APPENDIX A: FERASAFE® REGISTRY DATA USE POLICIES AND GUIDELINES

This document outlines policies and guidelines for the FeraSafe® Registry in the areas of Data Sharing, Data Access, Grant Proposals, Sub-studies, and Publications.

Summary

The FeraSafe® Registry is developed and established by investigators at The Regents of the University of California, on Behalf of its Los Angeles Campus (UCLA) to facilitate collaborations and the safe and appropriate use of ferumoxytol (Feraheme®) for magnetic resonance imaging. The FeraSafe® Registry Steering Committee consists of voluntary investigators from multiple institutions whose mission is to govern and oversee the direction of the FeraSafe® Registry.

Data are expected to be contributed in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and other local privacy legislation. All data are de-identified before being entered into the repository. No attempt will be made to identify individuals. Contributing Investigators may wish to maintain a key locally, which may be specified at the local IRB level. The database itself will contain no personal health identifiers as defined and specified by HIPAA. All users with data access should endeavor to protect the privacy of the individuals from whom the data were obtained.

Investigators who contribute data to FeraSafe® ("*Contributing Investigator(s)*") will be recognized and acknowledged appropriately on the FeraSafe® website and a hyperlink will be available on the site linking directly to the investigator's lab and/or institutional website. The FeraSafe® Registry website should be referenced in all publications in the acknowledgement section. Investigators who request data ("*Requesting Investigator(s)*") will be required to submit a proposal to the Steering Committee.

ICMJE recommendations regarding authorship and non-authorship will be followed to the extent possible. If journals allow, the Contributing Investigators of FeraSafe® should be listed using the following phrase "on behalf of the FeraSafe® Registry investigators" (www.icmje.org).

Data Sharing and Access

By contributing data to the FeraSafe® Registry, Contributing Investigators are giving permission for the data to be used in ongoing and future research studies (including meta-analyses) approved by the Steering Committee.

Data access is granted for the purposes of the specific research project detailed in the approved grant proposal or sub-study and publication plan, and under the terms and

conditions specified below:

1. The data will be used solely for the purposes outlined in the research study, and will not be used for any other purpose.
2. Data access is not transferable to another investigator. Substantive changes made to study, and/or appointment of another investigator to complete the study, should require execution of a new study proposal.
3. Researchers must comply with the FeraSafe® Registry publication policy.
4. Researchers must acknowledge the FeraSafe® Registry, its funding sources, and cite the main FeraSafe® Registry paper, in both oral and written presentations, publications, and disclosures resulting from data access.
5. Researchers agree that the data will not be used, either alone or in conjunction with any other information, in an effort to determine the individual identity of the individuals from whom data were obtained.
6. Researchers will retain control over the data, in a secure environment, and not transfer data to any other entity or any individual in a manner not previously approved the Steering Committee. When the study is completed, the data will be deleted from the researchers' computers, unless other arrangements are agreed upon or an extension is obtained.
7. Derived results and modifications of the data, including data cleaning, should be contributed to the FeraSafe® Registry for the benefit of future research.
8. To the maximum extent allowed by law, researchers should hold the FeraSafe® Registry Steering Committee and associated personnel harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of their use of FeraSafe® Registry data for any purpose.
9. Cost for data distribution should be borne by the researchers. No warranties express or implied, are offered as to the merchantability or fitness for any purpose of the data provided by the FeraSafe® Registry, or that the data may be exploited without infringing the intellectual property or proprietary rights of any third parties. The FeraSafe® Registry, its Steering Committee, and Contributing Investigators are not responsible for the accuracy of the data provided.
10. Amendments to the study should be made in writing and signed by authorized representatives of all parties.
11. The FeraSafe® Registry Steering Committee has the rights to examine the methods of data analysis (e.g. statistical analysis codes and post processed data files) by the researchers, should any issue relating to data integrity arises.
12. The FeraSafe® Registry Steering Committee may terminate access at any time.
13. Researchers must comply with any licensing arrangements or protection of existing intellectual property agreements under which data were contributed to the FeraSafe® Registry. Rights to any inventions or new information arising from the study, not relating to any existing agreements, will remain the property of the researcher.
14. The data cannot be used for commercial purposes without the permission of the FeraSafe® Registry Steering Committee.
15. Failure to comply with these conditions could result in denial of further access to the FeraSafe® Registry.

Grant Proposals and Sub-Studies

Requesting Investigators (which may include non-contributing investigators) requesting data access for either grant proposals or sub-studies will be required to submit a proposal to the Steering Committee for approval.

If approved, data access will be given to the researchers for a specific time period based on the magnitude of the work involved, and only for the purposes of the grant proposal or sub-study. At the time of the sub-study submission, a publication plan is also required detailing hypotheses, authorship, intellectual property created and timelines. Amendments and additions to the publications associated with a sub-study can be requested and are subject to the approval of the Steering Committee. As a part of the approval process, the Steering Committee may invite *Contributing Investigators* to collaborate with researchers and become co-authors on eventual publications.

Sub-studies may be approved even if there are existing overlapping studies already in progress; however, the Steering Committee may reject studies that substantially overlap (similar aims and methodology) with existing studies. Researchers will be notified if their proposal overlaps with an existing study, and will be given the option to modify their proposal accordingly. Multiple groups may work on similar or overlapping topics, particularly if the methodology differs or if confirmation of results by an independent group may be warranted. Obviously, this may lead to conflicting reports, but this is process will enable open scientific processes to occur.

Publications

Penultimate drafts should be submitted to the Steering Committee for review at least one month prior to submission to a journal. Abstracts for conferences should be submitted to the Steering Committee at least two weeks before the due date of the conference. Criteria for review include consistency with the goals of the FeraSafe® Registry, quality of the research, soundness of the methodology and interpretation of the results. The Steering Committee may request specific FeraSafe® Registry *Contributing Investigators* to be given the opportunity to become co-authors. However, all authors must have substantial contribution within an agreed time frame, not unreasonably impede publication timelines, and be accountable for all aspects of the work. Established guidelines for authorship of papers will be followed (http://www.icmje.org/ethical_1author.html). Where journals permit, *Contributing Investigators* of the FeraSafe® Registry should be listed in the author list and the phrase “on behalf of the FeraSafe® Registry investigators”. All publications should acknowledge any funding supporting the FeraSafe® Registry and cite the main FeraSafe® Registry paper when it is published. Researchers are requested to include the following line of acknowledge in the “abstract” and “acknowledgement” section of published work: “This research has been conducted using the FeraSafe® Registry.”

While every effort will be made to foster high quality research outputs, the FeraSafe® Registry Steering Committee cannot guarantee the integrity of every published study.

Intellectual Property

The FeraSafe® Registry seeks to facilitate collaborations among investigators using ferumoxytol and to further facilitate the safe and appropriate use of ferumoxytol for magnetic resonance imaging. These collaborations may lead to the development of valuable discoveries and inventions that benefit public health. In some cases, intellectual property agreements may be entered into as part of the contribution of data to the FeraSafe® Registry. These should be designed to protect specific existing intellectual property agreements and ensure the rights of *Contributing Investigators* to any intellectual property generated in these specific areas by third party researchers. Intellectual property generated by researchers, which does not pertain to these specific areas, should remain the property of the researcher.

The signature below indicates agreement with the above guidelines and promise to adhere to the guidelines as outlined.

_____ (Please type full name, which will serve as e-signature)

Name of institution: _____

DATE: _____