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CODE OF ETHICS OF THE ENDOCRINE SOCIETY

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Last Revised 6/13/13

Introduction

The Endocrine Society, recognizing the major ethical issues confronting its membership in their pursuit of science and clinical excellence, established an Ethics Advisory Committee in 1998. In 2001, a Code of Ethics was developed for both the Society as an organization and for its members. It considers relations within the Society, the scientific and general public, and with industry. The Code was designed to include general principles and guidelines to assist with emerging ethical issues.

Background to the 2013 Revision of the Code of Ethics

In 2012, the decision to revise the existing Code of Ethics by the Endocrine Society's leadership was motivated by several factors. First, many of the recommendations contained in the original Code required updating in part due to new developments in the standards of ethical conduct with industry and human subjects' protection. Moreover, several institutions including the US Health and Human Services, Office of Human Research Protection (OHRP), and the Office of Research Integrity (ORI), as well as the National Institutes of Health, Office of Human Subjects Research (OHSR) published guidelines that overlap with the contents of the Code and with which compliance is compulsory. Thus, an independent set of guidelines for human subjects' research within the Society's Code was duplicative. Similarly, both the American Medical Association (AMA) and the American College of Physicians (ACP) have developed comprehensive guidelines to govern ethical behavior in clinical practice which are relevant (but not mandatory) for guiding physician members of the Endocrine Society. Additionally, since the publication of the original Code, heightened awareness and sensitivity to transparency and self-disclosure has permeated the fabric of the Endocrine Society. The Society adheres to guidelines and regulations developed by accreditation bodies, research and medical institutions, and scientific journals. Most Society related conflicts of interest are managed by Council, the Society's journal editors, educational programming committee chairs, and at the committee level. Moreover, guidelines and statements pertaining to the expected standards of ethical conduct related to these areas have been developed separately. Thus this revision was guided by an effort to reduce the duplication of documents produced by the Society and to harmonize efforts that otherwise could overlap and conflict. Finally, standards of ethical behavior are rapidly developing in both their specificity and their breadth of application to members of the Society, as is the extent of oversight ensuring compliance with these standards at both the local institutional and national levels. Thus, the current revisions attempt to provide recommendations and appropriate referral to existing guidelines from relevant organizations rather than endorsing a specific set of guidelines

meant to apply to all members of the Endocrine Society and their local institutions. The revised Code is intended to be a living document that we hope serves the membership but is less vulnerable to becoming outdated due to the rapidly changing nature of human subjects' protections, relations with industry, and the ethics of human and animal research.

Executive Summary - Appended from 2001 Code of Ethics¹

The Code is divided into two sections, the Responsibilities of the Society and the Responsibilities of the Members. The Society's responsibilities are to support endocrine research, education, and clinical practice in an ethical manner with excellence, openness, and the highest integrity. The Society has a responsibility to promote high quality science and collegiality among its members and to protect member privacy. It should carefully manage its independent relationship with industry and ensure that its educational presentations remain objective and complete. The Society should be careful in endorsing or marketing products and services not of its own design. The Society's principal function is to advance excellence in endocrinology and promote its essential and integrative role in scientific discovery, medical practice, and human health. It must ensure that meetings, publications, and courses remain of the highest quality. The Society has a responsibility to provide leadership in the elucidation of ethical issues relevant to the field of endocrinology with the scientific and medical communities and the lay public.

The responsibilities of Endocrine Society members are to conduct themselves according to the highest standards of professional behavior in both research and clinical care. They should engage in responsible performance and reporting of research. They should behave in a collegial manner and share intellectual property appropriately. Members should abide by and educate trainees in the regulations for the safe and ethical conduct of research. Research employing animals should include respect for animals as sentient creatures. Genetic research features sensitivity to the privacy and confidentiality of the families and groups involved.

Those who pursue clinical practice have the responsibility to treat their patients with respect, regardless of their gender, age, religion, disability, race, ethnicity, social, financial, or medical status, life-styles, or sexual preferences. Patients' choices must be respected and patients have the right to participate in their choice of medical therapy. Physicians should act in the best interests of their patient and be guided by the principles of both beneficence and non-maleficence. Physicians must practice within their scope of expertise. Circumstances in which

¹ <https://www.endocrine.org/~media/endosociety/Files/About%20Us/Corporate%20Info/code-of-ethics.pdf>

the physician has a financial interest in clinical or research ventures must not be allowed to pose a threat to patient welfare.

Peter J. Schmidt, M.D., Chair

Advisory Panel on Ethics and Conflicts of Interest Members:

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I. RESPONSIBILITIES OF THE SOCIETY AS AN ORGANIZATION

A. Responsibilities of the Society: General

The Endocrine Society shall discharge its responsibilities to support endocrine research, education, and clinical practice with excellence, openness, and the highest integrity. The Society has a responsibility to promote high quality science and collegiality among its members and to protect member privacy.

1. The Society shall not allow its objectivity to be influenced by corporate or other sources of income. Dualities of interest² shall be disclosed in a timely and comprehensive manner.
2. The Society shall provide prudent management of funds, verified by periodic auditing. The audit report shall be made available to members.
3. Using objective written criteria, the management of the Society shall be subject to regular performance review by Council.
4. Members shall be kept informed of the activities of the Society. The affairs of the Society shall be open to the members, including the activities of its committees.
5. Member privacy and confidentiality shall be maintained with regard to personal data (e.g., email address, home address) and communications with Society officers. Consent for directory listings and sales of lists will be obtained on membership forms.
6. The Society shall conduct fair and democratic elections and ensure democratic decision-making among its committees.
7. The Society shall provide members with mechanisms for voicing their concerns. Resolution of complaints and concerns will be handled expeditiously

² An interest is a commitment, goal or value arising out of a social relationship or practice. A "conflict" of interest exists when a particular relationship or practice gives rise to two or more contradictory interests. A "duality" of interest arises when two or more interests are potentially in conflict, depending on the specific circumstances of an individual case.

with written or electronic acknowledgement of receipt of the member's communication and a goal of providing feedback on resolution of any concern without delay.

8. The Society prohibits discrimination on the basis of gender, race, ethnicity, national origin, religion, age, citizen status, sexual orientation, disability or any other characteristic protected by federal, state or local equal employment opportunity laws with respect to any decision or recommendation made by a member concerning (a) the participation of another member in a Society activity or (b) the hiring, performance evaluation, or a work assignment of a Society employee. The Society shall encourage diversity in all activities and all committees.
9. Society participation is based on volunteer efforts. While time commitments may be expected, members shall not be expected to incur significant financial expenses in their service to the Society. Service to the Society should not be based on economic considerations.
10. The Society shall organize its activities to recognize the diverse professional needs of its members.
11. The Society will develop strategic worldwide partnerships to advance the science, prevention, and treatment of endocrine diseases, and advance human health on a global scale.

B. Responsibilities of the Society: Relations with Industry

The Society appreciates that appropriate relationships with industry offer important benefits for the field and for the public it serves. Collaborations with industry partners permit the Society to expand its programs significantly in the service of its mission to "advance excellence in endocrinology and promote its essential and integrative role in scientific discovery, medical practice, and human health." These relationships also facilitate fruitful communications between industry research, research occurring outside industry and endocrinology practice.

The Society actively seeks outside financial or in-kind support for specific programs that further its fundamental goal of providing the highest quality education and professional development for endocrinologists. The Society will accept financial or in-kind support for specific activities from pharmaceutical, device or biotech companies that adhere strictly to guidelines and regulations of the Accreditation Council for Continuing Medical Education (ACCME), the American Medical Association (AMA), the Pharmaceutical & Research Manufacturers Association (PhRMA) and the Advanced Medical Technology Association (AdvaMed).

The Endocrine Society and its Hormone Health Network maintain complete independence between industry support of any and all of its programs and the

content development of such programs³. Recognizing the inherent risk of bias that accompanies the seeking and acceptance of outside funding, the Society has developed policies and procedures to ensure that, in so doing, its objectivity and credibility are not compromised in any way.

In the interest of transparency, the Society has developed the following principles to document its relationship to industry related to its educational products and services:

1. **Educational Meeting and Products (accredited and non-accredited):** The Endocrine Society is committed to developing educational opportunities that are in the best interest of the patient and medical practitioner. All accredited continuing medical education (CME) activities are developed in accordance with the Society's policies and procedures, as well as within the context of the ACCME's Standards for Commercial Support (SCS)⁴, the AMA's Physician Recognition Award (AMA PRA) requirements⁵ and the AMA's Council on Ethical and Judicial Affairs (CEJA)⁶. Adherence to these standards helps the Society ensure that its products are independent of influence by commercial interests and in the best interest of the public.

2. **Personal relationships with Industry:** As outlined in the Society's Bylaws and related policies, all Officers, Council members, volunteers serving in leadership positions, and senior staff of the Society have an "affirmative duty to avoid conflicts of interest which may occur during their tenure." To support these expectations, the Society employs the following practices:

- a. A Society statement addressing conflicts of interests from outside relationships is read at the beginning of all Society Council and committee meetings.
- b. All members and staff involved in Society activities must disclose any relationships with outside entities that may be relevant to their Society roles and responsibilities. Individuals involved in the planning of CME activities are also required to provide disclosure of relevant financial relationships in accordance with the ACCME requirements.
- c. Disclosures are requested annually and are reviewed, made publicly known as a matter of course, and concerns are resolved in a timely manner.

3. **Commercial Support Received for CME:** The Endocrine Society accepts

³ <http://www.endo-society.org/upload/The-Endocrine-Society-s-Statement-on-Industry-Relationships-Final-11-13-09.pdf>

⁴ <http://accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>

⁵ <http://www.ama-assn.org/resources/doc/cme/prs-booklet.pdf>

⁶ <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/ceja-reports.page>

commercial support for a portion of its educational activities. Signed written agreements are required for all commercial support received and do not impact the control or content of the activities. Promotional opportunities are considered and administered separately from any commercial support.

To support and document the implementation of these standards to its CME program, the Society utilizes numerous documents and forms which can be found at <http://dev.endocrine.org/education-and-practice-management/continuing-medical-education/societys-cme-program>. These materials are reviewed and updated periodically to ensure compliance with all applicable regulations.

Travel: Although commercial sponsors may wish to pay the costs of individuals who attend a supported meeting, this creates a serious duality of interest. It is appropriate to accept funds for trainees to cover the costs of attending educational conferences, provided that the selection of the recipient is made by the Society and/or the training institution. Travel support for speakers is acceptable as part of their compensation, as outlined in the ACCME's Standard for Commercial Support 3.13⁷. The Society should follow Section 8.061 of The American Medical Association's Code of Ethics that specifically addresses this issue.⁸

C. Responsibilities of the Society: Endorsements

As a professional organization representing a medical specialty, the Society may take positions intended to inform the public and/or educate legislators regarding specific issues related to endocrinology. The Society Bylaws state that it "shall promote research and study in the science of endocrinology." Pivotal to this responsibility, the Society may act to promote the study, or increase awareness, of specific medical conditions. It is appropriate for the Society to take positions regarding endocrine disorders and their treatment in the interest of public health.

In these cases, to the extent possible, the Society shall not support specific treatments in order to avoid compromising its objectivity and credibility. Further, such support should not be in return for a specific *quid pro quo*. Any such statements shall undergo formal internal review for their impact on the integrity of the Society.

⁷ SCS 3.13: The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

⁸ "Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of the physicians who are attending the conferences or meetings...." Available on-line at <http://www.ama-assn.org>

D. Responsibilities of the Society: Marketing

The Society has many opportunities to benefit from marketing royalties on products such as credit cards, insurance, and stationery. It can also benefit from the rental of its membership list. The Society may be approached to participate in the marketing of medical products as well.

1. The Society shall not participate in the marketing of health-related products with the exception of its own journals, including print and online advertising sales and journal reprints, educational materials and programs, and relationships with approved vendors.
2. The Society may make available to its members specific goods or services as a benefit (as in discounts or group availability), or that may raise money for the Society, provided that the rationale of the endorsement and the benefit to the Society members are fully disclosed in advance.

E. Responsibilities of the Society: Publications

In the publication of research results, the Society shall adhere to the highest standards of scientific integrity.

1. Authors

The accurate and truthful reporting of research is a requirement of authorship and is a goal of all journals. Authors are obliged to conduct research according to ethical precepts: to present an accurate account of the methods used, the results obtained, the relevant scientific literature, and to provide an objective discussion of the significance of the research. Authorship also implies a substantial contribution to the research and acceptance of responsibility for the content of the publication.

- a) All authors submitting manuscripts or abstracts to any Society publication are expected to abide by its publication guidelines.⁹
- b) Authorship should be based on a substantial intellectual contribution to the manuscript. Therefore, honorary authorship is inconsistent with the definition of authorship.
- c) Publications with results obtained from the use of human subjects shall have identified approval from the Institutional Review Board (IRB, United States) or equivalent review board, in the case of countries other than the United States.
- d) Publications with results obtained from the use of animal subjects shall have identified approval from the Institutional Animal Care and Use Committee (IACUC, United States) or equivalent review board, in the case of countries other than the United

⁹ *The Endocrine Society*. Ethical Guidelines for Publications of Research. (Approved by Council October 2007; updated by Publications Core Committee April 2010). Retrieved April 2, 2012, <http://endo.endojournals.org/site/author/endoethics.xhtml>

States.

2. Reviewers

Peer review is an essential step in the publication process to ensure that published articles describe well designed and executed research that provides a significant addition to the scientific literature. Objective review of the scientific rigor of manuscripts is essential, and peer reviewers are necessarily experts knowledgeable in the field under review. As volunteers, reviewers provide important services to the discipline of endocrinology, authors, and editors. They contribute to maintenance of high standards of Society publications.

3. Editors

The Society has the mandate to select editors for its journals and support the editorial process. Editors are responsible to ensure the quality of publications and maintain the confidentiality and integrity of the review process. To wit:

- a) Editors are responsible for acceptance or rejection of a manuscript.
- b) Editors must strive to ensure that all manuscripts are evaluated in a fair and impartial manner, focusing evaluations on the importance and quality of the work. Editors should endeavor to select reviewers with appropriate expertise and sound judgment.
- c) Reviewers with significant conflicts of interest should be rejected.
- d) Journal editors shall recuse themselves from reviewing work in which a potential or actual conflict of interest exists and transfer responsibility to an alternative editor.
- e) The editor shall treat unpublished material in a confidential manner, avoiding disclosure of information about a manuscript under consideration to anyone other than those from whom professional advice is sought or as part of the normal editorial process.
- f) The editor must provide an organized and timely editorial process that includes written feedback and reviewer comments to the author.
- g) The editors are responsible to correct publication errors.
- h) Editors should inform reviewers in writing at the time of receipt of manuscripts of their responsibility to identify and report suspected duplicative publication, fraud, or plagiarism.
- i) Editors may be obligated to conduct an initial inquiry into apparent or alleged misconduct involving manuscripts under consideration, in press, or published in Society journals. However, editors generally do not have the mandate or authority for substantive investigations and should generally refer the question to the institution(s) of the contending parties. Care should be taken to respect the scientific reputations of all parties and to maintain confidentiality in this process.

4. Scientific misconduct

The Society affirms that scientific misconduct in any form, including plagiarism, fabrication, or falsification of data jeopardizes the research endeavor.

5. Authorship Obligations

Authors should make unique resources (including but not limited to cell lines, software programs, organisms, antibodies, etc.) available to other investigators for academic research purposes. If there are restrictions to the availability of such resources, authors must disclose this fact in the cover letter to the editors at the time of submission, and include a comment on the restrictions in the Materials and Methods section. The Endocrine Society endorses the philosophy of open exchange of research materials.¹⁰

F. Responsibilities of the Society: Teaching Ethics

The Society should provide guidance to, and identify educational opportunities for its membership in the ethical aspects of research and clinical practice and actively promote a climate that values and fosters ethical conduct in research and clinical practice.

1. The Society has the responsibility to keep its members informed about the professional standards of conduct expected of them. Members are encouraged to seek guidance from the Society when an ethical concern arises that they feel unprepared to address.
2. The Society has a responsibility to provide educational and skill development opportunities for members in ethics.
3. The Society shall provide leadership in the elucidation of ethical issues germane to the field of endocrinology with the scientific community and the lay public.

G. Responsibilities of the Society: Sanctions

On occasion, the professional behavior of a member might be such as to warrant a sanction by the Society. The Society can suspend or expel a member or prevent her/him from publishing in any of the Society's journals for a period of time as referenced in the Society's Bylaws.

Procedures for Dealing with Allegations of Unethical Conduct: When a violation of ethical conduct is alleged, it is essential that the Society's leadership respond quickly and effectively. Allegations of misconduct are generally managed at the committee level and by editors.

¹⁰ <http://jcem.endojournals.org/site/author/endoethics.xhtml>

1) Concerns and allegations complex in nature, escalated from the committee level or brought forward by non-members abide by the following procedures approved by Council. Any Society member or non-member who has concerns regarding a potential violation of the Code of Ethics should send written or electronic communication to the Society's headquarter office (addressed to the President and the Executive Director), who will expeditiously review the concern with the appropriate parties and respond to the complainant in writing or by telephone. If necessary, the President or Council shall appoint an Ad Hoc panel to deliberate and resolve the case, seeking the Society's legal counsel on a case by case basis.

2) All complaints shall be treated as confidential. The anonymity of the person making the complaint shall be maintained unless the person indicates that he or she does not wish to remain anonymous.

II. RESPONSIBILITIES OF ENDOCRINE SOCIETY MEMBERS

A. Responsibility to Colleagues

1. Members shall treat their colleagues regardless of country of origin, gender, age, religion, disability, race, ethnicity, social, financial, or medical status, life-styles, or sexual preferences with respect and promote collegiality at both national and international levels.
2. Members shall promote the educational and professional growth of their colleagues and trainees.
3. Members shall give proper attribution to the accomplishments and works of colleagues, including junior physicians, trainees, and medical students.
4. Clinically related commercial ventures with colleagues shall maintain patient welfare as the top priority, not financial gain or academic promotion.
5. Members shall report to appropriate authorities the conduct of colleagues that threatens research integrity, the integrity of the medical profession or patient welfare.
6. Members who supervise trainees shall disclose to them their financial interests in projects directly involving the trainee's academic program. It is suggested that mentor-trainee relationships that involve these financial interests be delineated and approved by the institution's leadership.

B. Research (General)

Members are expected to conduct themselves according to the highest standards of professional behavior in both research and clinical care. They should engage in responsible performance and reporting of research. They should behave in a collegial manner and share intellectual property appropriately. Members should abide by and

educate trainees in the regulations for the safe and ethical conduct of research. Members should refer to the following current guidelines and regulations: ORI¹¹ ; OHRP¹² ; and OHSR.¹³

Additionally, members should comply with the regulations of the Ethics Office within their local institutions and participate in regular training in ethics provided at their institution. Members engaged in human research also should refer to FDA guidelines and reporting requirements: FDAAA and Clinicaltrials.GOV Documents.¹⁴

Members engaged in international collaborations should maintain respect for their colleagues from other countries or jurisdictions, and treat colleagues in an equal and collegial manner. Members should be aware and sensitive to differences in national and jurisdictional rules including regulations regarding conflicts of interest and human research protection (<http://www.hhs.gov/ohrp/international/index.html>). Additionally, members who collaborate with colleagues working in under-resourced institutions (both domestic and international) are encouraged to mentor and assist in the career development of those colleagues.

C. Research Tools

Sharing of materials should be a goal of investigators, and applied to the extent it is practical. It is desirable to encourage agreements and basic guidelines for the transfer of research tools¹⁵; the Society encourages dissemination of research tools without legal agreements whenever possible.¹⁶

1. Members are encouraged to disseminate their databases freely and to add new data to public databases with the caveat that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. NIH guidelines acknowledge that the rights and privacy of people who participate in research must be protected at all times. Thus, data intended for broader use should be free of personal identifiers that would permit linkages to individual research participants and variables that could lead to disclosure of the identity of individual subjects. Also see NIH guidelines as follows: http://grants.nih.gov/grants/policy/data_sharing/; <http://www.ott.nih.gov/pdfs/64FR72090.pdf>;

¹¹ <http://ori.hhs.gov/>

¹² <http://www.hhs.gov/ohrp/>

¹³ <http://ohsr.od.nih.gov>

¹⁴ http://grants.nih.gov/ClinicalTrials_fdaaa/the-basics.htm

¹⁵ Cell lines; monoclonal antibodies; reagents; animal models; growth factors; combinatorial chemistry libraries; DNA sequences; receptors and ligands involved in disease pathways; drugs and drug targets; clones and cloning tools [such as PCR]; methods; laboratory techniques, equipment and machines; databases and computer software.

¹⁶ Report of the National Institutes of Health (NIH) Working Group on Research Tools. June 4, 1998, http://www.ott.nih.gov/policy/research_tool.aspx

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.

2. Members are encouraged to use Uniform Biological Material Transfer Agreements and to develop other standard agreements to reduce the need for case-by-case review and negotiations when sharing is contemplated. Freedom of investigation should not be overly constrained by such agreements. See NIH guidelines at NIH Office of Technology Transfer.¹⁷

3. Members may be constrained by the terms of their employment with regard to patent and copyright and they should be aware of the rules that apply to them. Members wishing to retain title to inventions through patents or Reach-Through License Agreements (RTLAs), should be aware of laws, including the Bayh-Dole Act and the Federal Technology Transfer Act of 1986 which cover federally funded projects, the Consolidated Appropriations Act, 2008¹⁸ and the Digital Millennium Copyright Act.¹⁹

D. Human Research, Investigator Responsibilities

Research involving humans includes direct interaction with individual persons, and the acquisition or use of identifiable private information from participants.²⁰ Such data may be obtained directly, from existing records, from tissues or fluids, or through physiological testing.

All research must be justifiable in terms of its potential contribution to new knowledge, must be based on a thorough study of the existing literature, and must incorporate clearly stated hypotheses, methods and assessment of risks and discomfort to participants.²¹ Investigators must abide by the requirements of their IRB and their Institution's Ethics Office. Additional requirements for the conduct of research can be found at <http://www.hhs.gov/ohrp/policy/index.html> and <http://grants.nih.gov/grants/oer.htm>

International research collaborations are increasingly common and represent an important element of the Society's global health mandate. Additionally, collaborations with colleagues in other countries can provide a mechanism for more efficient sharing of resources to meet public health mandates. The HHS Guidelines for international collaborations can be found at <http://www.hhs.gov/ohrp/international/index.html>

¹⁷ http://www.ott.nih.gov/policy/research_tool.aspx

¹⁸ <http://publicaccess.nih.gov/policy.htm>

¹⁹ <http://www.copyright.gov/onlinesp/>

²⁰ U.S. Department of Health & Human Services. OHRP – Guidance on Research Involving Coded Private Information or Biological Specimens. (2008). Retrieved from April 2, 2012, from <http://www.hhs.gov/ohrp/policy/cdebiol.html>

²¹ AMA Code of Ethics, available online at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>

E. Human Research, Informed Consent

Informed consent is a practical application of respect for a person. Consent should be directly obtained from subjects with decision-making capacity. Special rules and protections apply to subjects who lack decision-making capacity, including children and the mentally impaired.²² Investigators should refer to the following web sites for specific requirements: OHRP, OHSR, and OHSR.

F. Human Research, Privacy, and Confidentiality

Research involving human subjects should respect the privacy of the participants and the confidentiality of any data obtained in the course of the research.

The protection of personal information is of paramount importance and is a primary responsibility of Investigators. Requirements and guidelines for the protection of personally identifiable information and the storage and use of human tissue samples are listed in the OHRP website and at <http://www.hhs.gov/ohrp/policy/index.html>; <http://www.hhs.gov/ohrp/policy/cdebiol.html>

G. Human Research, Clinical Trials

Clinical trials provide potential for divergence among the interests of the investigator, the sponsor, and the patient. On the part of the clinician, conflicts of interest include career enhancement and financial gain versus adequate concern for the needs and rights of the patient. The FDA's definition of a Clinical Trial has recently expanded to include several types of human research including pathophysiologic research and challenge studies. Investigators should consult with their local IRBs, Ethics office, and the requirements of HHS Office of Human Subjects Protection, and the FDA regulations and reporting requirement for the results of clinical trials.

H. Human Research, Management and Disclosure of Competing Interests

To address perceived or real dualities of interest, members should openly and readily identify all sources of direct or indirect financial support of their work or other conflicts of interest, including endorsement of products or services for financial gain. Investigators should abide by the requirements of their IRB and their institution's Ethics Office. Additional guidelines for proper disclosure include those published by the US FDA Financial Disclosure of Clinical Investigators²³, and the National Science Foundation Investigator Financial Disclosure Policy²⁴.

²² U.S. Department of Health & Human Services. Office for Human Research Protections. Policy and Guidance. Retrieved April 2, 2012, from <http://www.hhs.gov/ohrp/policy/index.html>

²³ <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>

²⁴ http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_4.jsp

I. Usage by Members of the Society Name or Image.

The Society will not verify or provide assurances of professional or scientific competence and integrity for any of its members. In addition:

- 1) No member shall use their affiliation with the Endocrine Society for commercial purposes, such as advertisements or endorsements. Examples of acceptable use of their association are in a resume, biographical sketch, curriculum vitae, or list of professional accomplishments for the purpose of introduction as a speaker or at a professional meeting
- 2) No member shall promote his or her personal scientific opinions and views as the official position of the Society unless specifically commissioned by Society to do so.
- 3) No member shall use the Society's logo or name on letterhead or elsewhere for commercial purposes in conducting non-Society business.

J. Genetic Research

Information gained from genetic studies may have implications beyond the individual subject. Matters of privacy and confidentiality take on special importance because misunderstanding or misuse of genetic data can have profound implications for families, society, and science. Only physicians with access to competent genetic counseling should provide subjects with the results of genetic tests obtained for research purposes. A clear understanding should be conveyed concerning the limitations in interpreting genetic tests due to technical variability and the limited knowledge about the clinical implications of specific polymorphisms. Thus, Society member clinicians participating in genetic investigation should receive training in genetic counseling or have effective collaboration with those who have such training if results are to be provided to subjects.

Because of the special requirements for consent for, and release of, genetic information Investigators planning genetic research should consult with their local IRBs, Ethics office, and the requirements of HHS Office of Human Subjects Protection. (See footnotes 11-13 and http://grants.nih.gov/grants/policy/hs/hs_policies.htm for additional guidance.)

K. Human Stem Cells

The Society supports the 2009 NIH guidelines for the use of stem cells <http://stemcells.nih.gov/policy> and developed a Position Statement on Stem Cells at <http://www.endo-society.org/advocacy/policy/upload/Stem-Cell-Position-Statement-October-2009-Final.pdf>

L. Animal Research

Animal research has led to substantial health benefits for both humans and animals. It has led to the advancement of our understanding of critical physiological processes and disease. Unlike humans, animals cannot give informed consent, nor will they receive benefit from the study, yet they are sentient creatures that must receive humane care. When using animals for teaching or research, members should ensure compliance with all legal statutes and regulations, and protocols should be approved by the institution's Animal Care and Use Committee, or equivalent. This code should be used as a supplement to governmental publications.²⁵ Investigators are obliged to ensure that any animal experimentation they perform is consistent with the guidelines noted below.

1. Only animals that have been lawfully acquired shall be used for research and teaching.
2. Animals shall be cared for and treated humanely. Unnecessary pain and suffering shall be minimized, and the animals shall be treated with anesthetics, analgesics and tranquilizers as appropriate, to the experiment's design. Per the Society's publication guidelines (<http://endo.endojournals.org/site/author/endoethics.xhtml>), the authors of manuscripts submitted to journals published by the Society are required to submit a statement indicating that the animals were maintained according to the NIH Guide for the Care and Use of Laboratory Animals.²⁶
3. The methods of euthanasia shall be consistent with the recommendations of the American Veterinary Medical Association Guidelines on Euthanasia.²⁷ The Society supports the responsible use of animals in research, as well as education of the public as to the merits of such research.

M. Ethics of Clinical Practice

Physicians specializing in endocrinology provide care in diagnosis, management and prevention of disease to individuals, each raising important ethical issues. These include the primacy of the patient in the clinical encounter, as well as the importance of the practitioner-patient relationship in influencing outcomes. Physicians must consider both the ethical aspects of clinical relationships and the social context within which these relationships occur. When ethical perplexity arises it is important to seek advice from colleagues or from other sources of assistance (institutional ethics committees, for example).

²⁵ Animal Welfare Act, the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, National Research Council Guide for the Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/phspol.htm>), and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association (<http://www.avma.org/issues/policy/ethics.asp>).

²⁶ <http://grants.nih.gov/grants/olaw/olaw.htm>

²⁷ <https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

The ethics of clinical practice and the relationships between physicians and industry have undergone considerable scrutiny during the past decade. Additionally, new developments in medical technology and patient care including the use of electronic communications and social networks to communicate with patients have prompted new guidelines that by definition are works in progress. Guidelines for these and other elements of clinical practice have been developed and members are referred to these websites and ethics manuals for additional guidance:

AMA Code of Ethics²⁸ and the American College of Physicians – Ethics Manual.²⁹

1. Responsibilities to patients

- a) Patients should be treated with respect, regardless of their gender, age, religion, disability, race, ethnicity, social, financial, or medical status, life-styles, or sexual preferences.
- b) Patients must be respected and have the right to refuse their treatment and to participate in their choice of medical therapy.
- c) Physicians should act in the best interests of the patient and be guided by the principles of both beneficence and non-maleficence.
- d) Physicians must act in a just and fair manner in matters involving the distribution of scarce health resources and in decisions pertaining to access to specific treatments
- e) Physicians must practice within their scope of expertise. Patients with conditions outside of this scope should, if possible, be referred to others with appropriate competence.
- f) The religious and cultural values of adult patients shall be respected; however, in the case of minors, ethical and legal counsel should be obtained when these considerations run contrary to sound health care.
- g) Conflicts of interest, that is, circumstances in which the physician has a financial interest in clinical or research ventures, must not be allowed to pose a threat to patient welfare.
- h) Privacy and confidentiality shall be maintained in patient relations in accordance with Health Insurance Portability and Accountability Act of 1996 HIPAA. The protection of personally identifiable information is critical and physicians must avoid breaches in privacy when employing either paper or electronic medical records and electronic media platforms to communicate with their patients. Only secure email, preferably through an established patient portal of communication, should be employed to communicate with patients.

²⁸ <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>

²⁹ http://www.acponline.org/running_practice/ethics/manual/

- i) Confidentiality may be breached when required by law, such as the reporting of certain infections (TB, syphilis, HIV, Hepatitis B and C) or the possibility of child, spousal, or elder abuse.

2. Consent

- a) While the ordinary practices of medicine including history taking, physical examination and provision of advice and medications involve the implicit consent of the patient, invasive procedures require explicit written consent.
- b) Obtaining consent is not always straightforward: for example, it may be limited by the nature of the illness, or by the ability of the patient to understand. Because of the close relationships that are often built up between doctors and their patients, great care must also be exercised to avoid undue influence. Difficult questions about consent may arise in relation to the medical management of children and minors, people with dementia or intellectual disabilities, and in research.
- c) Patients whose preferences cannot be known (for example, unconscious, no advance directive) should be treated according to the physician's estimate of the patient's best interests in consort with legally-designated surrogate decision-makers. When appropriate, physicians shall recommend the appointment of a responsible proxy or guardian to help make decisions in the patient's best interest.

3. Reporting

Medical practitioners should make a reasonable effort to ensure that all diagnoses, opinions and significant results of tests/studies are recorded and followed up appropriately.

4. Management of infertility

The practice of reproductive medicine often involves complex technologies, the interests of multiple parties (donor, surrogate, parent, and child), and sometimes unclear legal standing. The Society supports the AMA Council of Ethical and Judicial Affairs' policy, "Issues of Ethical Conduct in Assisted Reproductive Technology." It is also recognized that as technologies associated with this subspecialty evolve, new concerns will arise that require ethical review.³⁰

APPENDIX A: Definitions

Bayh-Dole Act (35 USC §§ 200–211): allows universities and small businesses to retain title to federally funded research and to grant licenses for patents arising from the

³⁰ E-2.055 Ethical Conduct in Assisted Reproductive Technology <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2055.page> and <http://www.ama-assn.org/ama1/pub/upload/mm/369/70b.pdf>

research. See <http://www.nih.gov/news/researchtools/>

Digital Millennium Copyright Act (Pub. L. No. 105–304, 112 Stat. 2860 (Oct. 28, 1998): provides incentives for copyright owners to make their work available on the internet, to implement the WIPO Copyright Treaty, and implement WIPO Performances and Phonograms Treaty. See <http://lcweb.loc.gov/copyright/legislation/dmca.pdf> and <http://lcweb.loc.gov/copyright/legislation/hr2281.pdf>

Federal Technology Transfer Act of 1986 (15 USC 1301 et seq.): supplements the Bayh-Dole Act with regard to the technology transfer activities of federal laboratories, authorizing, among other things, cooperative research and development agreements (CRADAs), retention of royalties, and royalty-sharing with employee-inventors. See <http://iti.acns.nwu.edu/clear/tech/jen2.html>

Research Tools: The full range of resources that scientists use in the laboratory. The term may include cell lines, mono-clonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, DNA sequences, receptors and ligands, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory techniques, equipment and machines, databases, and computer software.