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Osteoarthritis Initiative

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- Prospectus -

Scientific and Administrative Plans for the Osteoarthritis Initiative Public-Private Consortium

Preamble

This prospectus is presented by the National Institutes of Health (NIH) to pharmaceutical companies for discussions regarding a research project known as the Osteoarthritis Initiative. Proposed is a collaboration of the NIH Institutes and Centers, the Foundation for the National Institutes of Health, and private R&D organizations and their research foundations, collectively known as the Osteoarthritis Initiative Public-Private Consortium, to sponsor the development and management of clinical research resources to evaluate biomarkers for osteoarthritis. A glossary of terms used in this prospectus is provided in Appendix A.

The scientific and administrative plans in this prospectus were developed with broad input from the research community, including scientists working for pharmaceutical companies as well as those working for the U.S. Food and Drug Administration. The scientific plan provides the broad specifications of the research activities. The administrative plan provides a framework for the terms and conditions of the transactions among public and private sponsors of the Osteoarthritis Initiative Public-Private Consortium. Budget estimates for the project will be presented in a separate document.

I. Overview of the Osteoarthritis Initiative

A Objective of the Osteoarthritis Initiative

The overarching aim of the Initiative is to develop and support clinical research resources and tools to enable discovery, assessment, and validation of biomarkers for osteoarthritis. Among the motivations for the Initiative is the anticipation that these biomarkers will provide the not-for-profit and for-profit scientific enterprise with new opportunities to develop disease-modifying therapies and streamline the clinical trials assessing the safety and efficacy of these therapies. In addition, it is anticipated that the resources will facilitate the development of in vitro

analytical methods that may have utility in diagnosis and patient management. These biomarkers include biochemical markers of bone and cartilage to assess disease progression, genetic markers associated with osteoarthritis, and structural markers as determined by various imaging technologies (e.g., radiographs, magnetic resonance).

B. Background on Project Development - Osteoarthritis Initiative Steering Group

Consultations with many experts in the field identified a number of difficulties with drug discovery and clinical testing of disease-modifying therapies for osteoarthritis. They noted that lack of discrete indicators of disease progression, the long time periods needed to reach clinical endpoints, and complex interaction of muscle, cartilage, and bone in degenerative joint disease pose major challenges to clinical trials for these agents. Leaders from the research community also indicated that improvements in clinical tools and the development and evaluation of biomarkers would likely have a positive impact on drug discovery and clinical trials. Further, it was recognized that such a research effort would have maximal impact if public and private research organizations worked together to leverage their expertise and research resources.

Beginning in early 1999, a diverse group of experts from academia, government, (National Institutes of Health, U.S. Food and Drug Administration, and National Center for Health Statistics), industry (pharmaceutical, biotechnology, and medical imaging), professional research societies, and volunteer health organizations formed the Osteoarthritis Initiative Steering Group (Detailed information about Osteoarthritis Initiative Steering Group is found at: <http://www.niams.nih.gov/ne/reports/oisg/index.htm>.) to jointly explore a research agenda that would achieve the aim of the Initiative. This group held a series of public meetings, workshops, and conferences specifically devoted to considering the development of a research project(s) that identify and evaluate biomarkers for osteoarthritis. This group was organized into four subcommittees addressing epidemiologic, genetic, and statistical considerations; biochemical markers; structural markers assessed by various imaging techniques; and administrative, infrastructure, and management concerns. Several white papers on the state-of-the-science of osteoarthritis biomarkers were developed. Additional input to the research initiative was obtained from over 200 participants (U.S. and abroad) representing many disciplines and organizations: academic and industrial scientists, regulatory agencies, professional research societies, and volunteer health organizations. From these meetings and consultations, a scientific plan was developed to discover and evaluate clinical tools and biomarkers for osteoarthritis. Given the uniqueness of the anticipated collaboration among public and private research sectors, a new administrative model was proposed to manage the research plan.

C. Potential Impact of the Osteoarthritis Initiative

The underlying purpose of this initiative is to improve public health by preventing or alleviating pain and disability from bone and joint degenerative processes. Collectively, all forms of arthritis account for the leading cause of disability in the US, affecting approximately 43 million persons and costing approximately \$65 billion in 1992. (Impact of Arthritis and Other Rheumatic Conditions on the Health-Care System-United States, 1997. MMWR 1997;48:349-353.) The changing demographics of aged populations underline the growing need for therapies that prevent or delay degenerative joint diseases.

While recent advances have yielded highly effective disease-modifying therapies for rheumatoid arthritis, no such therapies exist for osteoarthritis and current treatment regimens are predominantly designed to relieve pain. Because of the chronic nature of the disease and variable clinical outcomes, clinical trials for new therapies are difficult, take a long time to conduct, and are exceedingly expensive. The development and validation of biomarkers would streamline the clinical trial process and provide incentives for private sector R&D of novel osteoarthritis interventions and novel in vitro diagnostic products with utility in clinical management.

There are other benefits expected to arise out of participation in the Osteoarthritis Initiative Public-Private Consortium. Private sector sponsors will be able to collaborate with academic and NIH scientists in the design of the research plan and use of research tools, and participate in the management of the Consortium and the resources developed by it. Participation in the Consortium will allow integration of data and technology into strategic plans for clinical trials. Important validation studies will be conducted with the data and results made available in the public domain, thereby negating the need for multiple private companies to repeat assays and redevelop techniques resulting in the conservation of fiscal and human resources. The participation of regulatory agencies (i.e., U.S. Food and Drug Administration) in the Consortium will improve communication in the regulatory process. This will streamline the development of regulatory guidances, enhance evaluation of surrogate endpoints in clinical trials, and support confirmatory evidence in new drug applications in the regulatory approval process. By establishing the clinical research resources through this Consortium, it is anticipated that private industry sponsors will experience shortening of time and lessening of cost for development and time to evaluate new osteoarthritis therapies.

II. Scientific Plan

The scientific plan for the Osteoarthritis Initiative was developed based on recommendations from the Osteoarthritis Initiative Steering Group in an open process with broad and detailed input from many interests. The core elements for the research plan were identified as follows:

- development of a population-based, longitudinal, human subject cohort to characterize the natural history of

osteoarthritis,

- application of imaging tools (radiographs and magnetic resonance) to evaluate joint structural markers (principally for the knee joints) as potential surrogate endpoints for clinical trials, and
- establishment of biospecimen repositories to enable evaluation of biochemical and genetic markers

A. **Development of an Osteoarthritis Study Cohort**

The Osteoarthritis Initiative Steering Group indicated that the critical element for discovery and evaluation of biomarkers was a well-defined longitudinal, natural history study in which biological samples and imaging studies were conducted. The Steering Group identified all current U.S. and international population studies for osteoarthritis and evaluated the clinical populations and research resources developed from them for potential use in addressing the Initiative's aim. (Longitudinal Studies of Osteoarthritis: A State-of-the-Science Evaluation.

(<http://www.niams.nih.gov/ne/oi/oaepip.htm>) The experts, while noting that many of the studies have made substantial scientific contributions, considered that none were suitable to meet the core elements of this Initiative's research plan, particularly with regard to the conduct of imaging studies to evaluate structural markers.

1 **Characteristics of the study population.**

To achieve the objectives of the initiative, the Osteoarthritis Initiative Steering Group endorsed the establishment of a new longitudinal cohort that was population-based, rather than clinic-based. This cohort would serve as a study population to evaluate the structural, biochemical, and genetic markers as clinical correlates for osteoarthritis progression. Moreover the experts recommended that the recruitment base over sample for subjects with high-risk profiles (e.g., sports injury, middle-aged obese females, developmental hip dysplasia), and with early overt clinical features of osteoarthritis. Enrichment of the cohort would provide the highest probability of identifying biomarkers that could serve as predictive factors for clinically meaningful endpoints. The cohort will include an over sampling of individuals at high risk for conversion of disease state (characterized by asymptomatic structural changes that progress to disability and pain). Recruitment criteria will be established to ensure appropriate gender, ethnic, racial, and socioeconomic distributions in the cohorts.

2. **Rationale for estimating the cohort study size and length of study.**

Experts recommended that the cohort size for the study be based on the evaluation of structural markers of joint degeneration using imaging

technologies. The Osteoarthritis Initiative Steering Group determined that genetic and biochemical markers offer substantial potential opportunity to serve as tools in clinical trials, but that the scientific evidence was not yet sufficiently compelling to consider as a candidate surrogate endpoints. The experts did feel, however, that structural markers of joint degeneration were promising and suggested that the cohort be sized to conduct a validation study of them

Statistical consultations were obtained to develop models that would enable estimation of the cohort size needed for the validation of structural markers with clinical features of disease progress. In a preliminary report, the statisticians noted that at the present time the best quantifiable parameter to characterize disease progression and predict clinical outcome is radiographic evidence of joint space narrowing. (Note that this is a parameter that is being considered by FDA in a draft guidance for sponsors as a structural marker for clinical trials) Based on data regarding the rate of joint space narrowing, particularly in knee osteoarthritis, the experts recommended a 5-year longitudinal study (conducted over 7-year period considering enrollment and analysis time) with annual measurements to validate a structural marker(s) of joint degeneration.

The experts considered that magnetic resonance imaging has promise for identifying other structural features of bone and cartilage that would also be candidate markers for disease progress. Given the limited amount of information on performance metrics of radiographic and magnetic imaging techniques, the measurement of joint space narrowing to predict disease progression was the cornerstone used for power calculations to determine the size of the population to be recruited. It was recognized that enrichment of the cohort with high risk subjects and the use of magnetic resonance imaging would yield additional robust parameters with greater sensitivity and specificity for predicting clinical outcomes. A formal statistical report will be completed for the final proposal and will include statistical calculations based on clinical outcome measures and performance metrics for magnetic resonance imaging studies.

3. **Establishment of the study cohort.**

Preliminary statistical calculations suggest that approximately 4,000 patients would be needed to in a 5-year longitudinal study (noting that including recruitment time and analysis time require a 7-year plan) with annual measurements of joint space width with 90% power and 5% type I error rate. With an estimate of a 20% drop out rate, a total enrollment of 5,000 subjects may be necessary.

The project specifications will designate the development of 8 to 10 clinical recruitment centers that will target completion of enrollment within 18 months of the study initiation.

B. Clinical Outcome Measures Used in Osteoarthritis Studies.

Based on a consensus reached by the Osteoarthritis Initiative Steering Group, a composite of clinical measures and instruments designed to assess disease-specific and patient-specific indices will be used at the same interval at which imaging studies are conducted. Disease specific measures include Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and patient specific measures include the health assessment questionnaire (HAQ) or Arthritis Impact Measurement Scales II (AIMS2). These outcome measures will be used in establishing the statistical relationships with biochemical, genetic, and structural markers.

C. Structural Markers and Imaging Technologies.

The Steering Group sponsored a meeting specifically to address the issue of using imaging technologies to identify structural biomarkers of osteoarthritis progression. (January 11, 2000 Osteoarthritis Imaging Workshop. <http://www.niams.nih.gov/ne/oi/imaging.htm>) The capabilities of multiple imaging modalities (e.g., X-ray, ultrasound, magnetic resonance, optical coherence and positron emission tomography) were considered from the scientific value of the ability to characterize joint structure and the changes that occur in osteoarthritis. These technologies were examined from the perspective of their potential application in evaluating structural markers in clinical trials. In this regard, the experts found that some technologies (near infrared spectroscopy, ultrasound, and positron emission tomography) offer potential as discovery tools but were not practical measurement instruments for clinical trials at this time.

The Osteoarthritis Initiative Steering Group identified two imaging modalities with promise to characterize structural markers for progression of osteoarthritis. One is the use of radiographic techniques that focus primarily on joint space width as a structural marker. In addition, the experts, although not uniformly, found that high resolution magnetic imaging technique has the potential to evaluate structural markers beyond joint space width in clinical applications. Preliminary studies have indicated the potential for this technology to define structural characteristics in detail such as cartilage volume, thickness, soft tissue, and bone structures (osteophytes) that may represent important biomarkers for clinical progression.

The experts concluded in recommending a three-tier approach to investigations that would seek to validate a structural marker(s) of osteoarthritis (Appendix B). They considered many factors in their recommendations including the cost of the imaging studies and the time required for

human subjects to be involved in imaging procedures. The consensus was that the tier 1 (radiographic imaging of hand, hip, and knee; magnetic resonance imaging of knee) protocol had the highest priority. Tier 2 and 3 studies, were valued, but recommended for application in select populations and if resources allowed.

The research plan will address the analysis of such radiographic and magnetic resonance images by: 1) standardizing measurement and analytical approaches, 2) conducting cross-validation studies among imaging centers, 3) comparing of imaging measurements with clinical outcomes, and 4) comparing of measurement characteristics among modalities (radiograph and magnetic resonance image structural marker parameters).

D Biochemical and Genetic Markers

A scientific assessment of more than 20 potential biochemical markers for osteoarthritis was conducted and results evaluated by the Osteoarthritis Initiative Steering Group. (Biomarkers.

<http://www.niams.nih.gov/ne/oi/oabiomarwhipap.htm>)

For many of these candidate biochemical markers, monoclonal antibodies represent clinical tools to assess disease progression. The experts indicated that, although some of these markers are potentially useful, none were deemed as poised for large-scale validation at this time. In addition, the experts recognized that biological specimens from well-characterized study populations are finite resources and their experimental use should be restricted for research of the highest quality with the largest public health impact. There was a consensus that future research would likely provide insights on the most promising of these biomarkers. They also suggested criteria to be met by assays prior to use of the biospecimens in validation studies. The establishment of a biospecimen repository composed of blood and urine, and perhaps synovial fluid and tissue, from the longitudinal cohort is a high priority and provides the research community with a valuable resource for future validation protocols. Future use of biospecimens will be decided upon by fulfilling scientific and public health criteria in accordance with Consortium research policies (see III Administrative, Part C Biospecimen utilization)

The collection of specimens and development of resources (cell lines and DNA) that will enable genetic analysis of individuals within the cohort may hold important future value. It was acknowledged that some private research organizations are currently investigating genes associated with high risk of joint degeneration, although there was little disclosure or specific discussion of these efforts in the public meetings. The group acknowledged the potential value of having the capability to conduct genetic studies on specimens from this proposed cohort. It was deemed a priority to establish cell lines for study subjects for future research purposes to be decided by the Consortium.

The final research plan will delineate the methods and approaches for specimen acquisition. The services of a

specimen repository will be provided under a contract mechanism through the data coordinating and analysis center.

III. **Administrative Plan for the Osteoarthritis Initiative Public-Private Consortium**

The research projects of the Osteoarthritis Initiative will be supported by a partnership of public and private R&D organizations known as the Osteoarthritis Initiative Public-Private Consortium. While there are many research collaborations among the public and private sectors, there is no existing mechanism by which NIH Institutes and Centers and private organizations manage and support research initiatives. The administrative subcommittee of the Osteoarthritis Steering Group developed a model that will serve as a framework for the collaboration. It was recognized that many details of the management model could not be provided until the composition of the Osteoarthritis Initiative Public-Private Consortium is determined. The administrative plan was approved by the Steering Group and presented for review at an open meeting held on February 28-29, 2000.

In developing the project model the Osteoarthritis Initiative Steering Group relied upon five basic tenets for collaboration among public and private research sponsors:

1. create an administrative management model that has well-defined rules and responsibilities, permits fair representation for all involved parties, and retains flexibility to meet emerging needs;
2. provide an open and fair process for decisions regarding use of research resources and the sharing of data and research results;
3. recognize certain limiting conditions of public organizations (e.g., government regulations) and private organizations (e.g., proprietary information);
4. utilize peer-review to evaluate the best scientific proposals; and
5. provide means to prevent conflicts of interest to fullest extent possible.

A. **The Osteoarthritis Initiative Consortium Project Model**

The Osteoarthritis Initiative Steering Group developed a model that would allow public and private organizations to sponsor and manage the research initiatives. After examining many options, the Osteoarthritis Initiative Steering Group developed a model that allows public (NIH) monies to be merged with those derived from private sources for common sponsorship of the Consortium's research activities. The model is shown in Appendix C and D. For glossary of terms, see Appendix A

An overview of the project model is provided here. Public and private sponsors will provide financial support for the scientific plan. When finalized, the specific terms of the

scientific plan will be published as request for proposals (RFP). Proposals will be submitted to NIH for consideration of funding. Those proposals meeting the terms of the RFP will be evaluated by independent scientific review and those presenting the best scientific proposals will be funded through contracts.

The major contracts will be used to develop approximately 8 - 10 clinical epidemiology sites that will serve to recruit participants for the study, collect specimens, and conduct imaging studies. An additional contract will be awarded for a data coordinating and analysis center for the Initiative. Subcontracts will be awarded for supporting services such as maintaining a biospecimen repository, and potentially for conducting biochemical validation studies (if agreed upon by the Consortium). The contractor deliverables to the Consortium will be information regarding the population cohorts, biospecimens, and imaging studies and analysis. The terms and conditions of the RFP will be represented in the contract and will include contractor deliverables.

The administrative subcommittee agreed to specific issues regarding the Consortium including the following:

- 1. Sponsorship.**

The Osteoarthritis Initiative Public-Private Consortium is composed of those organizations that contribute fiscal resources for the project. The NIH sponsorship will represent two principle Institutes: National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institute on Aging. Ad hoc (non-voting) representation to the Consortium will include the U.S. Food and Drug Administration and possibly professional and other government research organizations.

The Foundation for the National Institutes of Health, Inc. (<http://www.fnih.org/>) (FNIH), a 501(c)(3) charitable organization, will serve an important link between private sponsors and the NIH Institutes and Centers funding the Initiative. The FNIH was incorporated in 1996 to support the NIH in its mission and to advance collaboration with biomedical researchers from Universities, industry, and non-profit organizations.

The FNIH has extensive experience in working with private donors, including the pharmaceutical industry, to cooperatively support basic and clinical research and education programs. It is anticipated that some private industry participants in the Osteoarthritis Initiative Public-Private Consortium may have affiliated research foundations that may serve as the interface with the FNIH in their sponsorship.

Private sponsor resources will be used solely for the purpose of the Osteoarthritis Initiative research activities and may not be used for other research purposes.

2. Research support mechanisms.

The research projects of the Osteoarthritis Initiative will be funded solely through contract mechanisms - not research project grants (RPGs or R01 grants). The private resources will not be used to support any NIH research projects not associated with Osteoarthritis Initiative.

3. Development of request for proposals (RFP).

The details of the scientific plan will be described by open solicitation to the research community of a RFP by NIH on behalf of the Osteoarthritis Initiative Consortium. A draft RFP will be posted for public comment prior to the solicitation and private sponsors will be invited to provide suggestions or modifications that will improve the quality of the proposal.

4 Evaluation of research proposals.

An independent scientific review of the proposals will be conducted according to standard NIH protocols for review of special projects. Industry representation on review panels or consultation on specific issues regarding the review of the proposals will be considered based on needs for expertise and relevance to scientific issues. To avoid conflicts of interest in evaluating the research proposals, scientists from participating sponsor organizations, and universities or research organizations applying for the contracts are excluded from participating in the review process.

5. Contract awards and terms.

The NIH will award contracts for those scientific proposals deemed to be of the highest quality. The terms and conditions of the RFP will be represented in the contract and will include the contractor deliverables

6. Projected time lines.

The Osteoarthritis Steering Group proposed that a draft RFP be published in August 2000 for comment. Release of the RFP is anticipated for October 2000 with the review of the proposals conducted in late winter 2001 with awarding of contracts in September 2001.

B Management of the Osteoarthritis Consortium.**1. Committee structure.**

An executive committee that is composed of representatives from the private sponsors, epidemiology centers, data coordinating and analysis center, and NIH will govern the Consortium activities.

The private sponsors will be represented collectively on the executive committee. This position may be served by a rotation of representation on an annual basis. The executive committee will be charged with the broad oversight of the Osteoarthritis Initiative and have the responsibility of holding open meetings and communicating research plans and results. Once the Consortium membership is defined, a subcommittee structure will be developed to address issues such as: access to biospecimens, data monitoring, reporting and analysis, informed consent, data sharing and communications, etc. Private sponsors collectively will have representation on each of the subcommittees.

The Consortium will provide a web site that will serve as the conduit for communication among sponsors, and contractors about the Initiative.

The Consortium will sponsor open annual meetings to present updates on the scientific progress and discuss administrative issues associated with the Consortium.

2. **Project coordination.**

The coordination of the Osteoarthritis Initiative research activities will be conducted by a project officer from the NIH (National Institute of Arthritis and Musculoskeletal and Skin Diseases). The project officer will oversee the issuance of contracts, coordinate committee and subcommittee meetings, maintain communications among research sites and the data coordinating center, and perform other related duties required in the research contracts.

C. **Biospecimen Utilization.**

The Osteoarthritis Initiative Public-Private Steering Group regarded the access to, and use of, the biospecimens as a high priority issue for the Consortium's management. The Osteoarthritis Initiative Steering Group noted that the following issues contribute to this importance:

- human biospecimen resources are finite in quantity and will be insufficient to meet all possible needs,
- specimens should be used in the support of the highest quality research possible,
- specimens are intended for, and limited to, validation of the most promising biomarker assays from the scientific and public health aspects,
- specimens provide their greatest public health value when used as a public resource and made available to all research interests upon a stringent review of the scientific plan for their use, and

- biomarkers being accepted for assessment and validation through the use of the limited biospecimen resource will likely have differing degrees of intellectual property protection; nevertheless, access to validated markers for both further research as well as commercial development of new diagnostic and therapeutic products will be critical to achieving the Consortium's public health goals.

D The Osteoarthritis Initiative Steering Group recommended the development of an application process for public research access to the biospecimens. A subcommittee of the Consortium will establish scientific and public health criteria for the review of applications that propose to use the biospecimens. These criteria will emphasize that validated markers are considered to be research tools, and that applications for access to the biospecimens should include a detailed plan for sharing validated markers and any other research tools developed with the biospecimens. The public health objective is that any biomarker that is validated using Consortium-developed data and biospecimens should be made available to the scientific community for research and to the for-profit community for internal use in the development of new diagnostic and therapeutic products. Although the Consortium cannot govern how a third-party owner of a biomarker that is applying for access to Consortium resources will exercise its intellectual property rights, the Consortium will give priority to those applicants that have the best scientific proposals coupled with appropriate sharing plans such that the Consortium and other members of the public will not be blocked from using validated markers and other research tools. The applicant plans will be expected to be in accordance with the recent NIH Principles and Guidelines for Sharing of Biomedical Research Resources, (NIH Principles and Guidelines for Sharing of Biomedical Research Resources December 1999; http://www.nih.gov/od/ott/RTguide_final.htm) and may include non-exclusive cross-licensing with for-profit Consortium sponsors or the offering of validated biomarkers for sale to for-profit Consortium sponsors.

Proposals for access to biospecimens will be reviewed by an independent scientific review panel based on an evaluation of the scientific and public health merit of the research plan in consideration of the prioritization criteria established by the Consortium biospecimen utilization subcommittee. All research findings developed through the use of the biospecimens will be required to be reported to the data coordinating center for inclusion in the public database.

E. Reporting of Epidemiology Data and Imaging Studies.

The Steering Group considered that a public database of the research results to be a cornerstone of the Initiative. Among the responsibilities of the data coordinating and analysis center will be the development of a database that will provide detailed information regarding the epidemiologic characteristics of the study population, clinical outcome data, and analysis of imaging data. Recognizing the

importance of quality control measures and interpretation of the data by the center's scientists, the Osteoarthritis Initiative Steering Group recommended that detailed data be provided at the following intervals: 3 years, 4.5 years, 7 years

- F. **Intellectual Property** The Osteoarthritis Initiative Steering Group anticipated that the Osteoarthritis Initiative Public-Private Consortium will face many issues regarding intellectual property, particularly with regard to licensing rights involving validated biomarkers and other tools developed through the use of the biospecimens. The Osteoarthritis Initiative Steering Group noted that it is unlikely that the contractors will develop any new intellectual property due to the nature of the deliverables that will be required by the contract. However, with regard to any new intellectual property that may be developed by private sponsors and/or research contractors using the data and biospecimens developed by the Consortium, the Osteoarthritis Initiative Steering Group noted that (1) it is consistent with the aims of the Initiative that such new intellectual property may be developed, (2) the NIH cannot negotiate licensing arrangements among private sponsors and the research contractors, and (3) private sponsors of the Consortium are free to negotiate licensing arrangements among themselves and the research contractors.

The Steering Group noted that the public health criteria and the requirement for making research data publicly available will provide a means to make validated markers and other research tools available to the research community, and provide safeguards to the private sponsors of the Consortium that they will not be blocked from using what their sponsorship helped create.

G. **Exit and Entry Clauses for Private Sponsors.**

- H. The Steering Group recognized the importance of defining terms by which new corporate sponsors may participate or those who initially participate may voluntarily exit the Consortium. This matter pertains primarily to private sponsors in the Consortium, therefore it is suggested that the rules governing these issues be developed by the full membership of the Consortium.

I. **Conduct of Research Activities.**

All human research activities conducted by the Consortium will be subject to Federal rules and regulations. This includes abiding by guidelines for the inclusion of minorities and women in research studies, informed consent regulations, and protections involving the use of human biological specimens.

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