

CODE OF ETHICS OF THE ENDOCRINE SOCIETY

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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 and charged it with the responsibility to develop a Code of Ethics. The charge to the Committee includes a code for both the Society as an organization and for its members. It considers relations within the Society, with the scientific and general public, and with industry. The Code was designed to include general principles and guidelines to assist with emerging ethical issues.

Why should an organization such as The Endocrine Society have a Code of Ethics? The Endocrine Society is a professional organization whose members have the privilege and responsibilities that the body politic cedes to professionals. Professionals have specialized knowledge and skills that they are expected to exercise with competence and objectivity. In fact, their training and certifications provide them with a limited monopoly over their area of expertise.

Professionals are also given the responsibility for teaching and certifying their successors as well as great autonomy in deciding how to pursue their profession (e.g., what research to do or how to deliver health care). Balancing these privileges are the responsibilities to adhere to the norms of professional behavior and to enforce those norms. Professional societies represent their members to the public, and therefore, there are expectations by the public that the societies will identify, disseminate and enforce the professional norms of their membership.¹

Thus, codes of ethics have 1) aspirational features, identifying the highest standards of professional behavior; 2) educational features, indicating to members what collective expectations for their individual behaviors are; and 3) regulatory features; indicating and supporting the appropriate rules of behavior and issuing sanctions, on occasion, for violations.

Overall, the public has moved to an era of increased accountability for institutions and individuals. Professional societies are being charged to develop codes of ethics.^{2,3} The Endocrine Society is responding to these charges and to the perceived need for a code of ethics identified by its leadership.

The Code was developed by the Society's Ethics Advisory Committee for review by Council. After the initial review and revision processes, the Code was posted on the Ethics portion of the Society's Web site for review and comment by the membership for 90 days, after which the Council approved the amended Code in January 2001. The Code is considered a living document that will be revised or amended as ethical issues evolve.

Executive Summary of the Code of Ethics

The Code is divided into two sections, the Responsibilities of the Society and the Responsibilities of the Members. The responsibilities of the Society are to conduct the affairs of the Society in an ethical and prudent manner. It should be careful to maintain its independence from industrial support 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 disseminate knowledge about endocrine science and practice. It must ensure that meetings, publications, and courses given the Society's imprimatur remain of the highest quality. The Society has a responsibility to teach professional ethics and to respond to ethical dilemmas, as they become apparent.

¹ Wynia, M., et al. *NEJM* 1999, 341:1612-1616.

² Chalk, R., et al. AAAS Professional Ethics Project. American Association for the Advancement of Science, AAAS Publication 80-R-4, 1980.

³ Bauer, H. H. Scientific Literacy and the Myth of the Scientific Method. VPI&SU: Department of Science & Technology Studies, Blacksburg, VA 24061.

The responsibilities of Endocrine Society members include respect for colleagues, including their work and their reputations, the honest performance and reporting of research, and the honoring of predecessors and collaborators. This also includes appropriate sharing of research tools. Responsibilities involve high standards of research on humans, including respect for research subjects, informed consent, maintenance of privacy and confidentiality, approval of the research design, and honest reporting of adverse results. 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 and avoidance of unapproved use of samples, especially when the sample source is identifiable.

Those who pursue clinical practice have the responsibility to treat their patients with respect and within their scope of expertise, including obtaining informed consent when appropriate. They should avoid or disclose conflicts of interest and maintain patient privacy and confidentiality in the clinical setting. They should prepare patients and families for end of life decisions. They retain the right to refuse futile care. They must keep adequate records and inform patients of clinical developments. They must remain informed of developments in clinical endocrinology from objective and complete sources. Physicians should be cautious in accepting gifts from pharmaceutical and device companies because these gifts are surely intended to influence opinion. Physicians are obliged use their expertise to participate in decision-making regarding the distribution of resources in medicine for the benefit of patients, both as individuals and as groups.

Stanley G. Korenman, M.D., Chair

Ethics Advisory Committee Members: Mark Bach, M.D., Ph.D.; Katrina Bramstedt, M.A.; Paul Komesaroff, M.D., Ph.D.; Joan Lakoski, Ph.D.; Katherine Moore, Ph.D.; Robert Speth, Ph.D.

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. The Annual Meeting and other educational programs of the Society shall be conducted so as to provide the highest quality of objective information.

1. The Society shall not allow its objectivity to be influenced by corporate or other sources of income. Dualities of interest⁴ shall be disclosed in a timely and comprehensive manner.

⁴ 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.

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., e-mail 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. Timely and constructive responses to issues raised by members shall be an important Society function.
 8. The Society shall provide timely responses, as appropriate, to concerns and issues brought forth during public discussion regarding research and practice related to endocrinology.
 9. The Society shall strive to ensure that there are no barriers to any of its activities as a result of affiliation, sex, ethnicity or disability by encouraging diversity in all activities and all Committees.
 10. 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.
 11. The Society shall organize its activities to recognize the diverse professional needs of its members.
- B. Responsibilities of the Society: Relations with Industry
- Scientific societies and industry have a mutually beneficial relationship in which the Society receives substantial financial support and industry has an unparalleled opportunity to showcase its advances to a sophisticated and responsive audience. The Society needs to articulate and regularly update its policies related to funding from industry. This includes full disclosure and maintenance of independence in determining scientific content (including selection of sessions and speakers). Even with safeguards, the risk remains that meetings (and sessions) may appear to be influenced by commercial enterprises.
1. Meetings

Sources of commercial funding should not influence the scientific, educational, or public policy decisions of the Society.

 - a) Commercial supporters shall not control in any way the planning, content, speaker selec-

tion, or execution of any program of the Society, particularly those that are certified for continuing medical education credits.

- b) The display of commercial products or services in exhibit hall areas at Society meetings, advertisements in the Society's journals, symposium or social event sponsorship do not imply warranty, endorsement, or approval of these products or services, nor effectiveness, quality, or safety. Neither shall commercial sponsorships influence the subject matter of the Annual Meeting.
- c) Complete disclosure of commercial support is required for all Society-sponsored activities, as well as a balanced and objective presentation of data related to commercial products. Speakers are required to indicate at the time of their presentations any dualities of interest, including any relationship to the session sponsor.
- d) The Society will instruct program directors, speakers, and commercial sponsors about these policies prior to every presentation.
- e) The appropriate Society Committee will develop a policy for nominating chairs for continuing education programs. Session chairs (or the Committee) will determine the content of the session and invite speakers with the approval of the Committee. Speakers will be asked explicitly to ensure balanced presentations related to controversial issues, including presentation of advantages and disadvantages of specific therapies.

2. 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 acceptable to accept funds for trainees to cover the costs of attending educational conferences, provided that the selection of the recipient is made by the training institution. Travel support for speakers is acceptable as part of their compensation. The Society should follow the section 8.061 of The American Medical Association's Code of Ethics that specifically addresses this issue.⁵

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 posi-

tions 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.

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, educational materials, and programs.
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

Progress in understanding endocrine systems benefits human welfare. Such progress depends on integrity in the conduct of scientific research and the truthful representation of findings. 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 Endocrine Society publication are expected to abide by its publication guidelines.⁶
- b) Authorship should be based on a substantial intellectual contribution to the manuscript. Therefore, honorary authorship is inconsistent with the definition of authorship. The primary burden for ensuring appropriate authorship belongs to the research institution rather than the journal or The Endocrine Society. The Pub-

⁵ "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>

⁶ The Endocrine Society's Ethical Guidelines for Publication of Research, <http://endo.endojournals.org/misc/ifora.shtml>

lications Committee of The Endocrine Society establishes publication guidelines that generally conform to the guidelines of the International Committee of Medical Journal Editors.⁷

- 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 use committee (IUC, United States) or equivalent review board, in the case of countries other than the United 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, the authors, and the editors. They contribute to maintenance of high standards of Endocrine Society publications.

3. Editors

The Endocrine Society has the mandate to select editors for its journals and support the editorial process. The editors have the fiduciary responsibility for managing the journals prudently, ensuring the quality of publications and maintaining 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.
- j) Editors may seek confidential advice from the Ethics Advisory Committee (EAC) in cases of ethical concern.

4. Scientific misconduct

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

F. Responsibilities of the Society: Teaching Ethics

Respect for integrity of the scientific process, including high standards of ethical conduct, is required for research in endocrinology. The Endocrine Society should provide guidance and educational opportunities to its membership in the ethical aspects of research and clinical practice. The Society shall actively promote a climate that values and fosters ethical conduct in research and clinical practice.

- 1. The Endocrine 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 Endocrine Society when an ethical concern arises that they feel unprepared to address.⁸
- 2. The Endocrine Society has a responsibility to provide educational and skill development opportunities for members in ethics.
- 3. The Endocrine Society should provide formal and informal opportunities for members to discuss ethical issues of relevance to their professional behavior. Meetings sponsored by the Society should, when appropriate, include discussion of ethical issues.
- 4. The Endocrine Society shall provide leadership in the elucidation of ethical issues germane to the field of endocrinology with the scientific community and the lay public, not failing to include the

⁷ *Ann Int Med* 1997, 126:36–47.

⁸ The Ethics Advisory Committee is available for informal, confidential consultation on ethical issues to its membership.

endocrine issues of at risk populations. The EAC shall provide support and information in dealing with ethical dilemmas.

G. Ethics Referral Function of the Ethics Advisory Committee

Those requesting guidance from the EAC shall be treated with integrity and respect on all matters, respecting the privacy and confidentiality of all parties. EAC members who possess knowledge and skills appropriate to the case at hand shall thoughtfully consider requests.

1. The EAC shall provide guidance to individuals in the form of support. The guidance given shall be based upon historical cases and general ethical principles. Guidance reports will be documented and anonymized for publication on The Endocrine Society Web site.
2. The EAC shall operate as a sounding board, not as an investigative/policing body. The ethical guidance provided by a consultation should not be considered to be legal advice, and the EAC will accept no liability for decisions made by the requesting party in relation to that communication. The EAC shall provide links to other sources of information relating to research and clinical ethics; however, this does not imply endorsement of the information these other sites may offer.
3. The EAC will prepare position statements involving rapid response to current issues of ethical import, including responses to government requests for comment or issues under consideration by Congress. Such statements will be circulated electronically to Council for comment or approval. The amended document will be re-circulated to Council for approval and submission. The approved statement will be sent to the appropriate recipients over the signature of the Society President with the names of the Committee members who participated in its preparation appended. All such statements will be communicated to the membership electronically.
4. The EAC will not, in general, respond to requests from the general public. However, these requests shall be referred to the EAC information posted on The Endocrine Society Web site.
5. Informal communications with Society members will be recorded in a log by the EAC. If an informal inquiry generates issues to which a response by the Society might be considered, the Committee will request the President's approval to initiate a study, after explaining its possible policy implications.

H. Responsibilities of the Society: Sanctions

On occasion, the professional behavior of a member might be such as to warrant a sanction by the Society. Theoretically, 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. Such decisions require an unequivocal demonstration of

professional behavior that is unethical or illegal. Such decisions also require the administration of a due process procedure by the Society. The Society shall publish its criteria for membership in good standing.

II. RESPONSIBILITIES OF ENDOCRINE SOCIETY MEMBERS

A. Responsibility to Colleagues^{9,10}

1. Members shall treat their colleagues with respect and promote collegiality.
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. Guidance for this reporting process (also known as whistleblowing) has been researched and published.¹¹
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 of The Endocrine Society 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.

1. Performance and reporting of research. Scientific studies must be carried out in with rigor and honesty. Data should be reported fully and truthfully.¹²
2. To the extent possible, experimental results and analyses should be submitted promptly for publication. However, there are cases in which competitive and/or patent issues based on a proprietary interest in a new finding may require some delay in submission; this delay should be minimized. Dissemination of the results of negative studies is also important. This should be consid-

⁹ American Medical Association. *AMA Code of Medical Ethics*, Chicago, IL: AMA, 1997.

¹⁰ Jonsen, A., M. Siegler, and W. Winslade. *Clinical Ethics*, New York, NY: McGraw-Hill, 1992.

¹¹ Gunsalus, C. K. *Sci Eng Ethics* 1998, 4:51-64.

¹² Camenisch, P. *J Dent Res* 1996, 75:825-831.

ered both by authors and by the Society's journals.

C. Responsibility to Review

1. Members have a responsibility to review articles submitted to scientific journals including the Society's journals as well as research grants submitted to Federal and other agencies.
 - a. Reviewers should demonstrate respect for scientific inquiry, knowledge of the discipline, and willingness to provide judgment of publications in a fair and impartial manner.
 - b. When the request for review is made, reviewers have an obligation to inform the editor or manager immediately of actual or perceived conflicts of interest and to recuse themselves from the review, preferably without reading the submission.
 - c. Reviewers are obliged to maintain the privacy and confidentiality of the communication.

D. Research Tools

Sharing of materials should be a goal of investigators, applied to the extent it is practical. It is desirable to encourage agreements and basic guidelines for the transfer of research tools,¹³ and the Society encourages dissemination of research tools without legal agreements whenever possible.¹⁴

1. Members are encouraged to share materials described in their published manuscripts; however, the Society recognizes the conflict between the ideal of scientific sharing and the requirements of scientists with proprietary scientific or commercial interests in specific materials.
2. Members are encouraged to disseminate their databases freely and to add new data to public databases. User fees should be reasonable.
3. 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.
4. 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 fed-

erally funded projects, and the Digital Millennium Copyright Act.¹⁵ See Appendix B.

E. Human Research, Investigator Responsibilities

Research involving humans includes direct interaction with individual persons, and the acquisition or use of personal data from participants. Such data may be obtained directly, from existing records, from tissues or fluids, or through physiological testing. Data acquisition may be clinical, that is, undertaken in combination with patient care designed to confer diagnostic, prophylactic or therapeutic benefits on the individuals involved, and for the development of new knowledge; or, it may be purely non-clinical, that is, undertaken with the sole intention of contributing to new knowledge of a generalizable kind. 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.¹⁶ Studies should be properly statistically powered and include appropriate controls.

1. Members are responsible for ensuring that the welfare, rights, beliefs and customs of research participants are fully respected. They must give full informed consent to the proposed research (see Section F).
2. Members have a responsibility to ensure that the risk of harm or discomfort to participants in research is minimized. This responsibility exceeds that of any commitment to the goals or potential benefits of knowledge.
3. In the interests of distributive justice, groups likely to benefit from the results of the research should be represented proportionally in the research participants, including gender, age, socioeconomic status, ethnicity, and sexual orientation.
4. Members should honor their commitment to obtain new knowledge and communicate it to other researchers and society. This commitment should prevail over other motivations for conducting research, including economic or academic benefit.
5. All research involving humans must be conducted or supervised by individuals with the appropriate skill and experience in the conduct of human research.¹⁷
6. Adequate resources must be available for the proper conduct of the research, and provision must be made for adverse events.
7. Participants in research should be indemnified against costs associated with any injury related to

¹³ 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.

¹⁴ Report of the National Institutes of Health (NIH) Working Group on Research Tools. June 4, 1998, <http://www.nih.gov/news/researchtools/index.htm>

¹⁵ Available on-line at <http://lcweb.loc.gov/copyright/legislation/dmca.pdf>

¹⁶ AMA Ethical Opinion No. E-2.07, available on-line at <http://www.ama-assn.org>

¹⁷ Available on-line at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

the study and should be informed of the terms of this indemnity in their consent process.

8. Proper provision must be made for the secure storage of data obtained in the conduct of the work. Data should be safely stored for a specified period to allow verification of results and assessment of adverse events following administration of drugs.
9. While full reports of the research should be published, the confidentiality of individual participants must be maintained.
10. Where developing results suggest that the risks associated with a particular research project are significantly greater than originally anticipated, urgent IRB review¹⁸ should be requested, the participants notified, and the research stopped.
11. Whenever research is carried out in more than one country it should adhere to the appropriate guidelines, now under study.¹⁹ They should include the possibility of benefit to the participants, the probability of actually being able to get informed consent and the avoidance of bribes either to the participants or to the investigators. IRB/ERC approval of the research protocol and informed consent form is required for each site.

Consideration should be given to the contribution of a sample donor when commercialization of a human tissue is successful.

F. 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.

1. Before research involving human subjects is undertaken, the consent of each participant must be obtained. This involves the provision of sufficient information at a level, language and form appropriate to their knowledge, education and understanding. The purposes, methods, demands, risks (physical, psychosocial, economic and familial) and discomforts associated with the research should be disclosed in a context where a choice about whether to participate can be made free from coercion, pressure, or excessive inducements. The goal is the comprehension of the participants, not the teaching act of the investigators.
2. Special issues are raised by research conducted in particular contexts: for example, research involving children, persons with intellectual impairment, persons highly dependent on medical care or in dependent relationships and unconscious patients. Nonetheless, it is important to be able to conduct research on these special populations.

3. If consent cannot be obtained from the subject then parents, guardians or other individuals and organizations authorized by law must be asked for consent. Research involving people with intellectual impairment should only be conducted if participation in the research is not contrary to the best interests of the subject. Consent should be obtained from the subjects themselves, where competent to do so, as well as their guardians and/or others required by law.
4. Research involving children should only be conducted when it is not contrary to the best interests of the child, where consent has been obtained by the child's parents, guardians, or others as required by law. Where appropriate, assent should also be obtained from the child.
5. For research involving persons highly dependent on medical care (e.g. emergency care and intensive care and unconscious patients), it may be especially difficult or impossible to obtain consent. Communication with patients and/or relatives may also be difficult. Subject to local legal requirements, an ethics committee (if available) may consider it appropriate to assume responsibility for the consent process. The committee must verify that the research question is of particular importance to the treatment of this category of patients, that it cannot be answered in any other way, and that patients are not exposed to risks significantly greater than those associated with established methods of treatment.
6. Research involving groups of individuals distinguished by common cultural or religious beliefs or social structures should respect the cultural and religious beliefs of the individuals and conform to the standards within the relevant communities. Particular attention should be paid to the fair distribution of benefits and harms. On the other hand, cultural or religious beliefs should not be a deterrent to seeking participation in research.
7. If human biological samples are to be stored for future use, subjects should be advised of this fact. They should be informed of the nature of the storage, that is, if the samples will be identifiable, potentially identifiable, or de-identified. While it is appropriate to ask them to consent to unspecified future uses, they should be given the opportunity to refuse permission for future research use. If they do refuse, the material should not be utilized for another research purpose.
8. With regards to non-genetic research on existing biological specimens, US Federal regulations stipulate that this research may be exempt from IRB review if the subjects cannot be identified either directly or indirectly. Archived pathology or diagnostic specimens that are considered residual biological material and are destined to be destroyed can be used in research, and are considered exempt from committee review if there are

¹⁸ Also known as Institutional Review Board (IRB) in USA.

¹⁹ Refer to US Code of Federal Regulations (CFR) Chapter 45.

no identifiers linked to the specimen and if the data are not intended to be used in the diagnosis or treatment of a patient. If either identification is to be preserved or possible diagnosis or treatment may take place, consent of the research subject is required and the study must undergo IRB review. Specimens received as extra material or extra specimens requested from a physician conducting a clinical procedure are not pre-existing or “archived” and thus require written informed consent from the subject and committee review.

G. Human Research, Privacy, and Confidentiality

The protection of confidentiality is an important, but not an absolute, value of medicine. Research involving human subjects should respect the privacy of the participants and the confidentiality of any data obtained in the course of the research.

1. Personal information should only be collected and included in a research record if it is necessary for, or directly related to, the research. No identifiable personal data should be included in publications that arise from the research. This may be a special problem when publishing genealogies.
2. Circumstances in which it may be appropriate to release confidential information in clinical practice include where the patient consents, where such release is required by law, where the best interests of the patient demand it, or where it is necessitated by an overwhelming public interest. In research, such circumstances occur rarely; however, in such cases, it is permissible to access patient data.²⁰
3. Patient data, or the material from which it is derived, may be “identified,” in that the relation to specific individuals is given, “potentially identifiable” or coded, in which identifiers have been removed but could be restored, or “de-identified” or anonymous, in which it is not possible to link the data to individuals. In general, in the first two cases, consent is required to use the data. However, where this is inappropriate or impossible, for example, when the patients are likely to be untraceable or may have died, such materials may be utilized for research purposes, subject to the agreement of the responsible IRB. One must employ caution about de-identifying specimens because not only will they be much less useful, but also, individuals will lose the opportunity to benefit from the studies performed on the specimen. For prospective studies, participants should be asked to accede to the use of their specimens for research. When their consent is sought, their desires as to the degree to which they want to receive information about their results should be determined.
4. Precautions must be taken to ensure that both data and biological specimens are stored securely

and that access is restricted to authorized individuals. The duration of storage and disposal of data collected and biological material obtained during a research project should be disclosed to the subjects.

H. Human Research, Clinical Trials

A clinical trial is a research study directed to the examination of a new therapy on persons. It may involve new drugs, devices or procedures for which limited efficacy and safety data are available. A trial may require the involvement of individuals with specific conditions that may make them especially vulnerable. The participants in clinical trials are usually committed individuals who are making sacrifices and taking risks in the interest of science. They must be treated with the utmost respect. 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.

A guideline to follow when accepting a clinical trial is the US FDA “Financial Disclosure of Clinical Investigators” (63 CFR 6233). It requires that sponsors of clinical trials collect data on clinical investigators, including compensation affected by the outcome of the study, significant equity interest in the study sponsor, a proprietary interest in the tested product, and other payments to the investigator from the sponsor. Other guidelines for reference include the National Science Foundation Investigator Financial Disclosure Policy,²¹ US Public Health Service Objectivity in Research Policy,²² and the NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research.²³

1. Investigators should make their own decisions as to whether a clinical trial is well designed and ethical by understanding the literature and by ensuring adherence to the rules.
2. The use of a placebo treatment is often the most effective and efficient way of evaluating a new drug. Its use is acceptable only if no treatment of proven safety and efficacy is currently available in the environment in which the study is being conducted, or in the face of an effective therapy if the effect of the placebo would cause only temporary discomfort. Factors that must be considered in deciding whether use of a placebo control group is ethically justified include the severity, symptoms, and consequences of the condition being treated, the side effects of existing therapies, and the duration of the planned study. A more thorough discussion on this issue is found in the

²¹ Available on-line at <http://www.nsf.gov/pubs/1997/iin118/iin118.txt>

²² Available on-line at <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>; a related link is: <http://grants.nih.gov/grants/policy/coifaq.htm>

²³ Available on-line at <http://www4.od.nih.gov/orwh/outreach.pdf>

²⁰ Via the Federal Freedom of Information Act (FOIA).

AMA statement on Ethical Use of Placebo Controls in Clinical Trials (<http://www.ama-assn.org/ethic/ceja/71b.pdf>).

3. Appropriate interim analyses should be carried out by independent evaluators and safety monitoring should be available to ensure that the trial can be stopped at an early date if appropriate.
4. The investigator must ensure that individual participants understand that they are free to withdraw from a study without compromising their ongoing medical care.
5. The investigator should ensure that changes in the medical condition of the patient will be attended to in preference to the requirements of the trial.
6. There should be no additional cost to participants beyond that of standard therapy.
7. Potential participants should be advised whether a researcher has a financial or other personal interest in the product or technique under investigation and such dualities must be indicated in the Informed Consent form.

I. Human Research, Epidemiological Studies

Epidemiological Research involves the collection of data relating to the health of populations. It may require the use of identified, coded, or de-identified data.

1. Regarding identified or coded data, consent of the individuals concerned should be obtained, except as noted under Section F5, and where, the procedures required to obtain consent are likely to cause unnecessary anxiety, or where the public interest in the research outweighs private interest in the confidentiality of data.
2. Where analysis of identified or coded data reveals information of potential benefit to the individual concerned, careful consideration may need to be given to the question of whether that individual should be advised of the result. Two principles prevail. First, the subject has a right to know about her/his medical condition. Second, the subject has a right not to know about her/his medical condition.

J. Genetic Research

The field of human genetics is concerned with the study of genes and their alleles. However, the relationship between this information and the health of an individual is frequently unclear. Genetic studies are also special because biological relatives share genetic material and may be affected by the same conditions. Thus, the information gained from a study 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 competence in 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, Endocrine Society clinicians participating in genetic investigation should receive training in genetic counseling.

Special features of informed consent in genetic research include:

1. Genetics research subjects or, when appropriate, their guardians are required to provide the usual informed written consent to be research subjects as noted in Section F.²⁴
2. Participants should have the option of selecting whether or not they want access to the genetic information generated by the study. Their decisions should be recorded in the informed consent form.
3. Participants should be informed that in pedigree analysis and family linkage studies, the investigation might determine that some members of their family are not genetic relatives. However, those results will not be disseminated. Furthermore, it is sometimes possible that other family members may learn private genetic information about the participant.
4. Where genetic research may generate information important to the relative of a research subject, the subject's consent should be sought prior to approaching relevant family members. If there is a threat to a family member's health and the participant refuses permission to disclose his or her genetic information, the investigator must consider whether the threat is of a sufficiently serious nature so as to warrant disclosure without the participant's consent. In these cases, ethics committees are available for advice.
5. Researchers should be aware of the pressure that may be applied by other family members to participate in studies. They should be particularly sensitive to the issue in the context of research that is burdensome or carries risks, such as the possibility of revealing information that might be predictive of future illness. The recruitment of family members identified by a participant should only be undertaken if the participant agrees, and with the participant's assistance if possible.²⁵
6. Genetic research involving children involves special ethical obligations. Children may be at particular risk of perceived adverse consequences, both within and outside their families, as a result of genetic testing. There should be discussion with parents about the decision where and when to reveal genetic information to children. If the child is over eight (8) years of age, s/he should be

²⁴ Sample consent forms are available on-line at <http://www.oprs.ucla.edu/human/FORMS.htm>

²⁵ Operations Manual for Ethics Committees in Australia. Komesaroff, Paul. Section 4.8.3.4

given age-appropriate genetic counseling and where appropriate, consent forms for assent to the testing.

7. There are many levels of confidence in science and in the uses of information, making it difficult to propose universal standards for consent for unspecified future genetic research. Therefore, The Endocrine Society proposes three (3) tiers of consent for unspecified future genetic research.

a) De-identified

The sample source is completely de-identified:

a) only the sex and age of the source are identified; and b) the donor has no possibility of receiving individual results or rewards. This does not require prior consent but does require IRB approval.

b) Coded or potentially identifiable

If the sample source has the possibility of identifying a number of characteristics, such as, age, sex, dates of exposure or general health habits, but not individuals, the donor may receive general information, if desired, regarding research results. There will be no attempt to personalize the research results. To prevent the possibility of access to the information by others, the researcher will ensure all information of pertinence to individuals will be protected. Clinically relevant information can be given to the participant on request. This requires informed consent for the overall study but not for each specific use of the genetic materials. Researchers are obligated to consider how to deal with informing sample donors of clinically relevant results should they be discovered. IRB approval is required.

c) Identifiable

If the sample source is to have open-ended identification, the researcher can obtain as much coded information as necessary for the study. The subjects must be re-consented in advance and they may, if they desire, receive their individual research results.

K. Human Stem Cells

The Endocrine Society supports the American Society for Reproductive Medicine (ASRM) guidelines on the use of gametes and embryos for research²⁶ and the NIH guidelines on the use of stem cells for research purposes.²⁷ The Society also supports the report and recommendations of the National Bioethics Advisory Committee (NBAC) regarding human stem cell research.²⁸ Research utilizing human pluripotent stem cells for both basic knowledge and for clinical applications is encouraged.

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 Use Committee, or equivalent. This code should be used as a supplement to governmental publications.²⁹ Investigators are obliged to ensure that any animal experimentation they do 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 treated humanely. Unnecessary pain and suffering shall be avoided, and shall be treated with anesthetics and analgesics as appropriate to the experiment's design. Per The Endocrine Society publication guidelines (<http://endo.endojournals.org/misc/ifora.shtml>), 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.
3. The Endocrine 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).

1. Responsibilities to patients

- a) Patients should be treated with respect, regardless of their social, financial, or medical status, life-styles, or sexual preferences.
- b) 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.

²⁶ American Society for Reproductive Medicine Ethics Committee, "Informed Consent and the use of Gametes and Embryos for Research," 1997.

²⁷ Available on-line at <http://www.nih.gov/news/stemcell/draftguidelines.htm>

²⁸ Available on-line at <http://www.bioethics.gov/execsumm.pdf>

²⁹ 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://www.nal.usda.gov/awic/legislat/awicregs.htm>), and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association (<http://www.avma.org>).

- c) The religious and cultural values of adult patients shall be respected; however, in the case of pediatric patients, ethical and legal counsel should be obtained when these considerations run contrary to sound health care.
 - d) Physicians must maintain avenues of communication and/or access by patients after normal business hours and during holidays or vacations.
 - e) 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, and shall be identified and disclosed.
 - f) Sexual relationships with patients, employees, and students are ethically improper.
 - g) Privacy and confidentiality shall be maintained in patient relations. Conversations about specific patients should be held in private only with parties relevant to the care of the patient. Clinical records must also be held confidential and should not be released without the explicit or implicit permission of the patient, except when required by law.
 - h) Confidentiality may be breached when required by law, such as the reporting of certain infections (TB, syphilis) 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. There are other practices that may require explicit informed consent, for example, using medications in an off label manner, especially when the risks are significant.
 - 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. In addition, 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 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. The question of the decision-making abilities of minors is discussed in Section F4, in relation to participation in medical research. The main points mentioned there apply also to clinical practice.
3. End of life decision-making
- a) Decisions to forgo CPR (Do Not Resuscitate orders/DNR) should be made in advance, in accordance with patient and/or proxy's wishes. Additionally, a patient's Advance Directive should be respected, even if the expressed preferences go against the beliefs of the caregiver or the surrogate.
 - b) Physicians retain the right to withhold futile care (to perform a treatment without any reasonable expectation of a benefit), even when patients or their family members demand it. Further, it is not necessarily inappropriate for doctors to make clinical decisions about the management of pain or other medical conditions that may produce the effect of shortening the life span of the patient in the interest of a better quality of life.
 - c) The question of whether doctors should be able to take active steps to facilitate the death of a patient in exceptional cases continues to be the subject of vigorous public debate. No general consensus has been reached, and in all but a few jurisdictions both passive and active euthanasia remain illegal.
4. Non-compliance
- Some patients do not accept their physician's advice. They may refuse to undertake investigations or to take recommended medications, or persist in pursuing injurious health practices. Ultimately, it is the prerogative of a competent patient to decide whether he or she wishes to follow advice. However, this does not entirely relieve the doctor of moral responsibility for the patient's welfare. It is still appropriate for the physician to continue to pursue these issues in discussion, or in rare cases, such as where a public risk may be involved, to follow another course of action depending on local laws and regulations.
5. Reporting
- a) Medical practitioners have an obligation to ensure that all diagnoses, opinions and results of studies are recorded and followed up appropriately. A medical practitioner is obliged to attempt to inform a patient of significant results of tests.
 - b) Physicians have a responsibility to use existing, approved drugs in the most effective and appropriate way, to monitor their use, to report adverse reactions, and to keep up to date with scientific developments.
6. Clinical decision-making
- As far as possible, clinical decisions should be based on evidence, as well as experience. However, evidence can vary in quality, and may itself be subject to ethical values, either in relation to its acquisition or its application. Physicians have the responsibility to assess critically the nature of the

evidence on which their decisions are based and to remain aware that ethics and evidence cannot be separated.

7. Gifts

Drug and device manufacturers offer physicians many gifts, and members should be very sensitive to the potential influences these gifts may carry. In accordance with AMA guidelines,³⁰ physicians may receive gifts from industry (pharmaceutical, device, diagnostic) that primarily entail a benefit to the patient and are not of substantial financial value (generally US\$100 price range). Acceptable gifts include books, simple diagnostic kits or equipment, etc.

8. Clinical innovation

Recognizing that the boundary between clinical practice and research may be blurred, it is important that clinicians be committed to careful evaluation of new or potentially new treatments that are tried in the course of clinical practice. If clinical observation suggests that a new therapy may have promise, a more systematic evaluation of this therapy may be initiated. This systematic evaluation constitutes experimental therapy (or research). In this case, the clinician must ensure that appropriate procedures for ethical review and consent are followed.

9. New technologies

Physicians must become sensitive to the impact of informatics and new approaches to organizing health care on patient management, privacy and confidentiality, all of which present new ethical dilemmas. In light of the potential for electronic breeches, physicians need to remain protective of their patients' privacy.

10. 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 legal framework involved with these technologies is still evolving, and can vary between venues.

In addition to clinical competency, fully informed consent is crucial to the ethical practice of assisted reproduction. Further, the involved parties, including the practitioner, should be informed as to the distinction between clinical practice and research. To this end, The Endocrine Society supports the AMA Council of Ethical and Judicial Affairs' policy, "Issues of Ethical Conduct in Assisted Reproductive Technology."³¹ It is also recognized that as technologies associated with this subspecialty evolve, new concerns will arise that require ethical review.

- a) Clinicians must disclose valid success rates for the procedures they offer.
 - b) Patients, donors, surrogates, and spouses should be fully informed about all aspects of the technologies applicable to their particular clinical situation.
 - c) Physician fees based upon clinical outcome are unacceptable because they break the dissociation between physician reimbursement and the clinical outcome.
 - d) All potential gamete donors must be screened to the extent practical for diseases that could affect the mother or resultant child. Donors should be notified of these screening findings.
 - e) With regard to donor insemination, physicians should maintain a permanent, secure record of both identifying and non-identifying health and genetic information on gamete donors.
 - f) Only non-identifying information about donors should be released to the recipient in order to preserve their privacy.
 - g) Physicians should attempt to limit the number of pregnancies from a single anonymous donor source to avoid the possibility of miscegenation in the next generation.
 - h) Donors will be notified if their gametes produce a child with a disorder that may have been transmitted by the donor and further donations from that individual discouraged.
 - i) It is not unethical to provide single women or lesbian couples with artificial reproductive technology, including artificial insemination as an option in the U.S., but laws and customs vary in different countries.
 - j) Sex selection of sperm for the purpose of gender preference is not supported by The Endocrine Society; however, this practice may be appropriate when considering sex-linked inheritable diseases.
 - k) By law, anonymous sperm donors have no parental rights or obligations (financial or otherwise).
 - l) Regarding pre-embryos, gamete providers should be able to use them themselves or provide them for use by other parties. Both gamete providers should have an equal say in the use of their pre-embryos. Thus, the pre-embryos should not be available for use by either provider alone, or changed from their frozen state, without the consent of both providers.
- #### 11. Practice with new technologies
- The Endocrine Society encourages clinicians to apply the techniques and products of biotechnology and genetic engineering for diagnosis, to improve health and to ameliorate suffering.
- a) Patients undergoing genetic testing should know that they are doing so and the nature of tests being performed.
 - b) Patients should be protected from unauthorized disclosure of test results.

³⁰ AMA Ethical Opinion No. E-8.061, available on-line at <http://www.ama-assn.org>

³¹ AMA Policy No. H-460.935, available on-line at <http://www.ama-assn.org>

- c) Genetic analysis will be increasingly useful for therapeutic decision-making, as well as for decisions concerning reproduction and social and financial planning. The clinician should understand the implications of any genetic testing performed and must inform the patient of the degree to which each particular genetic risk factor correlates with the likelihood of developing a particular disease.
- d) Sequencing of genes relevant to the patient's condition, such as tumor markers, histocompatibility complexes, differential responses to drugs, etc. are encouraged. With the patient's informed consent, such sequences may be beneficially added to public databases.
12. Political role
- a) Physicians play an important role in determining the distribution of health care resources. Doctors are always under an obligation to exercise restraint and responsibility in the use of society's resources. However, physicians are not simply agents required to carry out mandates regarding health care. For the benefit of their patients and of society, they must use their knowledge and expertise to take initiatives to influence health care policy development and implementation.³²

APPENDIX A: Abbreviations

| | |
|-------|---|
| AMA | American Medical Association |
| ASRM | American Society for Reproductive Medicine |
| CFR | Code of Federal Regulations (USA) |
| CPR | Cardiopulmonary Resuscitation |
| CRADA | Cooperative Research & Development Agreement |
| DNR | Do Not Resuscitate |
| EAC | Ethics Advisory Committee (The Endocrine Society) |
| ES | The Endocrine Society |
| EST | Expressed Sequence Tags |
| FDA | Food and Drug Administration (USA) |
| FOIA | Freedom of Information Act |
| IRB | Institutional Review Board |
| IUC | Institutional Animal Use Committee |
| MTA | Material Transfer Agreement |
| NBAC | National Bioethics Advisory Commission (USA) |
| NIH | National Institutes of Health (USA) |
| PCR | Polymerase Chain Reaction |
| PTO | Patent & Trademark Office (USA) |
| RLTA | Reach Through License Agreement |
| SNP | Single Nucleotide Polymorphism |
| UBMTA | Uniform Biological Material Transfer Agreement |

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

Coding: the transformation of words or numbers into an incomprehensible series of symbols.

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>

Genetic Data: any type of data concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals.

License: a contract between the owner(s) of the subject matter of the license and one or more parties that seeks the right to make, use, sell, or import the subject matter of the license. Commonly, a license conveys rights to patented subject matter, but it may also convey rights to tangible subject matter that is not patented. Licenses are negotiated agreements that become binding contracts when signed by the parties. In order to reduce transaction costs, institutions may bundle multiple licenses. See <http://www.nih.gov/news/researchtools/>

Material Transfer Agreement (MTA): a negotiated contract between the owner of a tangible material and a party seeking the material and the right to use the material for research purposes. The material may be either patented or unpatented. MTAs serve to document the transfer and outline the terms of use, including identification of the research project, terms of confidentiality, publication, and liability.

Non-personally identifiable data: data that cannot be linked to a person.

One-Way Coding: the transformation of words or series of digits into an incomprehensible series of symbols that cannot be traced by means of a decoding key.

Patent: a patent contains a narrative description of the subject matter called the specification. It also contains one or more claims that describe the subject matter covered by the patent in highly technical and specific terms, much as the metes and bounds of a survey might exactly describe and identify the land conveyed by a deed. A patent represents the right to exclude others from making, using, or selling the subject matter described by the claims of the patent. Virtually every country in the world provides its government with the

³² Pearson, S., et al. *NEJM* 1998, 339:689–693.

right to issue patents in order to allow patent owners to exclude others from using the patented subject matter within its borders. See <http://www.uspto.gov>

****Regarding DNA or RNA patents:** for these to be patentable they must be novel and non-obvious in light of structurally related DNA or RNA information. It is probably counterproductive to patent sequences of genes and their regulatory regions and genome markers such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs) for which no function is known. See <http://www.uspto.gov>

Personal Data: data which has a direct or indirect relationship to an individual and can include an identity number or physical, mental, physiological, economic, cultural or social characteristics.

Polymerase Chain Reaction (PCR): a technique that is used to amplify the number of copies of a specific region of DNA, in order to produce enough DNA for testing. See <http://www.horizonpress.com/pcr/>

Reach Through License Agreement (RTLA): this type of agreement gives the owner of patented research used in upstream stages of research, rights in subsequent downstream discoveries. An RTLA may be an obligation to credit the inventor, to grant reasonable sublicenses for noncommercial discoveries and fields of use, or to pay royalties on sales that result from use of the upstream research tool. It may lead to an exclusive license on future discoveries or an option to acquire such a license. See <http://www.nih.gov/news/researchtools/>

Research Tools: The full range of resources that scientists use in the laboratory. The term may include cell lines, monoclonal 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.

****** It is offered that Endocrine Society members might streamline the process of transferring their research tools by: freely disseminating tools and materials that are far removed from any commercial product; using standard materials transfer agreements or letter agreements; drafting agreements that are clear and comprehensible to scientists and business people when standard ones are not appropriate; and incorporating reasonable terms in the first draft of license and materials transfer agreements. When entering into agreements for proprietary research tools with other institutions, members should identify personnel in their institution with the responsibility and authority to negotiate, allocate sufficient resources and personnel for this task, track agreements, and emphasize research and dissemination over profits.

Single Nucleotide Polymorphism (SNP): these are the most common genetic variations and occur once every 100 to 300 bases. A key aspect of research in genetics is the association of sequence variation with heritable phenotypes. It is expected that SNPs will accelerate the identification of disease genes by allowing researchers to look for associations between a disease and specific differences (SNPs) in a population. See <http://www.ncbi.nlm.nih.gov/SNP/>

Working Group of the NIH [on Research Tools]: formed by the Director of the NIH, this group was charged to inquire into problems encountered by NIH-funded investigators in obtaining access to patented research tools. See <http://www.nih.gov/news/researchtools/>

Uniform Biological Material Transfer Agreement (UBMTA): while most institutions have adopted a material transfer agreement form, they are not consistent with each other. The UBMTA addresses concerns about contractual obligations imposed by some MTAs and simplifies the process of sharing proprietary materials between non-profit institutions. See <http://www.nih.gov/od/ott/ubmta.htm>