The definition of justice has two parts:

* Fair procedures and outcomes are used to **select** research participants, and
* There is a fair distribution of benefits and burdens to populations who **participate** in research
* Individual Justice and Social Justice
* 
* The Belmont Report distinguishes social justice and individual justice in the selection of subjects:
* **Individual justice** requires that [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) “should not offer potentially beneficial research only to some patients who are in their favor or select only ‘undesirable’ persons for risky research.”
* **Social justice** “requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.”

## More on Social Justice



“The choice of participants in research needs to be considered carefully to ensure that groups (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are not selected for inclusion mainly because of easy availability, compromised position, or manipulability.” [**10**](https://phrp.nihtraining.com/citations.php#cite10)

Selection should depend on reasons directly related to the research questions. When research leads to the development of new treatments, procedures, or devices, justice demands both that:

* These advancements are provided to those who can benefit from them, and
* The research should involve persons from groups who are likely to benefit from subsequent applications of the research

## Equity vs. Equality in Human Subjects Research



The meanings of �equity� and �equality� are similar, but not the same. The difference between equity and equality has important implications for justice in research.

To treat **“equitably”** means to treat fairly;  
To treat **“equally”** means to treat in exactly the same way.

**Research should strive for equitable distribution of the risks and potential benefits of the research.** This means that [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) are treating the groups involved in the research fairly and justly. It does not necessarily mean that all groups are equally represented, but that their representation is fair and just based on the risks and potential benefits associated with the research.

Equitable Distribution

In order to achieve an equitable distribution of the risks and potential benefits of the research, [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) must determine the distribution of different groups (men and women, racial or ethnic groups, adults and [***children***](https://phrp.nihtraining.com/glossary.php#children), age, etc.) in the populations that:

1. May be affected by the disease or condition under study, and
2. That are anticipated to benefit from the knowledge gained through the research



## Challenges to Achieving an Equitable Distribution of Benefits and Burdens



[***Investigators***](https://phrp.nihtraining.com/glossary.php#investigator) must ensure that the participants recruited for the research will not be [***unduly burdened***](https://phrp.nihtraining.com/glossary.php#unduly_burden) and that recruitment reflects the diversity of the population that may benefit from the knowledge generated from the study.

Individuals with the advantages of wealth and education may have an unfair advantage in terms of reaping the benefits of research because they may be able to afford new and costly treatments more easily than individuals in resource-poor settings.

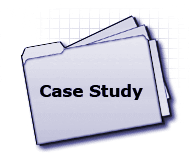
## NIH Inclusion Policies: Women and Minorities

One way the justice principle is applied is through the inclusion of women and minorities as participants in human subjects research. Because knowledge gained from clinical research may define health policy and shape standards of care for all patients, it is important to consider whether the intervention or therapy under scrutiny “affects women or men or members of minority groups and their subpopulations differently.”

The [**NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research**](http://grants2.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm) describes the Agency’s requirements for the inclusion of women and minorities in NIH-supported biomedical and behavioral research involving human subjects.

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## Case Study: Migraine Intervention Trial



A researcher seeks to improve treatment for severe migraines that are partially responsive to oral medication. He proposes to test whether acupuncture, in addition to a sufferer�s oral medication, is more effective treatment than oral medication alone. Because [**women are three times more likely to experience migraines than men**](http://www.ninds.nih.gov/disorders/migraine/migraine.htm), he proposes to enroll three times as many women as men. They will be recruited from racially and ethnically diverse communities.

**Does this study design fulfill the principle of justice?**

Text: What Do You Think?

**Yes, this study design does fulfill the principle of justice**

**Correct!**

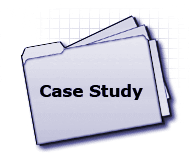
The research includes women and men in proportion to the rates of severe migraines experienced by each sex, and is designed to have racial and ethnic diversity. The study provides both sexes and racial/ethnic communities with the opportunity for benefits from the [***clinical trials***](https://phrp.nihtraining.com/glossary.php#clinical_trial), and does not unfairly burden any single group with the risks of research. Its design is fair.

**No, this study design does not fulfill the principle of justice**

**The correct answer is Yes.**

The study includes women and men in proportion to the rates of severe migraines experienced by each sex, and is designed to have racial and ethnic diversity. The study provides both sexes and racial/ethnic communities with the opportunity for benefits from the [***clinical trials***](https://phrp.nihtraining.com/glossary.php#clinical_trial), and does not unfairly burden any single group with the risks of research. Its design is fair.

## Case Study: Esophageal Cancer



A group of [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) proposes to investigate genetic factors that may increase risks for esophageal cancer. Genetic factors in esophageal cancer are not well understood and esophageal cancer occurs in many racial and ethnic populations. The investigators propose to collect DNA from cheek swabs and administer a risk factor questionnaire. Both cancer patients and age-matched controls will be included.

The investigators have access to a predominantly Caucasian sample, and have no plans to recruit participants outside of their available pool.

**Is this an acceptable strategy?**

Text: What Do You Think?

**Yes, this is an acceptable strategy**

**The correct answer is No.**

The NIH inclusion policies require that inclusion be generalizable to the population of the United States. Acceptable inclusion of women and/or minorities depends both upon the scientific question addressed by the study and the prevalence of the disease, disorder, or condition in these populations.

In this case, it is scientifically appropriate to include a broad population. Failure to include groups that would be affected by this condition could result in gaps in scientific knowledge.

**No, this is not an acceptable strategy**

**Correct!**

The NIH inclusion policies require that inclusion be generalizable to the population of the United States. Acceptable inclusion of women and/or minorities depends both upon the scientific question addressed by the study and the prevalence of the disease, disorder, or condition in these populations.

In this case, it is scientifically appropriate to include a broad population. Failure to include groups that would be affected by this condition could result in gaps in scientific knowledge.

Inclusion of Children in Research

NIH also applies the principle of justice through the [**NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects**](http://grants.nih.gov/grants/guide/notice-files/not98-024.html).



The policy emerged from the observation that children have often received treatments that have only been tested in adults, and that there is insufficient data on safe and effective uses for many treatments provided to [***children***](https://phrp.nihtraining.com/glossary.php#children). Although the past practice of excluding children may have stemmed from good motives, “protecting” children in this way has resulted in:

1. Denying children the benefits of participation in research, and
2. Preventing the collection of sufficient data about the effects of agents in children

Excluding Children from Research



The [**NIH Policy and Guidelines on the Inclusion of Children in Research Involving Human Subjects**](http://grants.nih.gov/grants/guide/notice-files/not98-024.html) states that [***children***](https://phrp.nihtraining.com/glossary.php#children) must be included in all NIH-supported human subjects research unless “… there are scientific and ethical reasons not to include them.”

If an [***investigator***](https://phrp.nihtraining.com/glossary.php#investigator) proposes to conduct clinical research that does not include children, the exclusion of children must be fully justified using one or more of the exceptions described in the Policy.

**Policy Exceptions**

1. The research topic to be studied is irrelevant to children …
2. There are laws or regulations barring the inclusion of children in the research …
3. The knowledge is already available for children or will be obtained from another on-going study, and an additional study will be redundant …
4. A separate, age-specific study in children is warranted and preferable …
5. Insufficient data are available in adults to judge potential risk in children … in some instances, the nature and seriousness of the illness may warrant [children�s] participation based on careful risk and benefit analysis ...
6. The study design is aimed at collecting additional data on pre-enrolled adult study participants …
7. Other special cases justified by the investigator and found acceptable to the review group and Institute Director

## Definition of Children: HHS Regulations and NIH Policy

Although the HHS Regulations and the NIH Inclusion Policies apply to research involving children, they vary in their definitions of [***children***](https://phrp.nihtraining.com/glossary.php#children).



**HHS regulations**

**NIH Inclusion Policy**

Research conducted or supported by the NIH must follow **both** the HHS requirements for prot

Justice and the Use of Placebos

The use of [***placebos***](https://phrp.nihtraining.com/glossary.php#placebos) in clinical research is relevant to all the issues addressed in this course. It raises issues related to justice, respect for persons, and beneficence. All three principles address a researcher�s duty not to exploit or [***deceive***](https://phrp.nihtraining.com/glossary.php#deception) research participants and to treat them fairly.

Risks associated with the use of placebos in research are:

The principle of Justice requires that when placebos are used, prospective research participants must be treated fairly. Unless justifications for a waiver are approved, the [***informed consent***](https://phrp.nihtraining.com/glossary.php#informed_consent) process must disclose sufficient information to ensure that potential research participants:

* Understand what placebos are
* Understand the likelihood that they will receive a placebo
* Are able to provide their fully informed consent that they are willing to receive a placebo

Justifying the Use of Placebos



Examples of justifications for the use of [***placebos***](https://phrp.nihtraining.com/glossary.php#placebo) include:

1. When there are no approved, effective treatments for the condition, or
2. If there is disagreement about whether standard treatment is better than placebo, or
3. When the additional risk posed by the use of placebo is minor and withholding the current standard therapy would not lead to serious or permanent harm, or
4. If the study is anticipated to result in widespread or major benefits and the receipt of placebo by individuals poses [***minimal risk***](https://phrp.nihtraining.com/glossary.php#minimal_risk)

Incomplete Disclosure and Deception



[***Incomplete disclosure***](https://phrp.nihtraining.com/glossary.php#incomplete_disclosure) and [***deception***](https://phrp.nihtraining.com/glossary.php#deception) may be useful for some research goals, but researchers may use them only after thorough consideration of:

* Whether the scientific goals of the research can be achieved by methods that do not involve incomplete disclosure or deception
* Whether participants would consider the information withheld during the [***informed consent***](https://phrp.nihtraining.com/glossary.php#informed_consent) process important to their decision to participate in the study
* Whether it is possible to inform participants that they will only learn about all the goals of the research after the research study is over

Waiver of Informed Consent



Incomplete disclosure and deception present challenges to justice because prospective participants� �[***informed consent***](https://phrp.nihtraining.com/glossary.php#informed_consent)� will not be fully informed. HHS regulations ([**45 CFR 46.116(d)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)) allow informed consent to be waived only if:

* Participation in the research involves no more than [***minimal risk***](https://phrp.nihtraining.com/glossary.php#minimal_risk)
* The waiver must not adversely affect the rights and welfare of research participants
* [***Incomplete disclosure***](https://phrp.nihtraining.com/glossary.php#incomplete_disclosure) or [***deception***](https://phrp.nihtraining.com/glossary.php#deception) must be essential to the ability to carry out the research
* Whenever appropriate, research participants will be given additional pertinent information after they have participated in such a study (debriefing)

To Debrief or Not to Debrief

Debriefing of research participants after the study involves an explanation of the [***deception***](https://phrp.nihtraining.com/glossary.php#deception) or [***incomplete disclosure***](https://phrp.nihtraining.com/glossary.php#incomplete_disclosure) of research goals to participants as well as a complete disclosure of the true goals of the research. Debriefing is generally considered to be appropriate, but must depend on whether the disclosure will result in harm.



Debriefing is appropriate when it will [**benefit the research participant’s welfare**](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm) by:

* “… correct[ing] misperceptions, or
* reduc[ing] pain, stress, or anxiety concerning the [research participant's] self-perception or performance …“

Fairness in International Research

When HHS-supported research takes place outside of the United States questions about fair treatment and fair standards may arise. This may be especially true of research conducted in countries where:

* Resources may be scarce and/or
* Other vulnerabilities may be pronounced

A few of the many issues that demand careful consideration with respect to justice, as well as beneficence and respect for persons, include:



* How can research conducted in resource-poor setting avoid exploiting participants?
* What is owed to participants in clinical research and to the population of the host country after studies are complete?
* In addition to following the HHS regulations, what standards and assurances to protect research participants should [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) and non-US institutions use when conducting research abroad?
* How can regional or cultural differences be negotiated?
* For settings where cultural values impact [***informed consent***](https://phrp.nihtraining.com/glossary.php#informed_consent), how should processes be altered?

Sustaining Benefits Locally



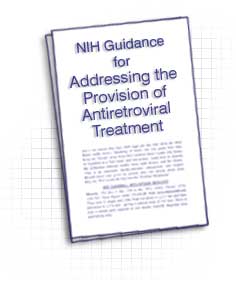
[***Investigators***](https://phrp.nihtraining.com/glossary.php#investigator) should think about how benefits to individual research participants and the local population may be sustained after the study is complete.

When planning a study, researchers and sponsors may:

* “… make reasonable, good faith efforts before the initiation of a trial to secure, at its conclusion, continued access for all participants to needed experimental interventions that have proven effective for the participants …” [**11**](https://phrp.nihtraining.com/citations.php#cite11)
* Consider how any effective treatment emerging from the research could be provided to the rest of the population

## Sustaining Benefits for Participants with HIV/AIDS in NIH-Supported Clinical Trials of Antiretroviral Agents

The NIH values continued treatment for research participants in HIV/AIDS antiretroviral studies.



*“For antiretroviral treatment trials conducted in developing countries, the NIH expects*[***investigators***](https://phrp.nihtraining.com/glossary.php#investigator)*/contractors to address the provision of antiretroviral treatment to trial participants after their completion of the trial. The NIH recommends investigators/contractors work with host countries� authorities and other stakeholders to identify available sources of antiretroviral treatment.”*

Information is found in the [**NIH Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following their Completion of NIH-Funded HIV Antiretroviral Treatment Trials in Developing Countries**](http://grants.nih.gov/grants/policy/antiretroviral/).

## Standards and Assurances for International Research

The HHS Office for Human Research Protections (OHRP) has set the expectation that the HHS regulations, as well as any additional [**institutional and local standards**](http://www.hhs.gov/ohrp/international/), will be followed in all research conducted or supported by HHS.



**Investigators:**

**Institutions:**

IRB Review for Research in International Settings



Institutions have a profound responsibility to ensure that all IRBs designated under Federalwide Assurance possess sufficient knowledge of the local research context to satisfy the requirements for human subjects protections regardless of the IRB�s geographic location relative to the institution and the research.

Knowledge of the local context may be provided by:

* Specialists with personal, direct knowledge of the local research context who participate in IRB discussions and provide insight on achieving protections for research participants
* An IRB situated within the local research context

Local Cultural Norms and Informed Consent

In unfamiliar settings, [***investigators***](https://phrp.nihtraining.com/glossary.php#investigator) should:

* Become familiar with local cultural norms and
* Seek guidance from community advisors and the IRB

Investigators should incorporate cultural norms into the research process whenever possible and appropriate. Examples of cultural norms include **community consent** and [***informed consent***](https://phrp.nihtraining.com/glossary.php#informed_consent)**from family representatives**:

If **community consent** is the cultural norm, it may be appropriate to obtain community consent in advance of obtaining informed consent from individuals. Community consent cannot replace the informed consent from individuals.

If cultural norms require permission from a family member before an individual may enroll in research, it may be appropriate to obtain permission from the family member in addition to informed consent from the prospective research participant.

Justice: Summary

**Justice** requires:

* Fair procedures and outcomes in the selection of research participants, and
* Distribution of benefits and burdens among the populations participating in research.

**Individual justice** requires that:

* Benefits of participation in research are offered to a diverse eligible population, and
* Risks of participation in research are shared by a diverse population

**Social justice** requires that consideration is given to classes of subjects that ought, and ought not, to participate in research. Considerations are based on:

* The ability of members of that class to bear burdens and
* The appropriateness of placing further burdens on already burdened persons.

This section also examines:

* Inclusion of women, minorities and [***children***](https://phrp.nihtraining.com/glossary.php#children)
* [***Placebos***](https://phrp.nihtraining.com/glossary.php#placebo)
* [***Incomplete disclosure***](https://phrp.nihtraining.com/glossary.php#incomplete_disclosure) and [***deception***](https://phrp.nihtraining.com/glossary.php#deception)
* Debriefing participants after the study
* International research
* Research in resource-poor countries

This section also discusses the NIH guidelines regarding continued treatment for research participants in HIV/AIDS antiretroviral studies.