Whereas, Current AMA policy calls for physicians to “report the results of research accurately, including subsequent negative findings”, particularly when “the findings do not support the research hypothesis”;¹ and

Whereas, There are hurdles to the publication of negative research findings because of publication bias wherein journals are less likely to accept manuscripts reporting negative findings;² and

Whereas, The AMA supports the reproducibility of research findings by advocating that scientific research “employ study designs that will yield scientifically valid and significant data”;³ and

Whereas, There is a systemic lack of reproducibility among published biomedical research studies⁴, as highlighted by a recent report finding that nearly 70% of researchers were unable to reproduce another scientist’s results;⁴,⁵ and

Whereas, Preregistration of a research study is the act of committing to clearly defined research questions and analytical plans prior to the observation of the research outcomes, usually achieved by posting an analysis plan to an independent registry;⁶ and

Whereas, Establishing hypotheses prior to observation of outcomes has been associated with a four-fold reduction in rates of reporting false positive findings, suggesting that preregistration can increase replicability of research;⁷ and

Whereas, The proportion of large clinical trials reporting negative findings increased from 43% to 92% after preregistration of clinical trials became mandatory in the United States, showing that “preregistration is correlated with outcomes that suggest reduced publication or reporting biases;⁸ therefore be it

¹ AMA Code of Medical Ethics Opinion E-7.2.1 Principles for Disseminating Research Results
³ AMA Code of Medical Ethics Opinion E-7.1.3 Study Design and Sampling
RESOLVED, That our American Medical Association support preregistration in order to mitigate publication bias and improve the reproducibility of biomedical research. (New HOD Policy)

Fiscal Note: not yet determined

Date Received: 09/21/18

RELEVANT AMA POLICY

E-7.1.3 Study Design & Sampling
To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design. Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable. Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

(a) Is consistent with the goals and fundamental values of the medical profession.
(b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.
(c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).
(d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.
(e) Provides mechanisms to safeguard confidentiality.
(f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.
(g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participants legally authorized representative, in keeping with ethics guidance.
(h) Has been reviewed and approved by appropriate oversight bodies.

AMA Principles of Medical Ethics: I,II,III,V,VII
Issued: 2016

E-7.2.1 Principles for Disseminating Research Results
Physicians have an ethical responsibility to learn from and contribute to the total store of scientific knowledge. When they engage in biomedical or health research, physicians have obligations as scientists, which include disseminating research findings. Prompt presentation to scientific peers and publication of research findings are foundational to good medical care and promote enhanced patient care, early evaluation of clinical innovations, and rapid dissemination of improved techniques. To fulfill their ethical responsibilities with respect to sharing research findings for the ultimate benefit of patients, physicians should:

(a) Advocate for timely and transparent dissemination of research data and findings. Physicians should not intentionally withhold information for reasons of personal gain.
(b) Report the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis.
(c) Maintain a commitment to peer review.
(d) Disclose sponsorship and conflicts of interest relating to the research, in keeping with ethics guidance.
(e) Be responsible in their release of research results to the media, ensuring that any information the researcher provides is prompt and accurate and that informed consent to the release of information has
been obtained from research participants (or participants legally authorized representative when the participant lacks decision-making capacity) prior to releasing any identifiable information. In rare circumstances, the potential for misuse of research results could affect the decision about when and whether to disseminate research findings. Physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit against potential harms from corrupt application. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against misuse.

AMA Principles of Medical Ethics: I,II,III,V,VII
Issued: 2016

Food Additives H-150.998
Our AMA supports the passage of legislation that would amend the Food Additive Act to require evidence based upon scientifically reproducible studies of the association of food additives with an increased incidence of cancer in animals or humans at dosage levels related to the amounts calculated as normal daily consumption for humans before removal of an additive from the market.

Citation: (Sub. Res. 4, A-77; Reaffirmed: CLRDPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Modified: BOT Rep. 6, A-10)

Increasing Minority Participation in Clinical Research H-460.911
1. Our AMA advocates that:
   a. The Food and Drug Administration (FDA) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.
   b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and
   c. Resources be provided to community level agencies that work with those minorities who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.
2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities in clinical trials:
   a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders’ support, and listening to community’s needs;
   b. Increased outreach to female physicians to encourage recruitment of female patients in clinical trials;
   c. Continued minority physician education on clinical trials, subject recruitment, subject safety, and possible expense reimbursements;
   d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and
   e. Fiscal support for minority recruitment efforts and increasing trial accessibility through transportation, child care, reimbursements, and location.
3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.