APPENDIX D: RESEARCH

The Heart Rhythm Society promotes the responsible conduct of research and encourages compliance with ethical standards and government regulations governing research. HRS members engaged in research activities are expected to protect the integrity of their scientific data and meet accepted ethical standards for conducting research and publishing scientific data. The Society's policy applies to all members, including physicians, scientists, students, and postdoctoral fellows, whether performing research funded by HRS or by other organizations.

Scientific Misconduct

Members involved in research activities shall comply with guidelines dealing with scientific misconduct and are expected to adhere to accepted standards and government regulations related to scientific misconduct. Scientific misconduct or misconduct in science is defined as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."

Vertebrate Animal Research

The Society supports research involving vertebrate animals and encourages the humane treatment of laboratory animals. Members of the Society are expected to adhere to accepted standards and governmental regulations on the humane care and use of laboratory animals and to comply with the requirements of their institutions concerning animals used in research. In

cases where research by a member or HRS postdoctoral fellow is supported by the Society, failure to adhere to this policy may mean the suspension of HRS funding.

Human Subject Research

The Society encourages members to develop new knowledge and participate in clinical research. Members conducting clinical research are expected to be transparent in all dealings with clinical trial subjects, and to work to enroll individuals of underrepresented groups.

The Society recognizes that, as investigators, members have two primary obligations: a) to conduct the study according to protocol, and b) to comply with legal and ethical responsibilities toward a subject who has given consent. Therefore, members must be familiar with both the experimental therapy to be tested and the guiding principles of human subject research.

It is the position of the Society that an investigator's obligation to a sponsor is superseded by his or her obligation to act on behalf of the subject independently from the sponsor, and that rules of engagement are needed to maintain appropriate independence while participating in a partnership with industry.

In cases where research by a member or HRS postdoctoral fellow is supported by the Society, failure to adhere to this policy may lead to suspension of HRS funding.

Informed Consent

Members conducting research with human subjects are expected to obtain Institutional Review Board's (IRB) approval prior to initiation of research, and informed consent should be obtained from subjects when applicable and/or if deemed necessary by the IRB review.

Data Analysis and Publication

HRS supports publication of results regardless of outcome, including having a contractual arrangement for publication in place at outset of the trial to avoid the potential for undue delay or obstruction by the sponsor.

While the preferred mechanism is publication in a peer-reviewed journal, posting on public website or other public access is allowed. In multicenter trials, the study's steering/ executive committee should have a formal mechanism to oversee publication established by contract prior to start of study to prevent control of the process by the sponsor, investigator, or "renegade" publication.

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