What Should IRBs Consider When Reviewing A Protocol in Which Race Will Be Identified?

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Definition of Race: Genetics

“An inherent biological characteristic that accurately reflects human ancestry and the flow of common threads of genetic material in biologically distinct populations over time and geography.”

(Fine et al. The role of race and genetics in health disparities research, *American Journal of Public Health*, 2125-2128, December 2005).

Definition of Race/Minority Group Used by the NIH

"A minority group is a readily identifiable subset of the U.S. population that is distinguished by **racial**, ethnic, and/or cultural heritage."

NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001.

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Racial Designations from NIH

- **Hispanic or Latino** - a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."
- **Not Hispanic or Latino**

The following definitions apply for racial categories.

- **American Indian or Alaska Native** - a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations 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. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Racial Designations from NIH continued

- **Black or African American** - a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
- **Native Hawaiian or Other Pacific Islander** - a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White** - a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

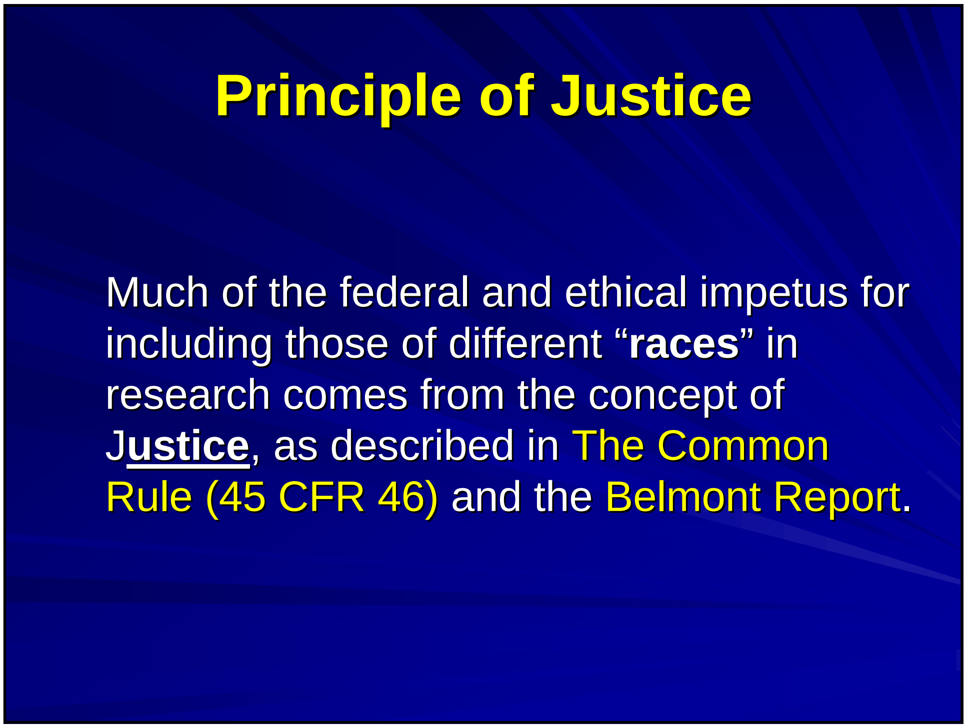
NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001.

http://grants.nih.gov/grants/funding/women__min/guidelines_amended_10_2001.htm

Collection of Race Information

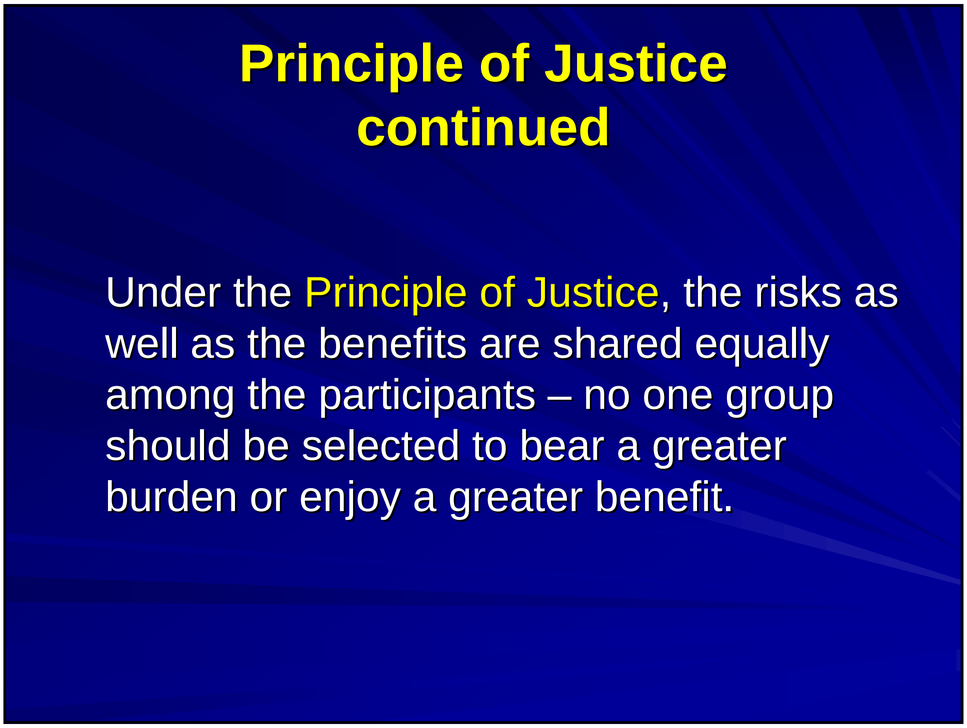
As just noted, Federal oversight agencies **require** collection of race and gender information to ensure equality in research.

This should also be taken into account when looking at genetics research.



Principle of Justice

Much of the federal and ethical impetus for including those of different “**races**” in research comes from the concept of J**ustice**, as described in The Common Rule (45 CFR 46) and the Belmont Report.



Principle of Justice continued

Under the Principle of Justice, the risks as well as the benefits are shared equally among the participants – no one group should be selected to bear a greater burden or enjoy a greater benefit.

Belmont Report – Principle of Justice

According to the *Belmont Report:*

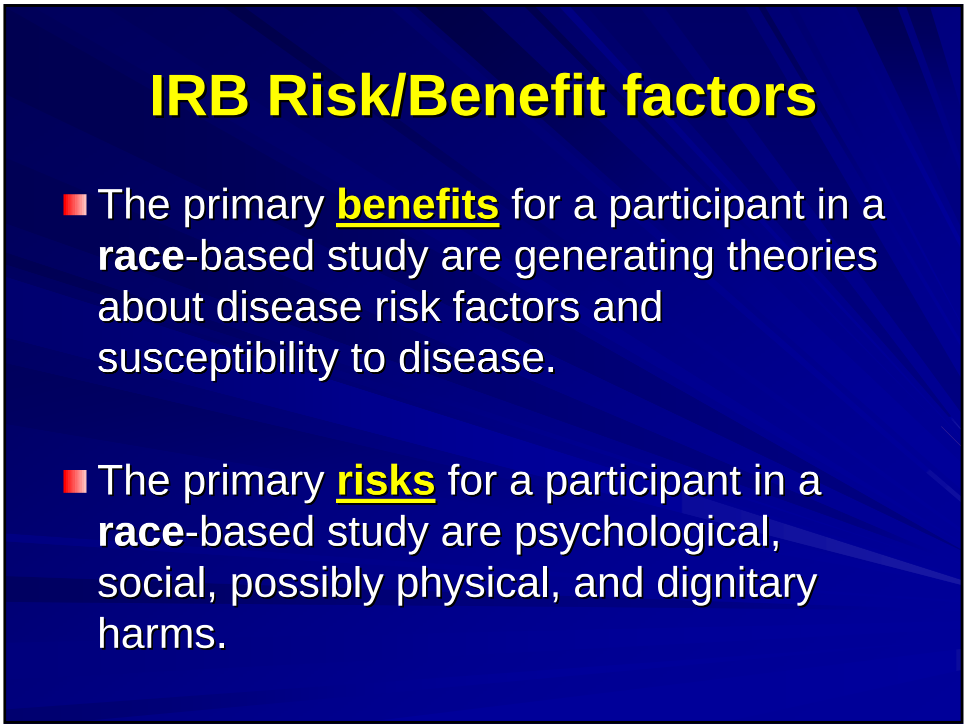
"The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular **racial** and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied."

They shouldn't also be systematically excluded.

http://ohsr.od.nih.gov/guidelines/belmont.html#gob3

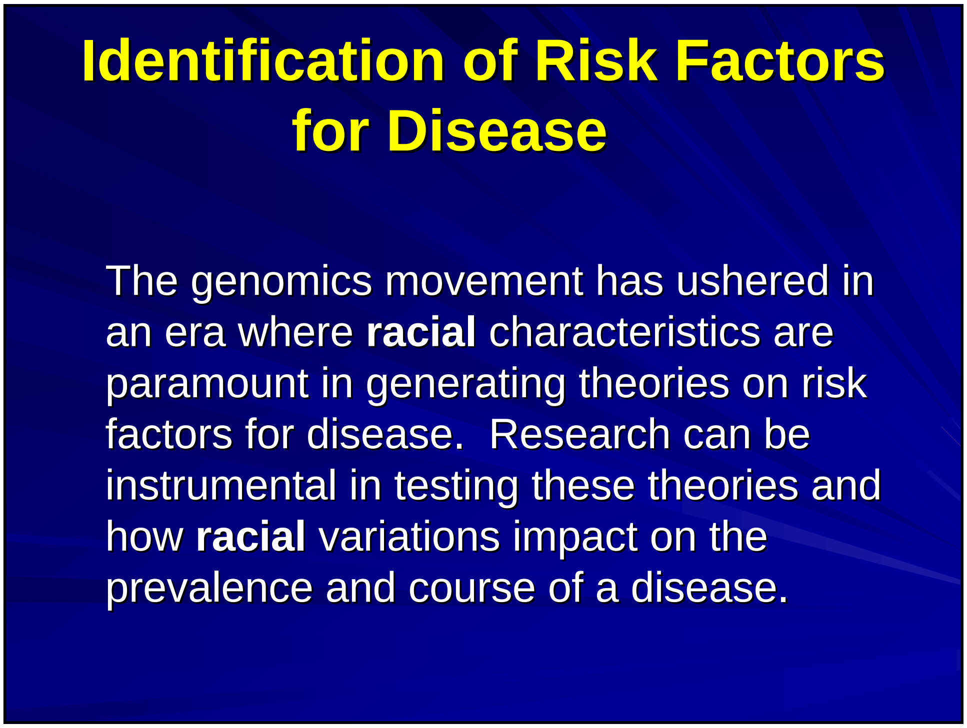
IRB "Players"

- Principal Investigator
- Co-investigators
- Participants
- Family members
- Consultants with expertise in **racial** issues



IRB Risk/Benefit factors

- The primary **benefits** for a participant in a **race**-based study are generating theories about disease risk factors and susceptibility to disease.
- The primary **risks** for a participant in a **race**-based study are psychological, social, possibly physical, and dignitary harms.



Identification of Risk Factors for Disease

The genomics movement has ushered in an era where **racial** characteristics are paramount in generating theories on risk factors for disease. Research can be instrumental in testing these theories and how **racial** variations impact on the prevalence and course of a disease.

Psychological Risks

- Ramifications of **race**-based information being disseminated to others.
- Disclosure of sensitive information.

Social Risks

- Discrimination and stigmatization
- Overlooking true socio-economic and environmental factors in the face of **race**-based research.
- Issues for the “community” members
- Disclosure to 3rd parties

IRB Protections for Race-based Research

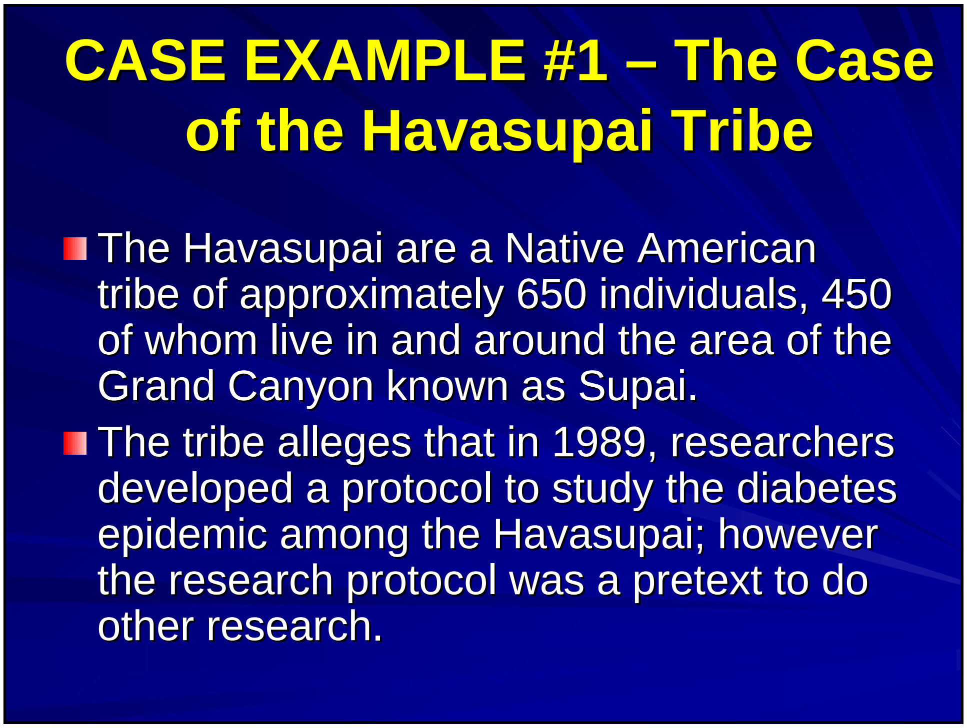
The IRB:

- should ensure that there are protections in place to warrant against inappropriate disclosures of private information.
- should understand the risks of disclosure of information.
- must ensure that there is expertise on their Board to review **race**-based projects as well as training and education for all members regarding **race**-based research.

IRB General Consent Form Requirements

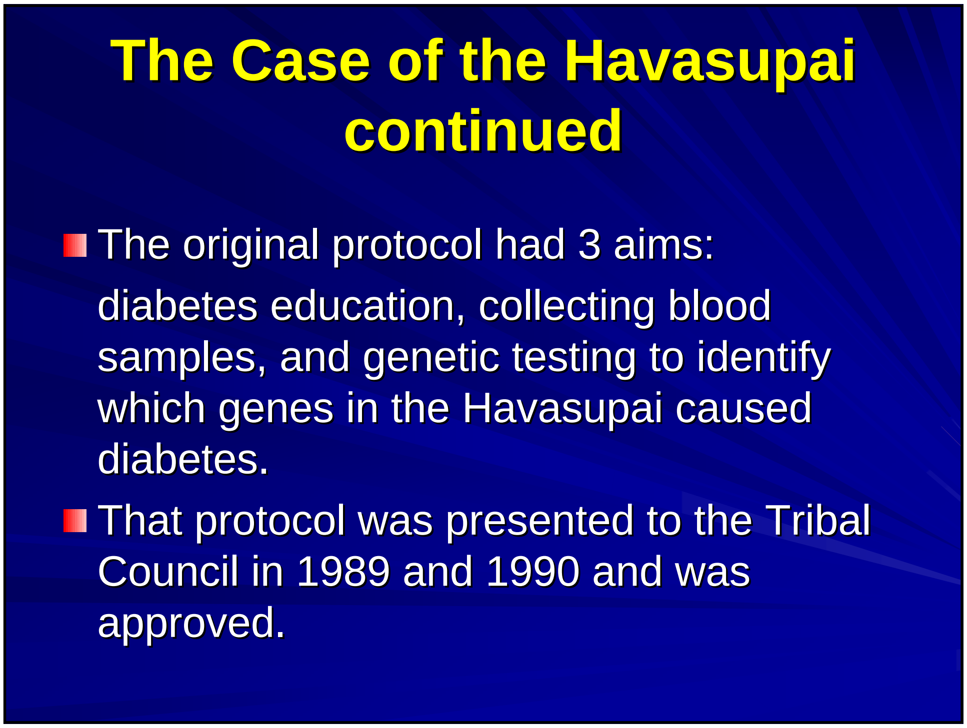
The IRB should consider the following when approving a consent form for **race**-based research:

- Access to medical records
- Consequences of withdrawal from the study
- Costs associated with the study
- Disclosure of information and the implications of disclosure for participants



CASE EXAMPLE #1 – The Case of the Havasupai Tribe

- The Havasupai are a Native American tribe of approximately 650 individuals, 450 of whom live in and around the area of the Grand Canyon known as Supai.
- The tribe alleges that in 1989, researchers developed a protocol to study the diabetes epidemic among the Havasupai; however the research protocol was a pretext to do other research.



The Case of the Havasupai continued

- The original protocol had 3 aims:

  diabetes education, collecting blood samples, and genetic testing to identify which genes in the Havasupai caused diabetes.
- That protocol was presented to the Tribal Council in 1989 and 1990 and was approved.

The Case of the Havasupai continued

- The Havasupai filed a lawsuit in 2004 against Arizona State University, the Arizona Board of Regents, and 3 researchers alleging that 400 blood samples from 180 donors were taken and either destroyed, used in studies looking at schizophrenia, looking at in-breeding among the Tribe, and looking at population migration of the Tribe, all without consent.

The Case of the Havasupai continued

The Tribe further alleged:

- That the researchers improperly obtained medical charts on members
- That the IRB did not stop the mishandling of specimens and data
- That the Tribe suffered dignitary harm from the study of their ancestral heritage

CASE EXAMPLE #2 – the Case of Prescribing BiDil

- In June, 2005, the FDA approved the drug BiDil for the treatment of heart failure for self-identified African-American patients.

  This is the first "Race-based" medication.
- BiDil is a combination of two older drugs, used to treat high blood pressure:

  hydralazine and isosorbide dinitrate.
- Neither of these drugs is approved for heart failure.

The Case of Prescribing BiDil continued

The original study of a general population showed BiDil was of no benefit. However, when the African American sample was examined, there was a significant reduction in death when compared to a placebo.

The Case of Prescribing BiDil continued

"Today's approval of a drug to treat severe heart failure in self-identified black population is a striking example of how a treatment can benefit some patients even if it does not help all patients . . . In the future, we hope to discover characteristics that identify people of any race who might be helped by BiDil."

Dr. Robert Temple, FDA Associate Director of Medical Policy. (June, 2005).

"Named Populations"

Diseases often associated with, though not necessarily always occurring, in certain populations with more frequency than others.

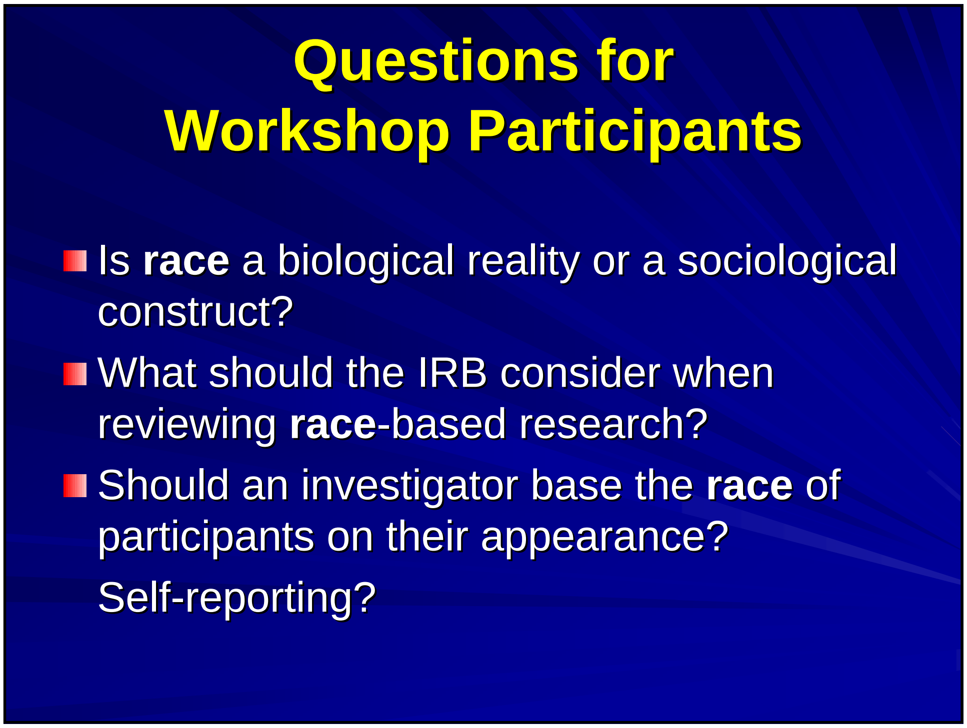
The IRB should ensure that groups that are "named" are not stigmatized or labeled.

Classification of Race

Because there is debate as to whether **race** is based on a **sociological construct** or on a **biological reality**, utilizing **race** as a classification in research is a topic of heated discussion.

IRB Review

- The IRB should be sure that research looking at **“race”** has a valid design and is scientifically sound.
- The IRB should be ever vigilant to ensure that no group is stigmatized or labeled.
- The PI should provide justification for the use of **race** and do so in a sensitive manner.
- The IRB should consider the implications of the potential results. Is there some research that should not be done?



Questions for Workshop Participants

- Is **race** a biological reality or a sociological construct?
- What should the IRB consider when reviewing **race**-based research?
- Should an investigator base the **race** of participants on their appearance?

  Self-reporting?