

# Inclusion Enrollment Report Form Instructions for Principal Investigators

Kim Witherspoon

Clinical Grants and Contracts Branch

CTEP/DCTD/NCI/NIH

# Why Does NIH Require Tracking of Sex/Gender and Minority Inclusion?

- Mandated by Congress, 1993 PL 103-43
- Ethical principle of justice and importance of balancing research burdens and benefits fairly across all groups.

# Changes in the Collection and Reporting of Data on Ethnicity & Race

- OMB Directive 15 Issued 1997:
- When collecting data using participant self-report:
  - At a minimum ask two separate questions:
    - Question 1: Ask about Ethnicity
    - Question 2: Ask about Race with the option to select more than one racial designation

# Changes in the Collection and Reporting of Data on Ethnicity & Race

- OMB Directive 15 Issued 1997:
- When collecting data using participant self-report:
  - At a minimum use the ethnic and racial categories specified in the directive
    - Ethnic Categories:
      - Hispanic or Latino
      - Not Hispanic or Latino
    - Racial Categories:
      - American Indian or Alaska Native
      - Asian
      - Black or African American
      - Native Hawaiian or Other Pacific Islander
      - White

# Changes in the Collection and Reporting of Data on Ethnicity & Race

- OMB Directive 15 Issued 1997:
- When collecting data using participant self-report:
  - Do NOT use the 5/01 Inclusion Enrollment Report to collect data from study participants!
  - Do use an instrument that allows participants to self-select their ethnic and racial affiliation separately
    - Example: Personal Data Form in PHS 398

# Reporting Cumulative Accrual Data

## – Selecting the Correct Format

- Cumulative accrual must be reported yearly in the progress report
- If data were collected from study subjects using the 1997 OMB standards:
  - two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, **then use the 5/01 Inclusion Enrollment Report.**
- Otherwise, use the 4/98 Version of the Inclusion Table.

Using the 5/01 Inclusion  
Enrollment Report in the Annual  
Progress Report

A Step-by-Step Guide

# The 5/01 Inclusion Enrollment Report (PHS 398, rev. 5/01)

Principal Investigator/Program Director (Last, first, middle): \_\_\_\_\_

## Inclusion Enrollment Report Table

**This report format should NOT be used for data collection from study participants.**

Study Title: \_\_\_\_\_

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

\* These totals must agree.

\*\* These totals must agree.



# General Information on Using the 5/01 Inclusion Enrollment Report

- Complete a separate Enrollment Report for each study or protocol
  - If you have multiple studies under one grant, do not combine accruals from all studies and report in one form.

# General Information on Using the 5/01 Inclusion Enrollment Report

- Studies with a Foreign Component should report foreign enrollment separately from domestic (USA) enrollment.

# General Information on Using the 5/01 Inclusion Enrollment Report

Foreign enrollment data can be reported in two ways:

1) All foreign enrollment for a particular **study** may be reported on one Inclusion Enrollment Report Table with the names of all foreign countries involved in the study listed in the study title.

**OR**

2) Separate Inclusion Enrollment Reports may be submitted for each country enrolling participants in **that study** with the name of the foreign country included in the study title.



Principal Investigator/Program Director (Last, first, middle):

## Inclusion Enrollment Report Table

*This report format should NOT be used for data collection from study participants.*

Study Title:

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

**STEP 1:** Enter the name of the Principal Investigator of the **award** for which enrollment data is being reported.

Principal Investigator/Program Director (Last, first, middle):

## Inclusion Enrollment Report Table

**This report format should NOT be used for data collection from study participants.**



Study Title: \_\_\_\_\_

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

**STEP 2:** Enter the **complete** title of the study (including foreign site information). The study title should remain the same each time enrollment data is reported for the award.

Principal Investigator/Program Director (Last, first, middle):

## Inclusion Enrollment Report Table

**This report format should NOT be used for data collection from study participants.**

Study Title:

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

**STEP 3: Enter the total number of enrolled participants in the study to-date.**

Principal Investigator/Program Director (Last, first, middle):

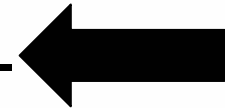
## Inclusion Enrollment Report Table

**This report format should NOT be used for data collection from study participants.**

Study Title:

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_



Grant Number: \_\_\_\_\_

**STEP 4:** Enter the protocol number of the study, if applicable. If this study uses an **NCI IND** agent, enter the **NCI** protocol number followed by the local protocol number in parenthesis. The protocol number(s) used to report the inclusion enrollment data should remain the same each time enrollment data is reported for the award.

Principal Investigator/Program Director (Last, first, middle):

## Inclusion Enrollment Report Table

**This report format should NOT be used for data collection from study participants.**

Study Title:

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_



**STEP 5:** Enter the **entire** NCI grant number for which you are reporting the enrollment data. Do not shorten the award number.



**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)**  
**by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

The enrollment totals entered in this portion of the form are for the ethnicity and sex/gender of the entire study population (**Total Enrollment**).

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)**  
**by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	#	#	#	# **
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

**STEP 6:** Enter the total number of female and the total number of male **Hispanic or Latino** enrollees.

-If the sex/gender is unknown or not reported, enter the total in the Unknown or Not Reported column.

- Enter the total number of **Hispanic or Latino** enrollees in the Total column.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)**  
**by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino	#	#	#	#
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

- STEP 7:** Enter the total number of female and the total number of male **Not Hispanic or Latino** enrollees.
- If the sex/gender is unknown or not reported enter the total in the Unknown or Not reported column.
  - Enter the total number of **Not Hispanic or Latino** enrollees in the Total column.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)**  
**by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)	#	#	#	#
Ethnic Category: Total of All Subjects*				*

**STEP 8: Enter the total number of female and the total number of male enrollees for which **ethnicity is unknown or not reported**.**

-If the sex/gender is unknown or not reported enter the total in the Unknown or Not Reported column.

- Enter the total number of Unknown or Not Reported enrollees in the Total column.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)**  
**by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

**STEP 9: Compute and enter the totals for all columns and rows.**

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or (Not Reported)	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)			#	
Ethnic Category: Total of All Subjects*				*

Step 10: If enrollees have chosen not to report ethnicity and/or sex/gender, circle the words as shown above, in the appropriate column.

Not reporting ethnicity – as shown in the left-hand column

Not reporting sex/gender - as shown in the sex/gender column

Not reporting ethnicity and sex/gender - circle both

If unknown sex/gender or ethnic values are entered in this table, a written explanation from the Principal Investigator of the awarded application is necessary. This explanation should be provided to the NCI Program Director of the awarded application along with the Inclusion Enrollment Report Table.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects*</b>				



**Step 11: The values entered into the Racial Categories section of Part A are for the total enrollment in the study. If you are using the 1997 OMB standards, you should have Ethnic data and Racial Data for all subjects.**



**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				**
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects*</b>				**

**STEP 12:** Enter the number of enrollees, by sex/gender, for each racial category for the **total** enrollment of the study.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects*</b>				

**STEP 13:** Enter the number of enrollees who selected More than one racial category, by sex/gender, in this row.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				**
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects*</b>				**

**STEP 14:** Enter the number of Unknown or Not Reported Racial group enrollees, by sex/gender, in this row.

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				**
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported			#	
Racial Categories: Total of All Subjects*				**

- If the enrollee chose not to report race and/or sex/gender, circle the words as shown above, in the appropriate column. Enter the total enrollment for that racial category.
- Not reporting race – as shown in the left-hand column
  - Not reporting sex/gender - as shown in the sex/gender column
  - Not reporting race and sex/gender – circle both

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects*</b>	#	#	#	

**STEP 15: Compute and enter the total number of enrollees for each separate column.**

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects<sup>a</sup></b>				
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
<b>Racial Categories: Total of All Subjects<sup>a</sup></b>				#

The sum of the “Racial Categories: Total of All Subjects” row should equal the sum of the Total column. These totals (#) must be the same.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date  
(Cumulative)**

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

\* These totals must agree.

\*\* These totals must agree.

**STEP 16: Part B is the Hispanic Enrollment Report for describing the sub-set of racial and sex/gender information for the Hispanic or Latino ethnic population reported in Part A.**

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date**  
 (Cumulative) ↑

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

\* These totals must agree.

\*\* These totals must agree.

**STEP 17:** For subjects who indicated **Hispanic or Latino ethnicity** for this study, enter the number of enrollees, by sex/gender, in the appropriate racial categories.



**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

\* These totals must agree.

\*\* These totals must agree.

**STEP 18:** For subjects who indicated **Hispanic or Latino ethnicity** for this study, enter the number of enrollees that have reported **More than One Race**, by sex/gender, in this row.

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

\* These totals must agree.

\*\* These totals must agree.

**STEP 19:** For subjects who indicated **Hispanic or Latino ethnicity** for this study, enter the number of enrollees, by sex/gender, whose racial category is Unknown or Not Reported. Place the total number of enrollees for this racial category in the Total column. Circle the appropriate words to indicate if totals are Unknown or not reported.

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date**  
 (Cumulative)


Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
<b>Racial Categories: Total of Hispanics or Latinos**</b>	★	★	★	**

\* These totals must agree.

\*\* These totals must agree.

**STEP 20: For subjects who indicated **Hispanic or Latino Ethnicity** for this study, compute the total number of enrollees for each separate column.**

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
<b>Racial Categories: Total of Hispanics or Latinos**</b>				# **

\* These totals must agree.

\*\* These totals must agree.

**STEP 29:** The sum of the “Racial Categories: Total of Hispanics or Latinos” row must equal the sum in the “Total” column. These totals # must be equal.

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative)  
by Ethnicity and Race**

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				★ **
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date  
(Cumulative)**

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				★ **

\* These totals must agree.

\*\* These totals must agree.

Both totals (stars) should be equal!

**Inclusion Enrollment Report Table****This report format should NOT be used for data collection from study participants.**

Study Title: \_\_\_\_\_

Total Enrollment: \_\_\_\_\_ ★

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				★ *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				★ *
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				** *

\* These totals must agree.

\*\* These totals must agree.

Check the forms for accuracy before submitting them to NCI for the awarded grant. Make sure the appropriate totals are equal.

Ethnic Category:  
Total of All Subjects,  
Racial Categories:  
Total of All Subjects,  
and Total  
Enrollment totals  
must all equal (stars).

**Inclusion Enrollment Report Table****This report format should NOT be used for data collection from study participants.**

Study Title: \_\_\_\_\_

Total Enrollment: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Grant Number: \_\_\_\_\_

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				★ **
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				★ **

\* These totals must agree.

\*\* These totals must agree.

The total for the Hispanic or Latino Ethnic Category in Part A must equal Racial Categories: Total Of All Hispanics or Latinos in Part B (stars).

Any questions...contact  
your NCI Program  
Director!