



| GENERAL-Implicit Bias Memorandum | | | |
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Implicit Bias Memorandum

The U.S. Department of Energy’s (DOE) Central Department of Energy Institutional Review Boards’ (CDOEIRBs) Administrative and Management Teams (Administrative Teams) have identified a need to evaluate the documents comprising the Human Subjects Protection Program’s “toolkit” to ensure that explicit and implicit biases are identified and managed in the implementation of the Administrative Teams’ responsibilities. The Administrative Teams thus are looking to identify and address barriers to participation in human-subjects research (HSR). For this purpose, the Administrative Teams established an Implicit Bias Task Force (Task Force) comprised of members serving on the CDOEIRBs, the Administrative Teams, and an individual from outside the HSR community. The Task Force, in turn, developed this document addressing bias.

Bias is a natural and necessary human trait resulting from the tendency and need to classify individuals into categories as each person strives to process information and make sense of the world. Such tendencies are not necessarily positive or negative, friend versus foe for example.

Explicit bias is the traditional notion of bias. With explicit bias, an individual is aware of their prejudices and attitudes toward certain groups. The common explicit biases concern those about race, ethnicity, and gender. Within those categories, however, are biases that can be more implicit than explicit.

Implicit bias can be defined as having attitudes and/or stereotypes that affect our understanding, actions, and decisions in an automatic or involuntary, unconscious manner, those responses being without an individual’s awareness or even intentional understanding or control. Although everyone has implicit biases, such biases as are inappropriate can be reduced through the very process of recognizing and acknowledging them.

Basic to the Task Force’s review of bias are certain primary documents:

- The Belmont Report prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research;
- The Regulations for the Protection of Human Subjects Research (45 C.F.R. Part 46), which include for oversight purposes the Department of Health and Human Services’ (HHS) Office of Human Research Protections, which in turn includes a structured Institutional Review Board (IRB) process;
- The Common Rule Regulations (10 C.F.R. Part 745; 45 C.F.R. Part 46 Subpart A);¹ and

¹ HHS in 1991 promulgated The Federal Policy for the Protection of Human Subjects or the “Common Rule” in 45 C.F.R. Part 46 Subpart A. It was further codified in separate regulations by the Federal departments and agencies listed below, one of which is DOE in 10 C.F.R. Part 745.

There are four subparts to 45 C.F.R. Part 46: Subpart A, the “Common Rule”; Subpart B, additional protections for pregnant women, human fetuses, and neonates; Subpart C, additional protections for prisoners; and Subpart D, additional protections for children. Each interested agency includes in its chapter of the Code of Federal Regulations language identical to that of the HHS codification at 45 C.F.R. Part 46, Subpart A. For all participating



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- DOE Order 443.1C (2019), Protection of Human Research Subjects.²

Basic also is the Task Force's recognition of the stakeholders:

- DOE:
 - CDOEIRB Administrative Team;
 - CDOEIRB Management Team;
 - Human Subjects Protection Program;
 - CDOEIRBs;
- The sponsors of the research;
- The Principal Investigators (PIs) and fellow researchers; and
- The research participants to whom there is an obligation.

The documents illuminating the Task Force's discussions are several, but what may be considered the first document is the Belmont Report.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Commission) was established by the National Research Act of 1974.³ The Commission was charged with

departments and agencies, the Common Rule outlines the basic provisions for Institutional Review Boards, informed consent and Assurances of Compliance.

This list displays the nineteen agencies and departments that must comply with the Common Rule and their C.F.R. numbers: Consumer Product Safety Commission (16 C.F.R. Part 1028); Department of Agriculture (7 C.F.R. Part 1c); Department of Commerce (15 C.F.R. Part 27); Department of Defense (32 C.F.R. Part 219); Department of Education (34 C.F.R. Part 97 Subpart A); Department of Energy (10 C.F.R. Part 745); Department of Health and Human Services (45 C.F.R. Part 46 Subpart A); Department of Homeland Security (6 C.F.R. Part 46); Department of Transportation (49 C.F.R. Part 11); Department of Housing and Urban Development (24 C.F.R. Part 60); Department of Justice (28 C.F.R. Part 46); Department of Veterans Affairs (38 C.F.R. Part 16); Environmental Protection Agency (40 C.F.R. Part 26); National Aeronautics and Space Administration (14 C.F.R. Part 1230); National Science Foundation (45 C.F.R. Part 690); Social Security Administration (20 C.F.R. Part 431); and the U.S. Agency for International Development (22 C.F.R. Part 225). In addition, the Central Intelligence Agency and the Office of the Director of National Intelligence must comply with all subparts of 45 C.F.R. Part 46 pursuant to Executive Order 12333 (1981) as amended.

² DOE Order 443.1C states as its purpose: "To establish Department of Energy (DOE)-specific policy and principles for the protection of human subjects involved in DOE research, and DOE procedures and responsibilities for implementing the policy and requirements set forth in Title 45 Code of Federal Regulations (C.F.R.) Part 46, Protection of Human Subjects, and 10 C.F.R. Part 745, Protection of Human Subjects, and the 1997 Presidential Memorandum, 'Strengthened Protections for Human Subjects of Classified Research,' dated March 27, 1997."

³ The Act was passed after a series of U.S. Congressional hearings addressed to human-subjects research as initiated by Sen. Edward Kennedy. It created the Commission to consider and recommend guidelines and regulations regarding the use of human-subjects research.



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identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, and with developing guidelines in accordance with such principles.

Two years later, the Commission published the Belmont Report,⁴ which set forth those ethical principles and guidelines.

The Commission noted in the Belmont Report that public attention had been drawn to a consideration of what constitutes the ethical principles of research involving human subjects by the abuses of human subjects in biomedical experiments, particularly those conducted during World War II. Indeed, during the Nuremberg War Crimes Trials that were conducted in 1945 and 1946, the Nuremberg Code was drafted as a set of standards for judging the doctors and scientists who had conducted biomedical experiments on prisoners held in the concentration camps. This code influenced many later codes intended to secure ethical research involving human subjects.

In its Belmont Report, the Commission sought to summarize three basic ethical principles it had identified as those “particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.”

The Commission divided “Respect for Persons” into two “ethical convictions”: (1) individuals should be treated as autonomous agents, and (2) persons with diminished autonomy are entitled to protection.

The Commission defined “Beneficence” as treating persons “in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.” It formulated two “general rules” as complementary expressions of “beneficent actions”: (1) do no harm, and (2) maximize possible benefits and minimize possible harms.

The Commission considered “Justice” in the context of equality before setting forth five “formulations”: “(1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.”

There is as a result a certain tension among the three principles, particularly between “Respect for Persons” and “Justice” as articulated by the Commission.

The Belmont report is specifically mentioned in 45 C.F.R. §46.101(c) and 10 C.F.R. §745.101(c) (“Department or agency heads retain final judgment as to whether a particular activity is covered by this policy, and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.”) and in 45 C.F.R. §46.101(i) and 10 C.F.R. §101 (i) (“Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report. ... The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.”).

⁴The report took its name from the Belmont Conference Center, then part of the Smithsonian Institution, the site where the document was drafted in large part.



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Specifically pertinent to the Task Force is 10 C.F.R. §745.111: Criteria for IRB Approval of Research, which states:

- (a) In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:
 - (1) Risks to subjects are minimized.
 - (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
 - (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The Belmont Report as specifically mentioned in 10 C.F.R. §745.101(c) refers to “equality” as part of “Justice,” whereas 10 C.F.R. §745.111(a)(3) requires an “equitable” selection of subjects. The Marin County, California, Department of Health and Human Services well-articulated the difference between equality and equity: “While the terms equity and equality may sound similar, the implementation of one versus the other can lead to dramatically different outcomes for marginalized people. Equality means each individual or group of people is given the same resources or opportunities. Equity recognizes that each person has different circumstances and allocates the exact resources and opportunities needed to reach an equal outcome.”⁵ The concept of “bias” implicates both “equity” and “equality.”

As stated earlier, bias is a natural and necessary human trait resulting from the need to classify individuals as a means of making sense of the world, and the possession of a bias is not inherently positive or negative. But this necessity does not mean that bias always is suitable; rather, whether bias is appropriate depends on its context.

⁵ www.marinhhs.org/sites/default/files/boards/general/equality_v._equity_04_05_2021.pdf.

See also Executive Order on Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce (No. 14035, June 25, 2021) sec. 2 “(c) The term ‘equity’ means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment.”

See also 45 CFR § 46.111: Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

* * *

(3) *Selection of subjects is equitable.* In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. [Emphasis added.]



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Explicit bias is arguably more easily identifiable than implicit bias because an individual is said to be aware of their attitudes toward certain groups, whereas implicit bias is subtle as the very definition of “implicit bias” from Merriam-Webster sets forth: “a bias or prejudice that is present but not consciously held or recognized.”⁶ Nonetheless, or, more likely, because the bias is not perceived, an implicit bias can have a significant influence in the consequence of interactions. Such biases can be reduced through the very process of recognizing them, and that is what the Task Force intends to achieve by articulating them through a list of examples, noting that the list is not exhaustive and that there is overlap between certain explicit biases and certain implicit biases.

*Some Common Examples of Bias*⁷ • Affinity Bias • Ageism • Anchor Bias • Attribution Bias • Authority Bias • Beauty Bias • Confirmation Bias • Conformity Bias • Contrast Effect • Convenience Bias • Gender Bias • Geographic location • The Halo Effect/The Horns Effect • Height Bias • Language Bias • Name Bias • Nonverbal Bias • Occupation • Overconfidence Bias • Political Bias • Race and Ethnicity Bias • Religious Bias • Sexual identity Bias

1. *Affinity bias*: a tendency to connect with other individuals who share similar backgrounds, experiences, and interests.
2. *Ageism*: a tendency to have a mindset about another person based on that person’s age.
3. *Anchor bias*: the regard of a person when that person holds a singular piece of information to make decisions.
4. *Attribution bias*: when one person tries to make sense of or judge another person’s behavior based on prior observations and interactions with that person such that it establishes a perception of them.
5. *Authority bias*: when an idea or opinion is given more attention or is thought to be more accurate because it was provided by an authority figure.
6. *Beauty bias*: when a person believes that beauty is significant to whether a person is more successful, competent and/or qualified.
7. *Confirmation bias*: a tendency to draw conclusions about a person based on a set of already held personal beliefs and prejudices.
8. *Conformity bias*: a tendency of a person to act similarly to the person(s) around regardless of personal attitudes, e.g., peer pressure.
9. *Contrast effect*: when there is a comparison of two or more people, either simultaneously or subsequently, causing an exaggeration of the abilities of one in contrast to the other.

⁶ www.merriam-webster.com/dictionary/implicit%20bias

⁷ See Bailey Reiners, “16 Unconscious Bias Examples and How to Avoid Them in the Workplace,” builtin.com (October 14, 2021).



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10. *Convenience*: a choice or selection made from convenience rather than from an honest and open consideration of relevant qualities.
11. *Gender bias*: a tendency to prefer one gender over another gender.
12. *Geographic location*: a tendency to regard a person from one geographic location as superior or inferior.
13. *Halo effect*: a tendency to regard a person as superior after learning something impressive about them.
Horns effect: a tendency to view a person negatively after learning something negative about them.
14. *Height bias*: a tendency to judge a person who is shorter or taller than the person making the determination.
15. *Language*: a tendency to judge a person by that person's language skills or accents.
16. *Name bias*: a tendency to judge a person by the familiarity of that person's name(s).
17. *Nonverbal bias*: a tendency to judge a person according to that person's nonverbal communication attributes, e.g., body language.
18. *Occupation*: a tendency to judge a person according to that person's occupation.
19. *Overconfidence bias*: a tendency to regard a person as whether more confident in their competences than they should be.
20. *Political bias*: a tendency to view a person with one political viewpoint more or less favorably than a person with a different political viewpoint.
21. *Race and ethnicity*: a tendency to prefer a person of one race or ethnicity over a person of a different race or ethnicity, including, but not limited to individuals of African, Asian, Hispanic and Latino, Indigenous and Pacific Islander descent.
22. *Religious bias*: a tendency to prefer or to view a person of a different religion more or less favorably.
23. *Sexual identity*: a tendency to prefer a person of the same or different sexuality over a person of sexual identity.

While the biases enumerated above are a non-exhaustive list of identified biases, the intent of the Task Force was to create a document to increase awareness of the variety of explicit and implicit biases with which HSR stakeholders should be familiar. In addition, the HSR stakeholders should question what other possible biases they might hold. It is important that these stakeholders evaluate the positive and negative impacts that different biases can have when defining the population of research subjects because the research results will be expanded to the broader population from which those subjects were identified. In order to be inclusive of the wide diversity of the population, and of the promotion of equity and equality, it is important to ensure that the HSR stakeholders are educated about this very important topic of explicit and implicit biases.