

2011 Web Seminar Series

Capturing Demographics in CTN Protocols

Presented on March 2, 2011 by:

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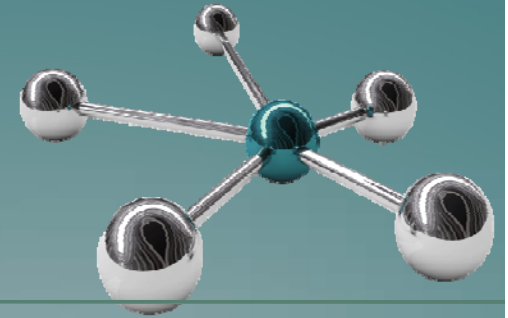
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Produced by Liz Buttrey, NIDA CTN CCC Training Office

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Training Objectives



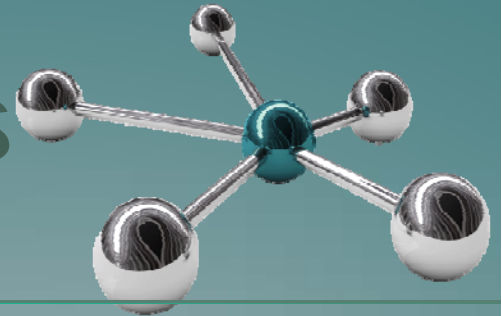
- Demographic assessment
 - purpose and background
- Factors affecting accurate data collection
- The process:
 - Tools and Tips for collecting racial classification
- Practice, Practice, Practice!

Demographic Assessment

The purpose and background

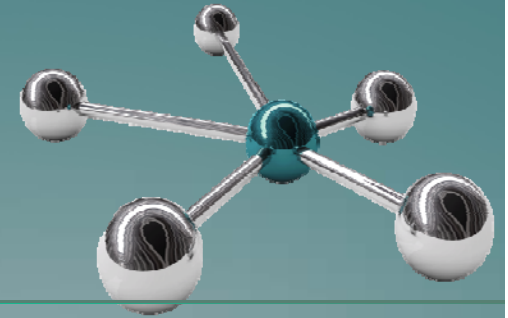


Racial Classifications



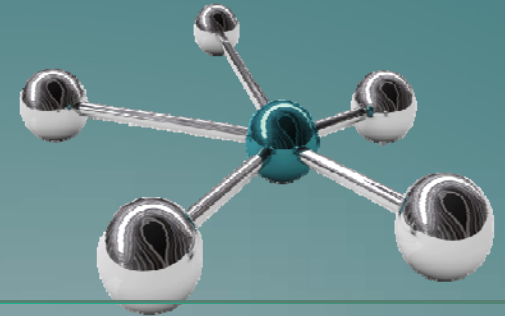
- The racial classifications used by the census bureau adhere to the October 30, 1997 federal register notice entitled, "revisions to the standards for the classification of federal data on race and ethnicity" issued by the office of management and budget (OMB).

Purpose



- Helps to characterize the target population for whom CTN protocols are designed
- Serves as a repository of data available for planning, analyzing and interpreting results of CTN studies
- Given today's diversity, classification of race and ethnicity presents challenges

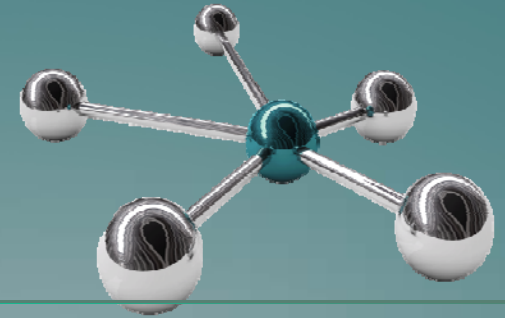
Background



DEMOGRAPHICS DEM eCRF

- Refers to a brief assessment procedure used in the CTN to gather information about all candidates for CTN protocols
- Basic descriptive data captured with DEM include gender, age, race and ethnicity
- Typically administered during screening, after conducting the Informed Consent

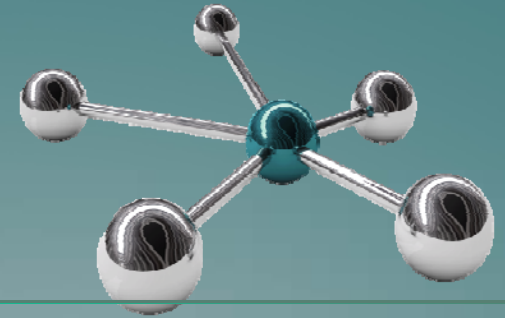
Definition



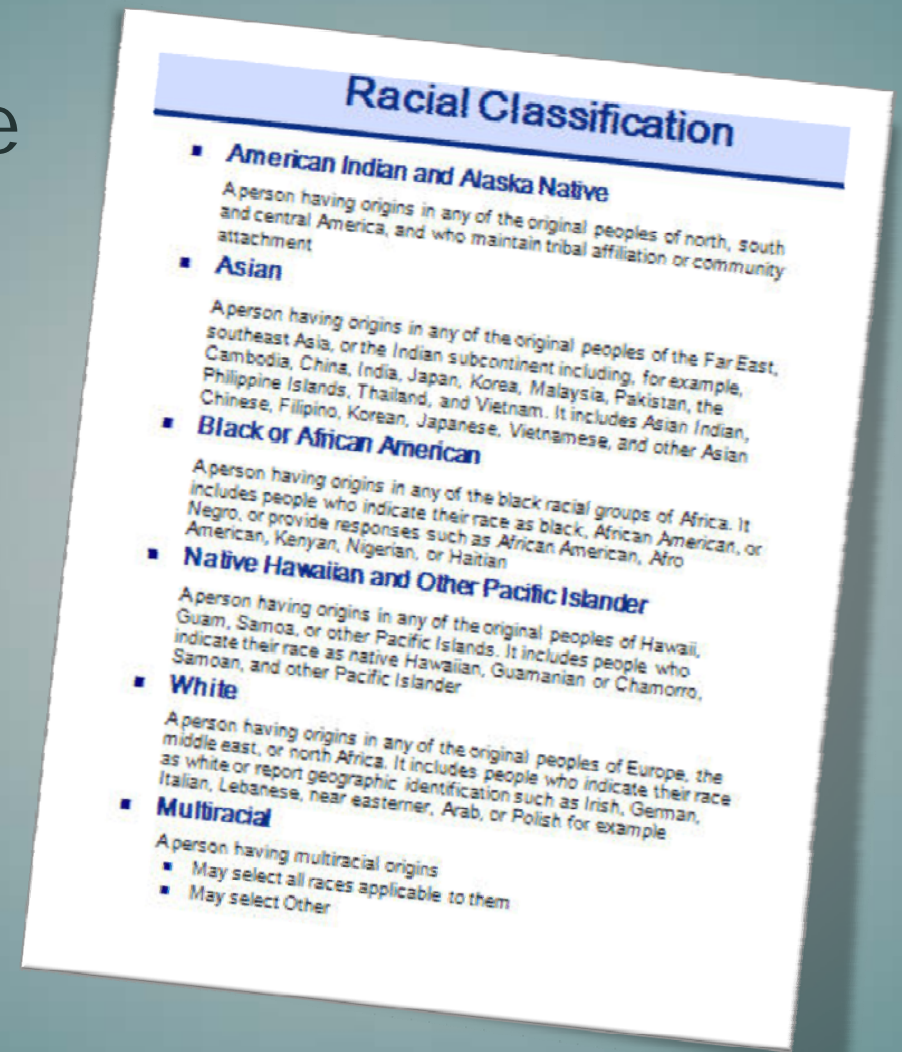
Race - is a socially created term

- It is one way we identify ourselves
- The federal government considers race and national origin or ethnicity as separate and distinct concepts
- Race does not conform to any biological, anthropological or genetic criteria
- Race is not determined by which country the participant resides

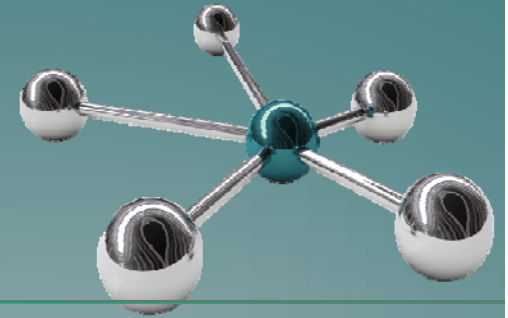
More About Race...



- It is the respondent's choice
 - Mixed
 - Unknown
 - May refuse to answer
- Never assume a participant's racial identification!



Definitions



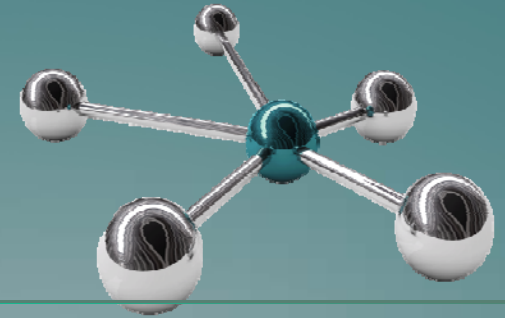
Ethnicity – is **defined by the Census Bureau** as the **heritage, nationality group, lineage, or country of birth** of the person or the person's parents or ancestors before their arrival in the United States

- **Do not confuse ethnicity with race**
 - people who identify their origin as Spanish, Hispanic or Latino may be of any race

Factors Affecting Accurate Data Collection

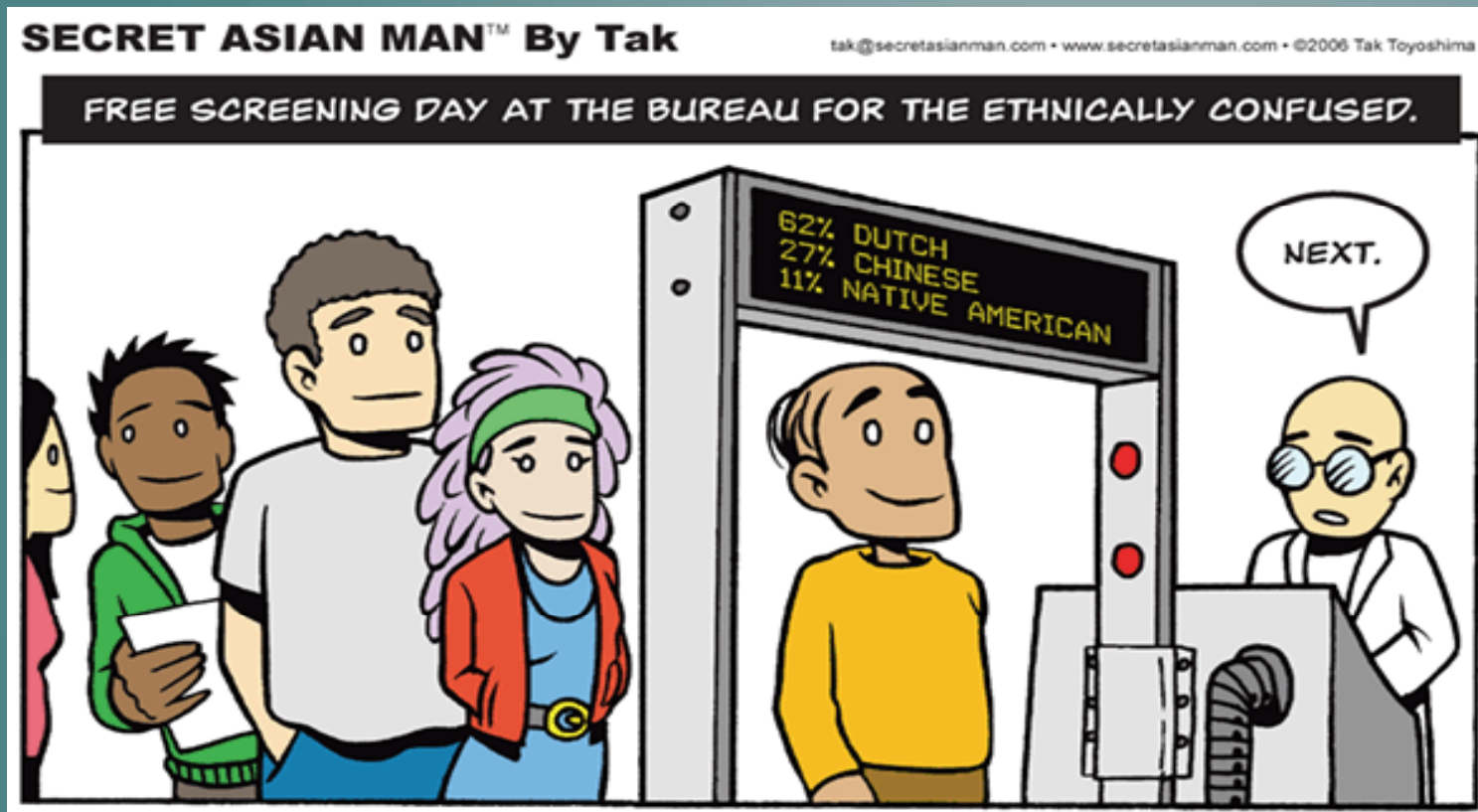


Key Principles

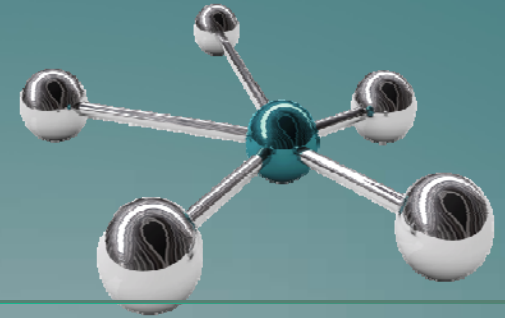


- Race is **not** determined by which country the participant resides
 - Race is a socially created term
- **Ethnicity and Race are not the same**
 - People who identify their origin as Spanish, Hispanic or Latino may be of any race
- **Please refer to racial classification descriptions instead of the titles**

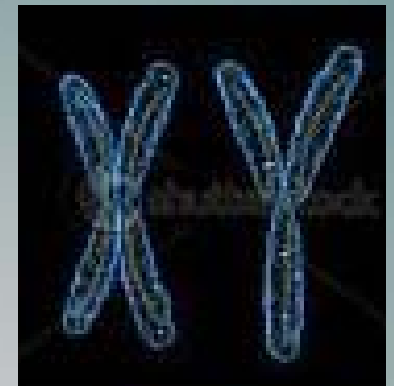
What are your Demographic Challenges?



Gender Self Report



- Biological vs. self identification
 - Transgender
 - Hermaphrodite
 - Pre-op surgical candidate



- This information impact study assessments performed

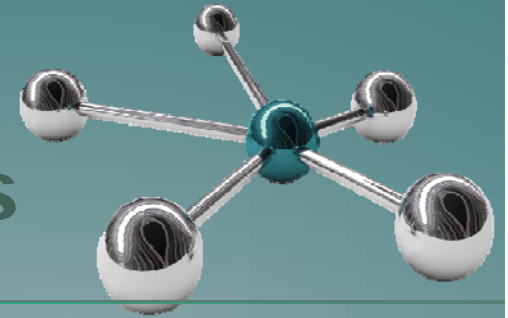
- **Bring to the Lead Team for Discussion**

Collecting Racial Classification

Tools and Tips



The Process: Administering Demographics



- Step 1: Preparation for interaction
 - Print and provide the Racial Classification Tool
 - **Be familiar & ready to assist with the categories**
- Step 2: Explain how to use the racial classification tool and their selection options
 - Help them find their racial classification
 - Highlight the subcategory for clarification
- Step 3: Verbally verify your documentation represents their choices

Racial Classification

- **American Indian and Alaska Native**

A person having origins in any of the original peoples of north, south and central America, and who maintain tribal affiliation or community attachment

- **Asian**

A person having origins in any of the original peoples of the Far East, southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. It includes Asian Indian, Chinese, Filipino, Korean, Japanese, Vietnamese, and other Asian

- **Black or African American**

A person having origins in any of the black racial groups of Africa. It includes people who indicate their race as black, African American, or Negro, or provide responses such as African American, Afro American, Kenyan, Nigerian, or Haitian

- **Native Hawaiian and Other Pacific Islander**

A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. It includes people who indicate their race as native Hawaiian, Guamanian or Chamorro, Samoan, and other Pacific Islander

- **White**

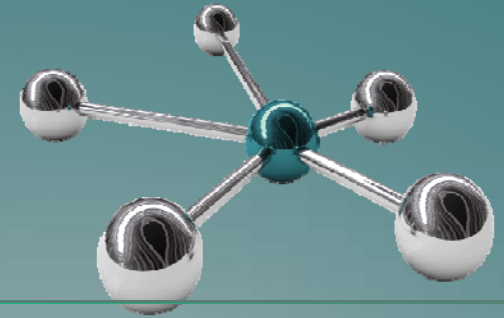
A person having origins in any of the original peoples of Europe, the middle east, or north Africa. It includes people who indicate their race as white or report geographic identification such as Irish, German, Italian, Lebanese, near easterner, Arab, or Polish for example

- **Multiracial**

A person having multiracial origins

- May select all races applicable to them
- May select Other

More About Race...



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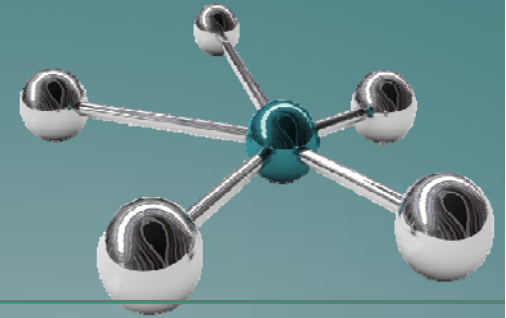
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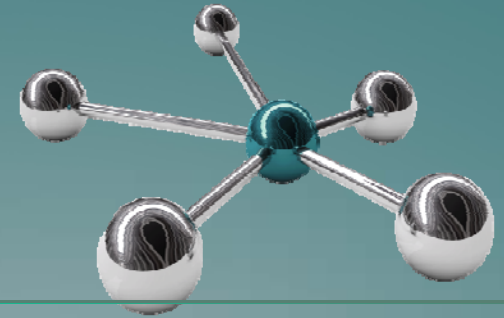
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- **Other & Multiracial**
 - Includes all other responses not included in the white, black or African American, American Indian and Alaska native, Asian and native Hawaiian and other Pacific Islander race categories described above. Respondents providing responses such as multiracial, mixed, interracial, or a Hispanic/Latino group (for example, Mexican, Puerto Rican, or Cuban) are included here

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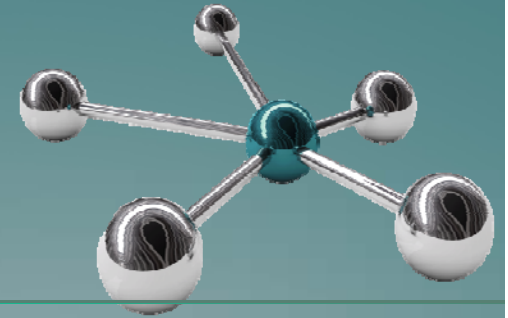
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Accuracy is important



- Accurate CRF completion is important because Demographics helps characterize target populations for which CTN protocols are designed.

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 1.00; 02-02-10

1. Date of birth: (mm/dd/yyyy)

2. Sex: Male Female Participant chooses not to answer

3. Ethnicity: Hispanic or Latino chooses not to answer Not Hispanic or Latino Participant chooses not to answer

4. Race:

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Pacific Islander

White

Other

If "Yes", specify:

No Yes

No Yes

No Yes

No Yes

No Yes

No Yes

OR

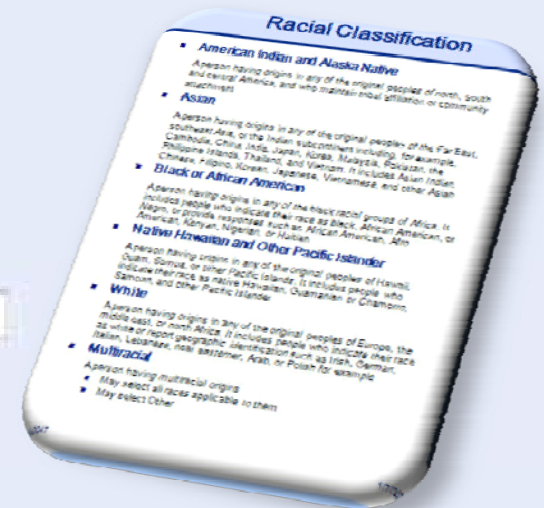
Unknown

Yes

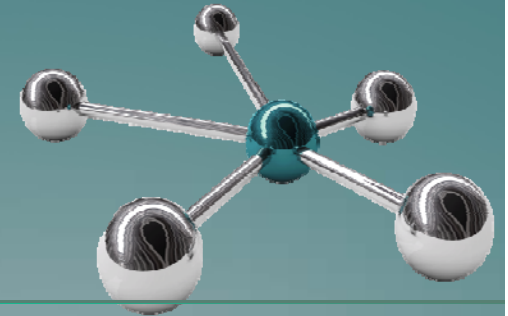
Participant chooses not to provide their race

Yes

Comments:

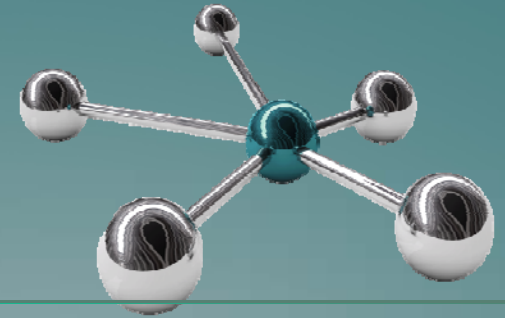


CRF Completion Challenges



- If a participant doesn't fit into one of the racial classifications
 - Ask which race category they feel is appropriate
 - Verify that the specified race is not included in one of the categories
 - See racial classification tool
 - If no categories fit be sure to select Other and specify race

CRF Completion Challenges

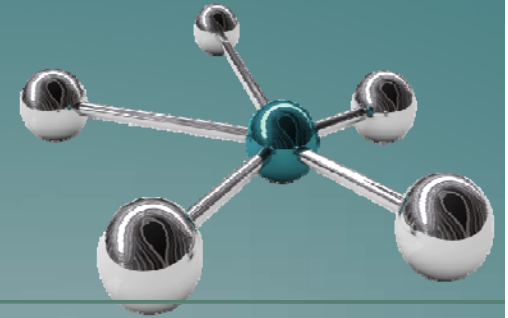


- If a participant is a mixture of the racial categories
 - Ask them to check whichever categories they feel applies to them.
 - *Remember – it is the participant's choice*

Practice!



Demographics Help



■ Your CCC Protocol Specialist

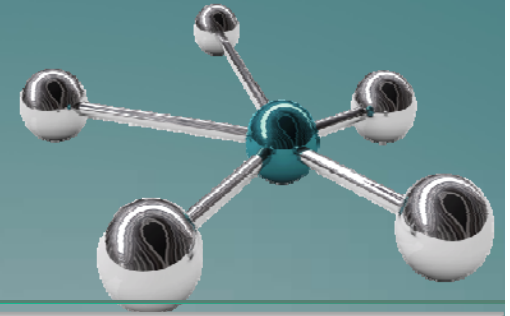
- 301-251-1161 (*ask for NIDA CCC*)
- ctnsupport@emmes.com

■ Your DSC 2 Data Manager

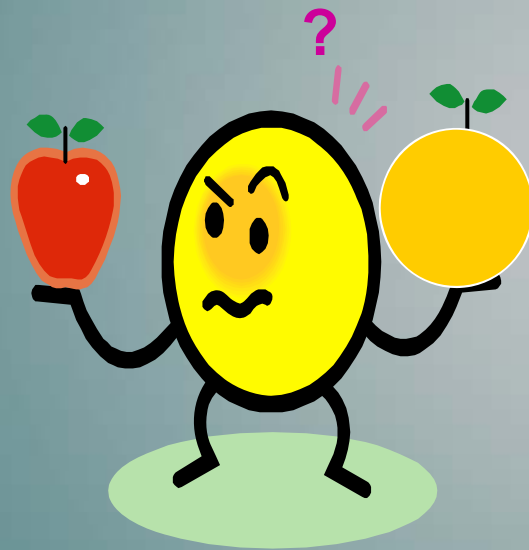
- 301-251-1161 (*ask for NIDA DSC 2*)

■ Help Desk

- Monday-Friday (8:00 a.m. to 8:00 p.m. ET)
- 888-337-7071 (toll-free)
- nidadsc2help@emmes.com



Questions or Comments?



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National Drug Abuse Treatment

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