
Appendix II: Human Subjects Research Landscape Project Methods

In order to respond to President Obama's charge, the Commission recognized that a critical first step would be to define and understand the landscape of "scientific studies supported by the Federal Government." Finding no comprehensive publicly available source for this information, the Commission asked the 18 federal departments and agencies that have adopted the Common Rule—and therefore were likely to support scientific studies with human subjects—to provide basic project-level data for department/agency-supported human subjects research in Fiscal Year 2006 to Fiscal Year 2010. These agencies are listed in Table I.1¹ and an overview of the Human Subjects Research Landscape Project is displayed in Figure II.1.

Commission Chair, Dr. Amy Gutmann, wrote to department/agencies regarding this request in early spring 2011. An example of the letter is provided in Figure II.2. As necessary, Commission staff clarified the data request with contacts at departments/agencies. The Commission asked departments/agencies to provide only data they maintained and that was readily available so that the Commission could respond to President Obama's charge in a timely manner. A summary of responsive data received is included in Table II.1.

Database and Electronic Data Collection Tools

The Commission engaged a contractor, SRA International, Inc. (SRA), to develop 1) an electronic data collection tool to assist departments/agencies in gathering data, 2) a website through which department/agencies could submit data (www.bioethics-rpd.net), and 3) a database in which to store these data, called the "Research Project Database" (RPD). The Commission, through SRA, also established a Help Desk to provide technical assistance to departments/agencies.

The Commission provided departments/agencies with the option to collect their data either in Microsoft Excel or XML format, and provided templates and instructions for each. (The data fields and instructions are listed in Table II.2.) These data collection tools were equipped with built-in data validations so that departments/agencies could pre-screen their data prior to upload to the RPD.

Registered department/agency users could access the password-protected RPD website to upload, delete, or review submitted data. Department/agency users uploaded data in a separate file for each fiscal year. The system validated all data fields upon upload, for example, to confirm that each “Study ID” (i.e., unique study identification number) was unique in a single fiscal year (and, therefore, that each study was listed only once per year). If data fields were found to have errors, the system provided the department/agency with an automated report explaining the errors encountered during the data validation along with a request to resubmit the data. If a department/agency did not enter “Site Data” (i.e., site country, number of sites per country, and number of participants per country) or “Other Federal Funding Data” (i.e., source of other federal funding and other federal funder identifier, such as an award number), the system displayed “warnings” asking the department/agency to either add these data, or to confirm that these data were not maintained or readily available. The department/agency could then add these data and resubmit, or confirm that these data were not maintained or readily available to bypass the warnings and submit the file as-is.

If a department/agency supported no human subjects research in a given fiscal year, Commission staff asked for written confirmation of that fact.²

Uploaded data were stored in an SRA-hosted SQL Server database. The original uploaded Excel and XML documents were also stored and retained on an SRA server. Following the data collection period, SRA exported the entire data set from the RPD into three “comma separated values” (.csv) files. The export process and naming conventions are detailed in Table II.3. Data were organized in three separate tables: (i) “study records” that provides project-level data; (ii) “site records” that captures Site Data; and (iii) “other federal funding records” that captures Other Federal Funding Data. A unique ID field common to all three tables allowed for linkage among them.

In the Human Subjects Research Landscape Project, the term “project” refers to a single line of data entered by a department/agency, whereas “study” refers to an individual human subjects research protocol or activity; and “award” refers to an extramural award, such as a grant or contract, which may fund more than one “study.” The Commission defined “project” broadly in order to accommodate different department/agency record-keeping

systems. Although study-level data were preferred, some departments and agencies provided award-level data for extramural human subjects research. Additional definitions are listed in Table II.2.

Data Cleaning

Generally, if department/agency data passed the system's validations, the Commission accepted these submissions as-is. Nonetheless, minimal data cleaning was performed to facilitate analyses, which is detailed below.

In the SQL database, SRA performed one cleaning task:

- *Incorrect "unit" names.* Departments/agencies could specify individual "units" for data submission. For example, NASA submitted data for four units: Ames Research Center, Johnson Space Center, Kennedy Space Center, and Langley Research Center. In total, six submitted files incorrectly omitted a unit designation. SRA corrected these unit names in the SQL database.

Prior to initial analysis of the data, consultant statisticians, Norman P. Ross, M.S., Ph.D. and Philip Kalina, M.A., ran a number of checks on the data tables, including making sure that:

- All variables were in columns and observation records were in rows;
- There was one unique id for each project record; and
- All missing data had been identified and the appropriate code had been inserted in missing data cells.

Once the data were screened and checked, statisticians performed a comprehensive data cleaning process on the analytical database to remove anomalies that could be detected through statistical screening; for example, looking for missing values and contradictions within or between records, duplicates, and outliers. Before final analysis, the data were further cleaned as follows:

- *Projects removed from the analysis dataset.* Some departments/agencies noted in the "Other Comments" field that they were unable to delete or remove records from their data submissions. Based on a manual review of these comments, a small number of awards (eight) were moved out of the analysis dataset.

- *Addition of data submitted after close of the database.* HHS-ASPR supplemented its data submission after the database was closed. So that all data submitted to the Commission were accounted for in its analysis, these data were added to the SQL database and provided as a supplemental export to the statisticians to incorporate into the analysis dataset. In addition, one agency (Agricultural Research Service [USDA-ARS]) inadvertently uploaded the same FY06 file for two different units. When brought to its attention, USDA-ARS deleted the duplicate file and submitted corrected data after the database closed. These data were provided as a supplemental export to the consultant statisticians to incorporate into the analysis dataset. Finally, although DOD submitted aggregate data before the database closed, it submitted project-level data to the database after it was closed. These data also were provided as a supplemental export to the consultant statisticians to incorporate into the analysis set.
- *Units combined.* In the interest of simplifying and presenting data, some units were combined before analysis. The specific changes were:
 - Within USDA, all units starting with “ARS” were combined into one unit, Agricultural Research Service.
 - Within HHS, all units starting with “IHS” were combined into one unit, Indian Health Service.
 - Within HHS, all units starting with “National Institutes of Health” were combined into one unit, National Institutes of Health. NIH data were submitted in several parts due to limitations on the number of rows of data that could be entered into the Excel template. Because these divisions were arbitrary and not reflective of actual functional operating units, they were combined.
 - Within DOJ, all units starting with “OJP” were combined into one unit, Office of Justice Programs.
 - Within VA, all units were ignored. Like NIH, VA submitted its data in several parts due to limitations on the number of rows of data that could be entered into the Excel template. Because these divisions were arbitrary and not reflective of actual functional operating units, they were combined.

- Within DOD, all units were ignored under the same reasoning.
- *Study classification.* Where not apparent from department/agency data submissions, Commission staff asked for clarification about whether the submitted data were award level (i.e., each line of data corresponded an award) or study level (i.e., each line of data submitted corresponded to a single study). An additional column, “Study or Award Level,” was added to the analysis dataset. Valid entries for this column were A (Award), S (Study), Q (Equivalent, where one award always supports a single study), U (Unclassifiable), and I (Intramural).
- *Site country data.* A few departments/agencies were able to state that all projects for which no country data were submitted took place in the United States.³ These records were updated, and blanks were replaced with “United States.”
- *Awardee institution names.* Departments/agencies submitted “Award Institution” names in a variety of formats (e.g., with differences in abbreviations, misspellings, etc.). Commission staff conducted a manual review of institution names and corrected obvious typographical errors and standardized institution names.
- *Awardee institution countries.* Awardee institution countries were manually added to the analysis dataset based on publicly available sources. If the awardee institution country could not be determined with certainty, the country was assigned a value of “Unknown.” If a value other than an institution name was found in the “Award Institution” field (e.g., a department/agency mistakenly entered an abstract in this column), the country was assigned a value of “Invalid.” If “N/A” had been entered in the institution name column, the country was assigned a value of “N/A.”
- *Total extramural award amount.* “N/A” was not an accepted response in the “Total Award \$ in FY” field. Because some department/agencies indicated that, although they entered “0” in the Total Award field, these data, in fact, were not available,⁴ a new column, titled ExtraAwardFundVal0 (i.e., indicating whether “0” in the Total Award field was a “valid” 0 or an indication that data was not available) was added to the analysis dataset, where acceptable values were Y (Yes), N (No), and U (Unknown).

- *Extramural/intramural/both indication clarification.* NSF initially classified all projects as “both” in the “Intramural or Extramural” field (i.e., with both intramural and extramural components), but later clarified that all reported projects are extramural. This change was made accordingly in the analysis dataset.⁵
- *Duplicate awards.* Instances appeared in the database where, for a given fiscal year, a department/agency submitted lines of study-level data with identical award IDs and total award amounts. This is not necessarily indicative of an error, as a single award can fund multiple studies. Commission staff checked the affected awards in a publicly available database, USASpending.gov. If the award amount in the RPD matched the award amount in USASpending.gov, it was assumed that the award amount in the database did indeed reflect the total award amount and should not inadvertently be counted twice when making overall funding calculations. Because of these concerns, extramural funding tabulations were run in two ways: (i) by adding all total award amounts; and (ii) by adding all total award amounts except those identified as duplicates through the above process.

Following these cleaning processes, a final dataset was ready for analysis, tabulation, and statistical report generation.

Data Analysis

Following completeness and accuracy checks, the .csv files were read into a Microsoft Access database for analysis. The tables produced (included in Chapter 2 and Appendix I to this report) are based on descriptive tabulations and computations of relevant summary data. The descriptive summaries and tabulations presented provide a broad “landscape” view of the human subjects research activities being undertaken by participating departments/agencies both in the United States and in other countries. Tabulations were provided for Fiscal Year 2006 to Fiscal Year 2010 for all departments/agencies that provided data.

Empirical Advisory Group

The Commission convened the Empirical Advisory Group (EAG) to assist the Commission with its empirical work, comprised of two Commission members and six outside experts in bioethics, statistics, clinical trials, and qualitative research (listed in Table II.4). The EAG met on multiple occasions to discuss the Human Subjects Research Landscape Project and other empirical approaches that might be used to inform the Commission's response to the President's charge. The EAG advised the Commission concerning analysis and interpretation of the Human Subjects Research Landscape Project data.

Limitations

The Human Subjects Research Landscape Project provides information that characterizes human subjects research projects supported by the federal government. While these data are extensive, they must be interpreted with some limitations in mind. These limitations include:

The information was reported by departments/agencies and was not independently audited or verified. As such the completeness of reporting cannot be verified.⁶

Each department/agency determined what constituted "relevant" work, which may have contributed to reporting bias as well as difficulty in comparing data across departments/agencies. The Commission asked departments/agencies to report all human subjects research projects, but definitions of "human subjects research" can vary across departments/agencies.⁷

Not all departments/agencies provided all of the information requested. Accordingly, there may be distorted estimates of some summary statistics (e.g., total number of studies, funding/award information), further complicating making meaningful comparison within and between departments/agencies as well as comparisons over time. In addition, NIH provided two sets of intramural data retrieved from two different databases (IMPACII and Protrak), which have overlaps. Without looking through both sets of data individually, NIH could not be sure of the extent of the overlap or eliminate overlaps.⁸ Thus, NIH intramural projects may thus be over-reported in these analyses.

A single extramural award can fund multiple studies. Thus, a department/agency's total extramural funding, calculated by summing relevant "Total Award \$" fields, is likely an overestimate to the extent that the award funding reported may fund more projects than the single project listed.⁹ Moreover, because some departments/agencies submitted award-level data and others submitted project-level data, the number of "projects" reported in the database is likely an underestimate of the total number of human subjects studies supported by the government because some projects may correspond to awards that fund more than one study.

The Human Subjects Research Landscape Project does not provide a robust understanding of research that was not reported because it is classified or because of national security concerns.¹⁰

Endnotes

- ¹ Because HHS is the largest government supporter of human subjects research, the Human Subjects Research Landscape Project results are often presented in more detail for HHS Operating Divisions. Table I.1 also lists the HHS Operating Divisions that responded to the Commission's data request.
- ² E-mail Correspondence: Theron Pride, DOJ, to Michelle Groman, PCSBI. (2011, August 2 and 2011, September 13); Phillip Smith, IHS, to Michelle Groman. (2011, September 20); Lori Putman, DOT, to Michelle Groman, PCSBI. (2011, October 17); Mark Grabowsky, NVPO, to Michelle Groman, PCSBI. (2011, October 3); Jeffery Rodamar, ED, to Michelle Groman, PCSBI. (2011, September 6); Richard Legault, DHS, to Michelle Groman, PCSBI. (2011, September 15); Mala Adiga, DOJ, to Michelle Groman, PCSBI. (2011, August 9; 2011, September 7, 2011; and 2011, September 12); MJ Fiocco, DOT, to Michelle Groman, PCSBI. (2011, August 26); Krista Fletcher, SAMHSA, to Michelle Groman, PCSBI. (2011, August 2); Amy Farb, OAH, to Michelle Groman, PCSBI. (2011, August 5); Memorandum from Jacquelyn White, CMS, to Dawn Smalls, CMS, Request from the Presidential Commission for the Study of Bioethical Issues for Information on Human Subjects Scientific Research OS#071220111044, July 26, 2011.
- ³ E-mail Correspondence: Valerie Bonham, PCSBI, to Kevin Neary, HUD. (2011, October 7); Alan Trachtenberg, IHS, to Michelle Groman, PCSBI. (2011, September 28); Barbara DeCausey, CDC, to Michelle Groman, PCSBI. (2011, October 14). Preeti Kanodia, HRSA, to Michelle Groman, PCSBI (2011, November 8). NIH explained that for awards to domestic institutions, it reported "United States" in the site country field; for awards to foreign institutions, it reported the name of the awardee country in the site country field; and for awards to domestic institutions that have a foreign component; it reported "United States" and "Foreign" in the site country field. Sarah Carr, NIH, to Michelle Groman, PCSBI. (2011, October 5). E-mail Correspondence. Thus, NIH projects understood as "foreign" (as opposed to "mixed," or with foreign and domestic components) represent direct awards to foreign institutions. Where a project reported no Site Data, a placeholder site record was created with blank values for country, sites, and participants. In addition, duplicate site records were removed from the analysis dataset; a small number of almost-exact duplicates were removed upon agency confirmation. Francis Chesley, AHRQ, to Michelle Groman, PCSBI. (2011, November 2). E-mail Correspondence.
- ⁴ Some departments/agencies and units indicated that they could not link some or all protocol-level data with extramural funding data. Letter from Richard Legault, DHS, to Valerie Bonham, PCSBI. (September 29, 2011). E-mail Correspondence: Michelle Groman, PCSBI, to Patty Decot, DOD. (2011, October 27); Jeffery Rodamar, ED, to Michelle Groman, PCSBI. (2011, September 6); Rhondalyn Cox, FDA, to Michelle Groman, PCSBI. (2011, August 5 and 2011, October 14); Barbara DeCausey, CDC, to Michelle Groman, PCSBI. (2011, October 13); Jeffrey Hill, NASA, PCSBI. (2011, August 2).
- ⁵ Michelle Groman, PCSBI, to Myron Gutmann, NSF. (2011, October 24). E-mail Correspondence.
- ⁶ For example, it cannot be stated with certainty that if the same project was reported in several fiscal years that the award amount, number of participants, etc., listed in each fiscal year data

set was the amount/number specific to that fiscal year or if the totals were repeated year after year. Similarly, for awards where ARRA funding was indicated, it is unclear whether the reported award amount is entirely or partially ARRA funded.

- ⁷ Other terms may be defined differently by different agencies as well, such as “extramural” and “intramural.”
- ⁸ Sarah Carr, NIH, to Valerie Bonham, PCSBI. (2011, October 5). E-mail Correspondence.
- ⁹ Total extramural funding was calculated by summing relevant “Total Award \$” fields rather than relevant “Total Extramural Study \$” fields because the mean response rate for this latter variable was less than 17 percent.
- ¹⁰ For example, the CIA did not submit project-level data to the RPD because “the application by the C.I.A. of certain research results may implicate intelligence sources and methods, and thus cannot be discussed in the public domain.” Letter from V. Sue Bromley, Associate Deputy Director, Central Intelligence Agency to Amy Gutmann, Ph.D., Chair, Presidential Commission for the Study of Bioethical Issues. (November 15, 2011). The CIA confirmed that all CIA-sponsored human subjects research is conducted in the United States – not abroad. CIA personnel also met with Commission staff to discuss the CIA’s human subjects research portfolio and made records available to appropriately cleared Commission staff. In addition, the Department of Energy provided de-identified data about three human terrain mapping projects that have not been accounted for in the RPD.

Figure II.1 Human Subjects Research Landscape Project Overview

	COMMISSION	DEPT/AGENCY	SRA	STATISTICIANS	EAG
March 2011 ↓	PREPARATION Identify Common Rule depts/agencies Request dept/agency liaisons Data request Work with SRA to develop tools for data upload Work with dept/agency liaisons to clarify data request	Work with Commission staff to clarify data request Initial data collection	Develop XML and Excel tools		
			Develop web interface		
			Develop and maintain SQL database		
			Establish help desk		
DATA GATHERING Respond to dept/agency questions	Collect data via XML or Excel Dept/agency users register for RPD website Files uploaded to the RPD by dept/agency users	Respond to dept/agency questions			
ANALYSIS Work with statisticians to clean and analyze data			Data cleaning		
			Export data	Receive .csv export from SRA	Advise Commission about data analyses and interpretation
				Data checks	
				Export data to Microsoft Access	
				Additional data cleaning	
			Statistical analysis and tabulations		
Dec. 2011 ↓					

Figure II.2 Sample Letter from Dr. Amy Gutmann to Department/Agency Liaison



PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

March 25, 2011

Dr. Warren Lux
Human Subjects Research Review Official
Director of the Program in Human Research Ethics
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Dr. Lux:

As you know, President Obama charged the Presidential Commission for the Study of Bioethical Issues (the "Commission") to conduct a "thorough review of human subjects protection to determine if Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government."¹ Towards this end, the Commission is seeking comprehensive and accurate data about the volume of scientific studies supported by the Environmental Protection Agency (the "Agency") that involve human participants and information about the standards for protection of human participants, both domestically and internationally. Specifically, the Commission is asking the Agency to:

1. Provide nature, volume, and spending data (meaning dollar amounts and number of studies, sites, and participants) for scientific studies supported by the Agency that involve human subjects for fiscal years 2006-2010, as well as any related additional volume and/or trend data that the Agency may keep. Please provide data for studies occurring domestically and studies occurring internationally, and distinguish data by country. The Commission staff is developing an electronic means through which to collect these data in a uniform and efficient manner, and will contact you regarding this system as soon as it is available. Enclosed, please find a table detailing the data fields that will be requested in the electronic system.
2. Identify the Agency's regulations that guard the health and well-being of human participants in scientific studies supported by the Agency, and any additional guidances, policies, summaries, or explanations of the same that the Agency may distribute.

¹ The complete charge is available at <http://www.whitehouse.gov/the-press-office/2010/11/24/presidential-memorandum-review-human-subjects-protection>.

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Dr. Warren Lux
March 25, 2011
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3. Identify the international standards with which the Agency complies or that it considers in guarding the health and well-being of human participants in scientific studies supported by the Agency, and any additional guidances, policies, summaries, or explanations of the same that the Agency may distribute.

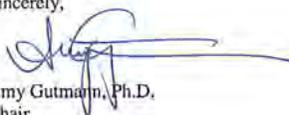
The Commission is to deliver its final report later this year, and is, therefore, working under a very tight deadline. The Commission would very much appreciate if you could supply the above-requested information by April 27, 2011. The Commission staff would be happy to accept information on a rolling basis as soon as it is available and work with you to facilitate these requests.

A member of the Commission staff will contact you to follow up on these requests. The Commission staff will also contact you with any further requests for information if they arise. In the meantime, please do not hesitate to contact Ms. Valerie Bonham, the Commission's Executive Director, at (202) 233-3962 or Valerie.Bonham@bioethics.gov if you have any questions.

In addition, as described in the enclosed Federal Register notice, the Commission has requested public comment on the Federal and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government. The Commission welcomes the Agency to submit comments and information in response to this request for public comment as well.

Thank you in advance for your help and consideration.

Sincerely,



Amy Gutmann, Ph.D.
Chair

Enclosures

Table II.1 Responsive Data Received†

DEPARTMENT/ AGENCY	UNIT	DATA SUBMITTED TO RPD				
		FY06	FY07	FY08	FY09	FY10
Agency for International Development		Y	Y	Y	Y	Y
Central Intelligence Agency		N	N	N	N	N
Consumer Product Safety Commission		Y	Y	Y	Y	Y
Department of Agriculture	Agricultural Research Service	Y	Y	Y	Y	Y
	Economic Research Service	Y	Y	Y	Y	Y
	National Institute of Food and Agriculture	Y	Y	Y	Y	Y
Department of Commerce		Y	Y	Y	Y	Y
Department of Defense		Y	Y	Y	Y	Y
Department of Education	Institute for Educational Sciences	Y	Y	Y	Y	Y
	Office for English Language Education	N-None	N-None	N-None	N-None	N-None
	Office for Elementary and Secondary Education	N	N	N	N	Y
	Office for Innovation and Improvement	N	N	N	N	Y
	Office for Postsecondary Education (including Fulbright-Hays fellowships)	Y	Y	Y	Y	Y
	Office of Planning, Evaluation & Policy Development	N	N	N	N	Y
	Office of Safe and Drug Free Schools	N	N	N	N	Y
	Office for Special Education and Rehabilitative Services (including National Institute for Disability and Rehabilitation Research)	N	Y	Y	Y	Y
	Office for Vocational and Adult Education	N	N	N	N	N
Department of Energy		Y	Y	Y	Y	Y

† “Y” indicates that the department/agency or unit submitted data to the RPD for the given fiscal year. “N-None” indicates that the department/agency or unit informed the Commission that it did not support human subjects research in the given fiscal year. “N” indicates that the department/agency or unit did not submit data to the RPD for the given fiscal year. The CIA did not submit project-level data to the Commission’s database because these data are confidential (although not classified). Letter from V. Sue Bromley, Associate Deputy Director, CIA to Amy Gutmann, Ph.D., Chair, PCSBI. (November 15, 2011). ED did not upload data as summarized here, but also reported that “OESE, OII, OPEPD and OVAE have very few studies that fall under the Common Rule.” Jeffery Rodamar, ED, to Michelle Groman, PCSBI. (2011, September 14). E-mail Correspondence. DHS reported that it had “no earlier data” than FY07. Richard Legault, DHS, to Michelle Groman, PCSBI. (2011, September 15). E-mail Correspondence.

DEPARTMENT/ AGENCY	UNIT	DATA SUBMITTED TO RPD				
		FY06	FY07	FY08	FY09	FY10
Department of Health and Human Services	Agency for Healthcare Research and Quality	Y	Y	Y	Y	Y
	Assistant Secretary for Preparedness and Response	Y	Y	Y	Y	Y
	Centers for Disease Control and Prevention	Y	Y	Y	Y	Y
	Centers for Medicare and Medicaid Services	N-None	N-None	N-None	N-None	N-None
	Food and Drug Administration	Y	Y	Y	Y	Y
	Health Resources and Services Administration	Y	Y	Y	Y	Y
	Indian Health Service [‡]	Y	Y	Y	Y	Y
	National Institutes of Health	Y	Y	Y	Y	Y
	OASH National Vaccine Program Office	Y	Y	Y	N-None	N-None
	Office of Adolescent Health [§]	N-None	N-None	N-None	N-None	Y
	Office of Population Affairs	Y	Y	Y	Y	Y
Substance Abuse & Mental Health Services Administration	N-None	N-None	N-None	N-None	N-None	
Department of Homeland Security		N	Y	Y	Y	Y
Department of Housing and Urban Development	Office of Healthy Homes & Lead Hazard Control	Y	Y	Y	Y	Y
	Office of Policy Development and Research	Y	Y	Y	Y	Y
Department of Justice	Bureau of Prisons	Y	Y	Y	Y	Y
	Federal Bureau of Investigation	Y	Y	Y	Y	Y
	Office of Community Oriented Policing Services	N-None	N-None	N-None	N-None	N-None
	Office of Justice Programs [¶]	Y	Y	Y	Y	Y
	Office on Violence Against Women	N-None	N-None	N-None	N-None	N-None

[‡] Within IHS, the Billings Area Office did not support human subjects research in FY09.

[§] Because it is a “new” office, OAH did not have FY06-FY09 data to report. Amy Farb, OAH, to Michelle Groman, PCSBI. (2011, August 5). E-mail Correspondence. OAH. About the Office of Adolescent Health. Retrieved from <http://www.hhs.gov/ash/oah/about-us/> (last accessed December 8, 2011) (“OAH was established through the Consolidated Appropriations Act of 2010, within the Office of the Assistant Secretary for Health.”).

[¶] Within OJP, the Bureau of Justice Assistance did not support human subjects research in FY07, FY08, or FY10 and the Office of Victims of Crime did not support human subjects research in FY06.

continued

Table II.1 Responsive Data Received[†]

DEPARTMENT/ AGENCY	UNIT	DATA SUBMITTED TO RPD				
		FY06	FY07	FY08	FY09	FY10
Department of Transportation	Federal Aviation Administration	Y	Y	Y	Y	Y
	Federal Highway Administration	Y	Y	Y	Y	Y
	Federal Motor Carrier Safety Administration	N-None	Y	Y	Y	Y
	Federal Railroad Administration	Y	Y	Y	Y	Y
	Maritime Administration	N-None	N-None	N-None	N-None	N-None
	National Highway Traffic Safety Administration ^{††}	Y	Y	Y	Y	Y
	Research and Innovative Technology Administration	Y	N-None	Y	Y	Y
Department of Veterans Affairs		Y	Y	Y	Y	Y
Environmental Protection Agency		Y	Y	Y	Y	Y
National Aeronautics and Space Administration	Ames Research Center	Y	Y	Y	Y	Y
	Johnson Space Center	Y	Y	Y	Y	Y
	Kennedy Space Center	Y	Y	Y	Y	Y
	Langley Research Center	Y	Y	Y	Y	Y
National Science Foundation		Y	Y	Y	Y	Y
Social Security Administration		Y	Y	Y	Y	Y

[†] "Y" indicates that the department/agency or unit submitted data to the RPD for the given fiscal year. "N-None" indicates that the department/agency or unit informed the Commission that it did not support human subjects research in the given fiscal year. "N" indicates that the department/agency or unit did not submit data to the RPD for the given fiscal year. The CIA did not submit project-level data to the Commission's database because these data are confidential (although not classified). Letter from V. Sue Bromley, Associate Deputy Director, CIA to Amy Gutmann, Ph.D., Chair, PCSBI. (November 15, 2011). ED did not upload data as summarized here, but also reported that "OESE, OII, OPEPD and OVAE have very few studies that fall under the Common Rule." Jeffery Rodamar, ED, to Michelle Groman, PCSBI. (2011, September 14). E-mail Correspondence. DHS reported that it had "no earlier data" than FY07. Richard Legault, DHS, to Michelle Groman, PCSBI. (2011, September 15). E-mail Correspondence.

^{††} NHTSA data for FY06-FY09 does not include information about safety-related studies involving human subjects. Lori Putnam, DOT, to Michelle Groman, PCSBI. (2011, December 1). E-mail Correspondence.

Table II.2 Data Fields and Instructions

FIELD	INSTRUCTIONS
1. Study ID#	Enter a unique study identification number such as IRB or institute protocol number, IND number, or other unique identifier assigned by the Department/Agency. Note that award number is acceptable here but, because it is requested separately, an alternative identifier is preferred. NCT number is also acceptable here but, if available, should be provided in the "NCT#" field as well.
2. NCT# [N/A is option]	Enter NCT number, if available. For trials entered in ClinicalTrials.gov, ClinicalTrials.gov assigns a unique NCT identifier of the form NCTxxxxxxx where each x is a numeric digit. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
3. Title of Study	Enter the title of the study, as maintained by the Department/Agency. "Title of Study" is intended to be as specific as possible, with protocol title preferred. Award title may be substituted for protocol title when necessary. It is understood that an award may support more than one protocol.
4. Abstract [N/A is option]	Enter the study or award abstract if it is readily available. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
5. PI(s)	Enter the name or names of the study's principal investigator(s). Names may be provided in any format, and can be separated by a "," or ";".
6. Year X of Y [N/A is option]	Enter the duration of the study, for example, "Year 2 of 4." "X" should be entered in reference to the fiscal year for which the Department/Agency is reporting. That means, for example, that a study reported in FY06 as "Year 2 of 4," would be reported in FY07 as "Year 3 of 4." Enter N/A if the Department/Agency does not maintain this data, or it is not readily available. If the full duration of the study is unknown, enter N/A for "Y."
7. Exempt or Non-Exempt [Ex/N] [N/A is option]	Enter Ex if the study is human subjects research "exempt" from 45 CFR 46 or applicable agency regulations. Enter N if the study is non-"exempt." Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
8. Total # Sites [N/A is option]	Enter the total number of locations where the study is being conducted, which may not correspond to where the approving IRB is located. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
9. Site Country [N/A is option]	Enter all countries in which the study is being conducted. Enter each country in a separate row. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
10. # Sites [Per Country] [N/A is option]	Enter the total number of locations where the study is being conducted in the listed country. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
11. # Participants [Per Country] [N/A is option]	Enter the total number of participants in the listed country in the relevant fiscal year. There is no need to list participants for each site within the country separately. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
12. ARRA Funded by Reporting Entity? [Y/N]	Enter Y if Department/Agency funding (if any) for the study is from American Recovery and Reinvestment Act (ARRA) funds. Enter N if Department/Agency funding (if any) for the study is not from American Recovery and Reinvestment Act (ARRA) funds.
13. Other Fed Funding? [Y/N] [N/A is option]	Enter Y if this study was funded in the reported fiscal year by another federal funder, in whole or in part. Enter N if this study was not funded in the reported fiscal year by another federal funder, in whole or in part. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
14. Source of Other Fed Funding?	If this study was funded in the reported fiscal year by another federal funder, in whole or in part, select the Department/Agency that is the source of that federal funding. If more than one, enter each Department/Agency that is the source of other federal funding in a separate row. Select "Other" if the Department/Agency that is the source of other federal funding is not listed in the drop-down menu and, if known, enter its name in the "Other Comments" field. If this study was not funded in the reported fiscal year by another federal funder, in whole or in part, leave blank.

Table II.2 Data Fields and Instructions

FIELD	INSTRUCTIONS
15. Other Fed Funder Identifier [N/A is option]	If this study was funded in the reported fiscal year by another federal funder, in whole or in part, enter a study identification number assigned to the study by the Department/Agency that is the source of other federal funding, such as award number or IRB protocol number, if known and readily available. Enter N/A if not known or readily available. If this study was not funded in the reported fiscal year by another federal funder, in whole or in part, leave blank.
16. Other Non-Fed Funding? [Y/N] [N/A is option]	Enter Y if this study was funded in the reported fiscal year by another non-federal funder, in whole or in part. A non-federal funder could be, for example: foreign, state, or local governments or university, industry, non-profit, or philanthropic organizations. Enter N if this study was not funded in the reported fiscal year by another non-federal funder, in whole or in part. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available.
17. Intramural or Extramural [I/E/B]	Enter I if the study is considered intramural by the Department/Agency. Enter E if the study is considered extramural by the Department/Agency. "Intramural," generally, means internal agency research programs. "Extramural," generally, means research supported by the Department/Agency through grant, cooperative agreement, contract, interagency agreement of any type, and "other transaction authority," e.g., 10 U.S.C. 2371 (DOD). For studies funded with both intramural and extramural monies, enter B.
18. Total Intramural Study \$ in FY from Reporting Entity [N/A is option]	If intramural, enter the Department/Agency's intramural funding of the study in the reported fiscal year. Do not include funding from other federal or non-federal sources. This may be "0." If the Department/Agency does not track total study funding by project, aggregate amounts by fiscal year are acceptable, e.g., laboratory or program. Please provide an explanation in the "Other Comments" field. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available. If extramural, leave blank.
19. Award ID#	If extramural, enter unique identification number assigned to the award by the Department/Agency. "Award" means grant, cooperative agreement, contract, interagency agreement of any type, and "other transaction authority," e.g., 10 U.S.C. 2371 (DOD). If intramural, leave blank.
20. Award Institution	If extramural, enter the name of the institution receiving the award. If intramural, leave blank.
21. Award Title	If extramural, enter the title of the award, as maintained by the Department/Agency. If intramural, leave blank.
22. Total Award \$ in FY	If extramural, enter the amount of award extramural funding in the reported fiscal year. If intramural, leave blank.
23. Total Extramural Study \$ in FY from Reporting Entity [N/A is option]	If extramural, enter the Department/Agency's extramural funding of the study in the reported fiscal year. Do not include funding from other federal or non-federal sources. This may be "0." Enter N/A if the Department/Agency does not maintain this data, or it is not readily available. If intramural, leave blank.
24. Direct Award \$ in FY [N/A is option]	If extramural and "Total Study \$" is not given, enter the amount of direct award funding in the reported fiscal year. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available. If "Total Study \$" is given, leave blank. If intramural, leave blank.
25. Indirect Award \$ in FY [N/A is option]	If extramural and "Total Study \$" is not given, enter the amount of indirect award funding in the reported fiscal year. Enter N/A if the Department/Agency does not maintain this data, or it is not readily available. If "Total Study \$" is given, leave blank. If intramural, leave blank.
26. Other Comments	Enter any necessary explanations, as well as any additional information that may be helpful to the Commission about the listed study. If no other comments, leave blank.

Table II.3 SRA Methodology

Values as Stored in Database

SPREADSHEET FIELD	DATABASE FIELD	VALUE AS STORED IN DATABASE	VALUE FOR ANALYSIS (INVERSE OF VALUE STORED)
Study ID#	StudyID	As supplied	As supplied
NCT #	NCT	As supplied	As supplied
Title of Study	Title	As supplied	As supplied
Abstract	Abstract	As supplied	As supplied
PI(s)	PI	As supplied	As supplied
Year X	Year_X	Integer => As Supplied; N/A => NULL	Integer => As Supplied; NULL => N/A
Year Y	Year_Y	Integer => As Supplied; N/A => NULL	Integer => As Supplied; NULL => N/A
Exempt or Non-Exempt	Exempt	Ex => 1; N => 0; N/A => NULL	1 => Ex; 0 => N; NULL => N/A
Total # of Sites	Sites	Integer => As Supplied; N/A => NULL	Integer => As Supplied; NULL => N/A
ARRA Funded by Reporting	Arra	Y => 1; N => 0	1 => Y; 0 => N
Other Fed Funding	Other_Fed_Funding	Y => 1; N => 0; N/A => NULL	1 => Y; 0 => N; NULL => N/A
Other Non-Fed Funding	Other_NonFed_Funding	Y => 1; N => 0; N/A => NULL	1 => Y; 0 => N; NULL => N/A
Intramural or Extramural	Funding_Type	As Supplied	As Supplied
Total Intramural Study \$ in FY	Intramural_Funding	IF FUNDING TYPE == E => NULL IF FUNDING TYPE == I,B {Money Value => As Supplied, without dollar formatting; N/A => NULL}	IF FUNDING TYPE == E => NULL IF FUNDING TYPE == I,B {Money Value => As Supplied; NULL => N/A}
Award ID#	Award_ID	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied
Award Institution	Award_Inst	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied

continued

Table II.3 SRA Methodology

Values as Stored in Database

SPREADSHEET FIELD	DATABASE FIELD	VALUE AS STORED IN DATABASE	VALUE FOR ANALYSIS (INVERSE OF VALUE STORED)
Award Title	Award_Title	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B => As Supplied
Total Award \$ in FY	Total_Funding	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B {Money Value => As Supplied, without dollar formatting; N/A => NULL}	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B {Money Value => As Supplied; NULL => N/A}
Total Extramural Study \$ in FY from Reporting Entity	Extramural_Funding	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B {Money Value => As Supplied, without dollar formatting; N/A => NULL}	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B {Money Value => As Supplied; NULL => N/A}
Direct Award \$ in FY	Direct_Funding	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B and EXTRAMURAL_FUNDING == N/A => {Money Value => As Supplied, without dollar formatting; N/A => NULL}	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B and EXTRAMURAL_FUNDING == N/A => {Money Value => As Supplied; NULL => N/A}
Indirect \$ in FY	Indirect_Funding	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B and EXTRAMURAL_FUNDING == N/A => {Money Value => As Supplied, without dollar formatting; N/A => NULL}	IF FUNDING TYPE == I => NULL IF FUNDING TYPE == E,B and EXTRAMURAL_FUNDING == N/A => {Money Value => As Supplied; N/A => NULL}
Other Comments	Comments	As Supplied	As Supplied

Table II.4 Empirical Advisory Group**Robert M. Califf, MD**

Vice Chancellor for Clinical Research
 Duke University Medical Center
 Director, Duke Translational
 Medicine Institute

Ruth Faden, Ph.D., M.P.H.

Philip Franklin Wagley Professor
 of Biomedical Ethics
 Director, Johns Hopkins Berman
 Institute of Bioethics
 Professor, Department of Health Policy
 and Management
 Johns Hopkins Bloomberg
 School of Public Health
 Professor, Department of Medicine
 Johns Hopkins School of Medicine

Kenneth A. Getz, M.B.A.

Founder and Board Chair
 The Center for Information and Study
 on Clinical Research Participation
 Senior Research Fellow
 Tufts Center for The Study of
 Drug Development
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Christine Grady, R.N., Ph.D.*

Acting Chief of the Department of Bioethics
 National Institutes of Health
 Clinical Center

Philip W. Lavori, Ph.D.

Professor, Health Research and Policy
 Stanford School of Medicine

Bernard Lo, M.D.

Professor of Medicine
 Director, Program in Medical Ethics
 University of California San Francisco
 National Program Director, Greenwall
 Faculty Scholars Program in Bioethics

Kathleen M. MacQueen, Ph.D., M.P.H.

Senior Scientist, Behavioral &
 Social Sciences
 Coordinator of Interdisciplinary
 Research Ethics
 FHI 360

Daniel P. Sulmasy, M.D., Ph.D.*

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 and Ethics, Department of Medicine and
 Divinity School
 Associate Director, The MacLean Center
 for Clinical Medical Ethics
 University of Chicago

* Commission member