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## **WorldWide DOPPS Data Sharing and Publication Policy**

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### **Section 1) INTRODUCTION**

The Dialysis Outcomes and Practice Patterns Studies (DOPPS) is a worldwide investigation of the associations between hemodialysis practice patterns and patient outcomes. The goal of DOPPS is to improve the well-being of hemodialysis patients by investigating and understanding the associations between hemodialysis practice patterns and patient outcomes of mortality, hospitalization, vascular access and quality of life.

DOPPS is coordinated by the University Renal Research and Education Association (URREA), a not-for-profit research organization, and involves co-investigators from Amgen, URREA, the DOPPS Country Investigators and the Japan DOPPS Steering Committee. The group of Amgen and URREA investigators including Ken Chen, David Goodkin, Philip Held, Marcia Keen, Donna Mapes, Brad Maroni, Friedrich Port, Robert Wolfe and Eric Young is collectively known as the Amgen/URREA Study Coordinating Committee (SCC) for the purposes of this Data Sharing and Publication Policy (the "Policy"). In addition to the provisions outlined specifically below, the SCC will have a courtesy review of all plans for data analyses, in addition to the post-analysis review for all publications.

### **Section 2) SCOPE AND OBJECTIVES**

This Policy outlines the preconditions precedent to release of DOPPS Data (the "Data") to any party, the limitations on acceptable use of the Data, and the guidelines and implications for publishing with the Data. The sensitive nature of the Data and the ongoing research surrounding it demands that the protocol outlined herein is intentionally restrictive when considering requests to release Data. At stake is the maintenance of the integrity and scientific validity of the study, and the protection of patient confidentiality, and every effort should be taken to preserve these facets of the study.

This Policy will direct the adherence to general principles that govern scientific publications in the medical community, thereby giving WorldWide DOPPS the credibility it deserves and



ensuring the impact of the ensuing results. The Policy is also designed to encourage the acknowledgment of direct and substantial contributions to research publications, thereby creating the incentive for significant, groundbreaking, creative and productive research using the Data. Finally, the Policy will promote the due recognition of those contributing to these efforts.

### **Section 3) DATA RELEASE AND REQUESTS**

As a not-for-profit scientific research organization, URREA recognizes the desirability and need to share the important work conducted as part of the DOPPS project. This Section describes the conditions for release of Data to sponsors and to parties not explicitly possessing rights to such Data pursuant to the terms and conditions of existing DOPPS contracts. The following protocol balances the desire to release Data to study sponsors, DOPPS co-investigators, and independent researchers, with the burdens of protecting publication and other interests represented in the Data.

Organized pursuant to § 501(c)(3) of the IRS Code, URREA must observe strict guidelines of business conduct in order to maintain its status as a not-for-profit scientific research organization. Such guidelines mandate that URREA must operate exclusively for one or more of the “exempt purposes” of § 501(c)(3) under which it was created. Specifically, URREA was created to accomplish scientific research and education and is therefore precluded from engaging in activities that do not meet this description, including but not limited to the promotion of study sponsors or supporting marketing initiatives. URREA will not provide Data to individuals or organizations or for purposes that may endanger the duly organized status of URREA as a not-for-profit scientific research organization pursuant to § 501(c)(3) of the IRS Code.

#### **a) Data Release to Sponsors**

For the reasons outlined above, requests to release Data are typically honored for contracted sponsors and to those entities possessing rights to the Data pursuant to the terms and conditions of existing DOPPS contracts. Release of Data to entities outside of this contracted sponsor relationship is discussed under the sub-heading entitled, “**Other Requests for Data**” to follow. Notwithstanding, all “preconditions of release” must be met prior to any release of Data by URREA; these preconditions are described more fully under the subheading entitled “**Preconditions of Release.**”



## **b) Other Requests for Data**

This Policy does allow for the release of DOPPS Data to independent researchers. However, such release shall only occur with the approval of the URREA/Amgen Study Coordinating Committee (SCC). Independent researchers are encouraged to utilize the analyses and related DOPPS findings already published by URREA, though researchers may also submit a proposal to obtain Data to conduct their own independent research. The SCC will review each request for DOPPS Data in order to determine the appropriateness of release of such Data. As previously stated, URREA will not provide Data to individuals or organizations or for purposes that may endanger the duly organized status of URREA as a not-for profit scientific research organization pursuant to § 501(c)(3) of the IRS Code. The SCC will consider such factors while reviewing data requests.

It will be customary for the SCC to recommend that URREA perform the statistical analyses and share these with the requester. Under certain circumstances and at the discretion of the SCC, however, independent researchers will be allowed to receive Data. Furthermore, the results of any research conducted with DOPPS Data shall not be published without the review and approval of the SCC; more detail about approval for publication may be found in Section 4 of this Policy.

## **c) Preconditions of Release**

With respect to each Phase of DOPPS, no Data will be released prior to (1) cessation of all data collection activities relating to each Phase of DOPPS, and (2) completion by URREA of the necessary procedures to sanitize the Data and organize them in such a way that renders identification of individual patients and facilities practically impossible. Release of Data and the schedule for such release will be determined so as not to jeopardize the current or prospective publication initiatives of the SCC. For these reasons, release of Data will not occur prior to one year from the end of data collection for the respective Phase of DOPPS. The following table highlights the timetable for potential release of Data.

	<u>End of Data Collection</u>	<u>Date of Availability</u>
Phase I DOPPS	December 2001	December 2002
Phase II DOPPS	December 2004	December 2005



If the SCC determines to release Data to a requester, the requester will be asked to complete and sign a Data Use Agreement, attesting to the general terms and conditions applicable to Data to be provided to the requester. No Data release shall take place prior to the execution of a Data Use Agreement that has been completed and signed by the requester or an authorized representative of the organization with which the requester is affiliated and for whom the requester will be conducting the proposed research with the Data. The Data Use Agreement request will require approval by the SCC prior to release of the Data to the requesting party.

#### **d) Limitations on Data Use and Publication Implications**

Use of the Data is restricted to conducting *bona-fide* clinical and scientific research. Recipients of the Data may not use the Data for promotional, commercial or marketing purposes. Other uses of the Data expressly prohibited by this Policy include, but are not limited to, the identification of facilities and comparisons between facilities.

Any Data obtained from URREA may not be used in conjunction with, or as the basis of, publication or presentation without the approval of the SCC. The procedures governing publication are outlined below in Section 4 of this Policy, and must be followed for any publication involving Data obtained from URREA and therefore subject to the policies discussed herein. Furthermore, no Data or related material may be used for purposes other than those described to and approved by the SCC. Material may not be reproduced, redistributed or re-presented without the explicit approval of the SCC.

#### **Section 4) PUBLICATION POLICY**

As stated in Section 2, this Policy will direct the adherence to general principles that govern scientific publications. The Policy is also designed to encourage publication from WorldWide DOPPS Data and to acknowledge direct and substantial contributions to research publications, in order to create the incentive for significant, groundbreaking, creative and productive research using the Data. Finally, the Policy will promote the due recognition of those contributing to these efforts.

The group consisting of the investigators from Amgen, the investigators from URREA, investigators involved through a subcontract or other arrangement, the DOPPS Country



Investigators and Members-at-Large, and the Japan DOPPS Steering Committee will hereafter be referred to as the “**WorldWide DOPPS Committee.**”

### **a) Participation and Authorship**

The policies described in Section 3 of this Policy guide the release of WorldWide DOPPS Data to outside investigators for research projects, however, it is the role of the SCC to identify and prioritize topics for publication and suggest timelines for the publications.

Authors of publications will include members of the WorldWide DOPPS Committee as well as investigators from the DOPPS Advisory Board, URREA staff, Amgen/Kirin staff or any other investigators who make a direct contribution to the work associated with a publication.

The SCC will be responsible for extending the opportunity to participate in the development of a research publication to the appropriate investigators. Determination of those appropriate will be based on expressed interest and work associated with a particular area of investigation. Prior interest and associated work do not constitute a direct contribution to a particular research project however; they only help to determine whether an offer to participate might be appropriate.

Authorship credit among those associated with research using World-Wide DOPPS Data will follow actual individual contributions, recognizing that there are many ways to contribute: creation of the analysis plan, special data collection, conduct of analysis, and direct authorship of methods, results and for discussion. The lead investigator for a paper is generally apparent from the degree of initiative, interest and effort devoted to the particular topic. If the lead investigator for a research publication is not apparent, the SCC will make this determination.

The lead investigator is generally (but not always) the author who writes the research publication. The lead investigator should, in general, determine the respective responsibilities of co-investigators and the order of authorship. Order of authorship should be discussed and agreed upon by all authors prior to submission of a publication.

### **b) Proposal of Research Projects**

A realistic procedure is needed to facilitate creative responsiveness to opportunities and to ensure involvement of the Study Coordinating Committee. In general, it is expected that research projects will be proposed periodically by members of the SCC, selected country investigators, and other members of the research team. Such research ideas should be discussed with the DOPPS



Principal Investigator (PI), who will make an initial judgment as to whether the proposed project is compatible with the overall research goals and priorities established by the SCC. The PI must also determine whether the proposal conflicts with ongoing projects in terms of scientific priority and resource requirements. If the PI finds the project acceptable from these above viewpoints, preliminary feasibility analyses may be undertaken (e.g. to determine if the data are complete enough to address the question). If the project appears to be feasible, the proposer will then prepare a brief statement describing the research question or hypothesis, Data to be used, planned analytic approach, and potential scientific implications. The statement will be circulated to members of the SCC.

Meanwhile, the project can proceed although it remains open to discussion by the SCC. Committee members may query the PI or the proposer directly or at the next SCC meeting. The committee may elect to formally review the project at a scheduled or ad hoc meeting. A cumulative listing of all such projects will be maintained and periodically reviewed by the SCC. The project list will provide the framework for expected publications.

#### **c) Template for Project Notification Form**

1. Proposed Title
2. Proposer(s)
3. Hypothesis or research question
4. Data to be used
5. Proposed analytic approach
6. Potential implications, limitations and other issues

#### **d) Resolution of Conflicts**

Any disputes about authorship credit or order will hopefully be settled collegially among the parties. If, however, a dispute cannot be resolved in this manner, the PI in conjunction with the SCC will be asked to address the dispute.



#### **e) Recognition of WorldWide DOPPS Committee**

WorldWide DOPPS is a collaborative project that has involved important and substantial contributions of intellectual effort that may not be directly applicable to a particular publication. For example, the investigators who developed the DOPPS questionnaires will not necessarily be included as authors on every WorldWide DOPPS publication. Nevertheless this is a major contribution that deserves special recognition. Therefore, each WorldWide DOPPS publication will cite the “*WorldWide DOPPS Committee*.” This will be accomplished by listing the authors as usual under the title of the publication followed by an asterisk indicating a footnote. The footnote will state: “This publication is for the World-Wide DOPPS Committee. The “Committee” consists of... (In alphabetical order a list of all committee members).”

Research results included in a planned publication or presentation will be distributed, whenever possible, to the members of the WorldWide DOPPS Committee prior to the submission of a manuscript for publication. This provides a means of informing the Committee of specific results before they are published.

#### **f) Specific Guidelines for Abstracts**

Practical realities make it difficult to comply with this publication policy with respect to the submission of abstracts. Time frames are short and abstracts generally include preliminary analyses that are newly conducted for the specific purpose of the abstract. In general, the SCC will make a reasonable effort to contact appropriate investigators and offer an opportunity to participate on a given abstract. Furthermore, recognition will be given to the WorldWide DOPPS Committee as part of the presentation of the abstract.