONTRACTING PLAN, DISABLED VETERANS GOAL
- 116**      SIGNAL - LATEST RECORDED CONTRACT ACTION
- 117**      DATE - END OF CURRENT FUNDING PERIOD
- 118**      AGENT CODE
- 119**      COMPETITIVE SERVICE CENTER
- 120**      SBIR RESEARCH TOPIC CODE
- 124**      GOVERNMENT PROPERTY
- 125**      CHILDREN
- 130**      EXCEPTION TO TRACKING
- 131**      CONTRACTING OFFICER NAME
- 132**      INDICATOR - TASK ORDER ON MASTER AGREEMENT

ITEM	ITEM NAME
133	RFP/IFB NUMBER
134	DATE CONTRACT ADMINISTRATIVELY CLOSED
135	FCRDC or NITAAC INDICATOR
137	DOLLARS OBLIGATED ON ACTION
138	PROGRAM CLASSIFICATION CODE
139-142	COMMON ACCOUNTING NUMBER (CAN) TABLE
143	DELEGATED PROCUREMENT

**ALL SUBCONTRACTING PLAN DOLLARS SHALL BE ENTERED BY THE CONTRACTOR via eSRS see website for additional information [HTTP://WWW.ESRS.GOV](http://www.esrs.gov)**

*RETIRED Codes on any base or modification will be carried forward for historical purposes.*

## CHART 1 WHO DO I CALL FOR HELP?

<b>CDMP Representative</b>	<b>Office of Acquisitions</b>	<b>OA Director</b>	<b>Customer(s)</b>	<b>Contracting Office Code</b>
Dee Dansby	CC	Susan Nsangou	CC	269
Paulette Smith	NCI	Acting – Teresa Baughman	NCI NCCIH	261 305
David Redd	NHLBI	John Taylor	NHLBI CSR NIAMS NIDCR NIBIB NHGRI	268 307 264 274 303 302
Malinda Mullen	NIAID	Charles Grewe	NIAID HHS Biodefense	272 266
David Redd	NICHHD	Olga Acosta-Polston	NICHHD NIAAA FIC NIDDK	275 281 308 267
David Redd	NIDA	James Quinn	NIDA NINDS NIMH NIA NCATS	271 265 278 311 319
Malinda Mullen	NIEHS	Charles Conrad	NIEHS NIEHS (R&D)	273 291
Paulette Smith	NLM	Daniel Hartinger	NLM CIT OD	276 310 317
Dee Dansby	OLAO	Greg Holliday	OLAO DRA NIMHD NEI NIDCD NIGMS ORS OD NINR BPA Branch	263 260 313 301 304 306 318 317 312 263
Paulette Smith	ORF	Sharon Bruce	A&E Construction Leasing New Facilities - Support Services	292 314 315

<b>CDMP Representative</b>	<b>Office of Acquisitions</b>	<b>OA Director</b>	<b>Customer(s)</b>	<b>Contracting Office Code</b>
Malinda Mullen	NITAAC	Acting – Bridget Gauer	NITAAC	316

For assistance, please submit Help Desk tickets via the NIH IT help desk at <http://itservicedesk.nih.gov/Support/>

## CHART 2 NEW NIH ACTIVITY ADDRESS CODES (AAC)

Effective April 1, 2016, the Federal Acquisition Regulation Subpart 4.6 Contract Reporting, requires the use of new Activity Address Codes (AACs) to identify both contracting office (DCIS/FPDS Item **4B Contracting Office Code\***) and program/funding office (DCIS/FPDS Item **4D Program/Funding Office Code\*\***) for all procurement awards captured in the Federal Procurement Data System-Next Generation (FPDS-NG).

Acquisition staff will need to know both the contracting office code (FPDS 4B\*) as well as the program/funding office code (FPDS 4D\*\*) to record their actions in DCIS/FPDS-NG. Attached is an Excel spreadsheet which lists the AACs for NIH.

- Actions with a Date Signed (FPDS Item 2A) of March 31, 2016 or earlier, will use the codes in column B of the attached spreadsheet.
- Actions with a Date Signed (FPDS Item 2A) of April 1, 2016 and forward will use the codes in column C of the attached spreadsheet.

\*Item FPDS 4B Contracting Office Code – Enter the code for the contracting office that awarded or is responsible for the action.

\*\*Item FPDS 4D Program/Funding Office Code – Enter the code that provides the majority of funds being obligated on the action.

Institute/Center	Previous Contracting Office Code	New Activity Address Code (AAC)
BPA Branch	263	75N980
CC	263	75N900
CIT	310	75N97A
CSR	307	75N92A
FIC	308	75N94C
NCATS	319	75N95C
NCCIH	305	75N91A
NCI	261	75N910



Institute/Center	Previous Contracting Office Code	New Activity Address Code (AAC)
NEI	301	75N98B
NHGRI	302	75N92E
NHLBI	268	75N920
NIA	311	75N95D
NIAAA	281	75N94B
NIAID (HHS Biodefense)	266/272	75N930
NIAMS	264	75N92B
NIBIB	303	75N92D
NICHD	275	75N940
NIDA	271	75N950
NIDCD	304	75N98C
NIDCR	274	75N92C
NIDDK	267	75N94A
NIEHS (R&D)	273/291	75N960
NIGMS	306	75N98D
NIH-OD	317/318	75N98E
NIMH	278	75N95B
NIMHD	313	75N98A
NINDS	265	75N95A
NINR	312	75N98F
NITAAC	316	75N981
NLM	276	75N970
OLAO	260/263	75N980
ORF	292/314/315	75N990