Inter-Institutional Memorandum of Understanding Between the Consortium Members in the Grand Challenges for Global Health Program entitled: Improving Cassava for Nutrition, Health, and Sustainable Development, also known as BioCassava Plus

This inter-institutional memorandum of understanding indicates the willingness of the following BioCassava Plus Consortium members. cooperation to increase the nutritional status of sub-Saharan Africans by developing viable cassava cultivars with enhanced quantities of bio-available zinc, iron, protein, Vitamin A, Vitamin E, reduced quantities of toxic cyanogenic glycosides, delayed post harvest physiological deterioration and high resistance to geminivirus disease.

At the start of the BioCassava Plus project, the institutes planned to be involved are:

- **Donald Danforth Plant Science Center, (DDPSC), USA** (awarded institute)
- International Center for Tropical Agriculture, (CIAT), Colombia
- International Institute Tropical Agriculture, (IITA), Nigeria
- Shanghai Center for Cassava Biotechnology at the Institute of Plant Physiology & Ecology (SIPPE), China
- Swiss federal Institute, (ETH), Switzerland
- University of Bath, UK
- University of Nebraska, Nebraska, USA
- University of Puerto Rico, (UPR), Puerto Rico
- Washington State University, Washington, USA
- Washington University, Missouri, USA

This list of participants may be revised according to the development of the overall project, the performance of each consortium member, the modifications to the plans following some changes made by the POC, or on the advice of the SAC.

Definitions of Terms

• BMGF is the Bill and Melinda Gates Foundation

• GCGH is the Grand Challenges for Global Health

• GAS is the Global Access Strategy

- Charitable Objective is .to ensure that innovations (and related rights) are managed and public health solutions are optimized for the purpose of facilitating: (i) the broad availability of data and information to the scientific community and (ii) the access to affordable health solutions for the benefit of people most in need within the developing world...

- A BioCassava Plus Consortium member is an institution receiving a subcontract from DDPSC, the official awardee of the GCGH.

- The POC is the Project Oversight Committee of the BioCassava Plus project.

- The SAC is the Scientific Advisory Committee of the BioCassava Plus project.

- A Research Focus Team (RFT) is a group of scientists and support professionals tasked with research and development activities focused on a specific trait (e.g., protein enhancement, vitamin enhancement, etc.) within the context of the BioCassava Plus project.

- A Research Focus Team Leader is a person designated in the grant proposal to lead a Research Focus Team.

In order to ensure that the BioCassava Plus project will achieve the Charitable Objective, the collaborating institutes agree to comply with the three-tiered management strategy proposed to the GCGH in April 2005. This approach is outlined below:

- Research Focus teams will have the primary responsibility for research and project management decisions. These teams will include investigators engaged in the production and characterization of transgenic plants, product biosafety/IPR issues, focus on field performance trials, and the performance of human trials. Each research focus team will have a leader who will be responsible for developing a prioritized set of research goals towards the completion of the milestones of the project, posting research results on the BioCassava Plus Team web site for review by all members of the project, and preparing quarterly reports for evaluation by the BioCassava Plus POC.

- The Project Oversight Committee (POC) The members of the POC are Dr. Claude Fauquet, Dr. John Beeching, Dr. Mark Manary, Dr. Ada Mbanaso, and Dr. Martin Fregene. The members of the committee were selected by the BioCassava group as a whole prior to submission of the grant proposal. The members of the POC will serve for five years. Members are permanent but can be replaced if for some reason they step down by nomination and a simple majority vote of the co-investigators. The POC will be responsible for the evaluation of the overall programmatic progress and adjustments to financial support for each project team in accordance with progress towards meeting their research objectives and milestones. If a given team fails to meet 30% or more of its research objectives in a given six month period, the POC will consider fund reallocations to investigators who have better capabilities and capacities to complete the research objectives. It is recognized that unanticipated research

obstacles may appear that impede research progress. If a team has not met 30% of their total number of research objectives but can demonstrate good progress they will continue to be supported. If the team has not made substantive efforts towards meeting 70% their research goals or has through bad management or poor scientific design failed to meet their goals the POC will consider transferring the project to another group that has been identified as being capable of meeting the research goals based on current and past research performance. The POC also will evaluate the progress of field trials and will take necessary measures to ensure success. If required, the POC will use the contingency plan for field testing. The contingency plan shall be to conduct the field trials at an alternate site. Alternate sites include several in Africa (IITA and KARI), CIAT and Puerto Rico as described in the Terms and Conditions of the project and subject to approval by the BMGF. The POC also will be responsible for providing research reports to and meeting with the GCGH Scientific Board on a biennial basis.

- Scientific Advisory Committee (SAC), an independent committee composed of distinguished scientists who have expertise in the scientific fields of this project, will annually evaluate the activities of the POC and the research teams. The SAC will participate in the annual meeting at which research progress reports will be made by each group. The SAC will also have access to online team research reports. The SAC will comment on research progress, its quality and make suggestions for improvement. The SAC will use the research milestones and objectives met as the standard for making good progress. The quality of the science will be evaluated on the basis of the SAC committee member's own personal standards of scientific quality. The SAC evaluation will be made available to the entire BioCassava Plus Team and reviewed by the POC, PI and the BMGF program officer. Suggested research or policy changes will be implemented following review by the POC, PI and BMGF program officer with the final decision being made by the PI. If the SAC recommend a change in the management of BioCassava Plus (POC or research teams) the PI, in consultation with the members of the appropriate management team and the program officer at the BMGF make the recommended changes. The SAC annual report will be posted on the BioCassava Plus web site one month after the annual meeting and will be made available to all members of BioCassava Plus, as well as, the GCGH Scientific Board. The recommendations of the SAC will be instituted by the POC.

Project Management and Funds Allocation

- The BioCassava Plus project is led by Dr. Richard Sayre, Director BioCassava Plus at DDPSC and PI of the project. Dr. Sayre is responsible for managing and directing the entire project and will be helped by an assistant. His duties include: coordination of the project, financial oversight along with the assistance of the DDPSC, interaction with the POC members to discuss and make decisions as needed, elaborate the six month report to the GCGH Scientific Board, report with the POC members to the GCGH Scientific Board, partake in the organization of the yearly meeting of all the project's participants, organize the yearly meeting of the SAC, put in place and update the BioCassava Plus website, elaborate and produce the promotional material, coordinate PR activities with DDPSC and other institutional PR offices, identify new

Research Focus Team leaders in consultation with the POC if needed, and elaborate the final report of the project in order to present it to the GCGH Scientific Board.

- DDPSC is the official awardee of the BioCassava Plus project, and therefore, will receive all the funds from the GCGH Scientific Board. DDPSC will manage the subcontracts for all the Research Focus Teams according to both the budgets provided at the time of the award and on a six months time schedule.

- Changes to the original budget categories can be made within a range of 10% without any prior requirement / authorization from neither the DDPSC nor the GCGH Scientific Board.

- Depending on the results obtained, the Research Focus Team may have to modify their activities, and therefore, their corresponding budgets, by shifting money from one year to another. Adequate research progress will be evaluated by the POC by the mechanisms described above with final approval from the program officer at the BMGF. These changes will be proposed to the POC. After discussion and agreement with the corresponding Research Focus Team, the POC will inform of such changes to the GCGH Scientific Board and will seek their approval before implementation. Subcontract amendments will be issued by DDPSC to reflect these budget changes. More specifically:

- On a six months basis, after analysis of the progress made by each Research Focus Team, the POC may suggest changes to activities/actions, and therefore, changes in the corresponding budgets. The POC, after discussion and agreement with the corresponding Research Focus Team, will inform of such changes to the GCGH Scientific Board and will seek their approval before implementation.

- On a 12 months basis, after analysis of the progress made by each Focus Team, the SAC may suggest changes to activities/actions, and therefore, changes in the corresponding budgets. After discussion and agreement with the corresponding Focus Team, the POC will inform of such changes to the GCGH Scientific Board and will seek their approval before implementation.

Organization of each constituent of the BioCassava Plus

- The Research Focus Teams are each assigned to a different objective or major activity indispensable for the execution of the proposal. These objectives and activities include: RFT#1: Micronutrients; RFT#2: Proteins; RFT#3: Vitamins; RFT#4: Cyanogenesis; RFT#5: Postharvest Physiological Deterioration; RFT#6: Cassava mosaic disease; RFT#7: Cassava Transformation and Enabling Technologies: RFT#8: Field and Human Nutrition Trials: RFT#9: Global Access Strategy.

- The Research Focus Team Leaders have been elected by the BioCassava Plus participants at the time of the elaboration of the research proposal.

- The POC is composed of the PI, three co-PI's, country PI (Nigeria), and PDM of the project. Members were elected by the BioCassava Plus participants at the time of the elaboration of the research proposal.

- The SAC is composed of five experts chosen from the different fields covered by the project and the members have been elected by the BioCassava Plus participants at the time of the elaboration of the research proposal.

Procedure for naming and replacing POC and SAC members

- Because of unexpected reasons (sickness, death, under-performance, under-participation to mandatory meetings, moving to other functions.), some Research Focus Team Leaders may have to step down. Correspondingly, new leaders would be proposed by the Research Focus Team members and would become co-PIs in the BioCassava Plus project. In the best interest of the project, the POC, in consultation with the BMGF, will make the final choice and the vote of the chair will prevail in case of a tie vote. Final approval of any change will be required from the program officer of the BMGF.

- Because of unexpected reasons (sickness, death, under-performance, under-participation to mandatory meetings, moving to other functions.), some members of the POC may have to step down. Correspondingly, new members would be made co-PIs in the BioCassava Plus project through the proposal from either POC remaining members or other BioCassava Plus members. In the best interest of the project, the remaining members of the POC will make the final choice and the vote of the chair will prevail in case of a tie vote. The BMGF will be consulted prior to any final decision for approval.

- Because of unexpected reasons (sickness, death, under-participation to SAC meetings, moving to other functions.), some members of the SAC may have to step down. Consequently, new scientific advisers would have to be nominated. New members are able to be proposed by either POC members or other BioCassava Plus members. In the best interest of the project, the members of the POC will make the final choice and the vote of the chair will prevail in case of a tie vote. The BMGF will be consulted prior to any final decision for approval.

Withdrawal or Addition of any collaborator/Consortium member

For either personal or scientific reasons, a collaborator may want to withdraw his/her participation from the BioCassava Plus project. After discussion with the relevant Research Focus Team leader, the POC will decide if the withdrawal is jeopardizing the outcome of the Research Focus Team and if so will look for a substitute. Financial implications would be taken into consideration and the POC would decide what should be done with the corresponding budget with the prior approval of the BMGF.

For scientific reasons, a new collaborator may be either proposed or required in the BioCassava Plus project. After discussion with the relevant Research Focus Team leader, the POC will decide if the addition is justified and will consider the financial implications. Such a change will be made only with the prior approval of the BMGF. If the addition was pending

on resources to be made available, the POC would contact BMGF to investigate the possibility of extra funding.

Confidential Agreement among the parties

A confidential agreement will be signed between all members of the Biocassava Plus Consortium. The agreement will allow the sharing of data either directly between Consortium members or indirectly via the BioCassava Plus web pages. It will also cover the disclosure within the BioCassava Plus members of information that may disclose patentable inventions and the sharing of scientific data. This confidential agreement will be a separate document signed by all Consortium members.

Inter-Institutional Visits of Personnel and Sharing of Know-How

Whenever possible, team members will visit other teams to learn new technologies, transfer know-how and share knowledge, and to aim at increasing the overall success of the project. Any type of scientific exchange should be promoted within the BioCassava Plus project. The personnel visiting other Consortium members will have to follow the local rules of the hosting institution in the context of the BMGF Terms and Conditions of the grant.

Resolution of Disputes

Disputes will be resolved by non-binding arbitration in a hierarchical manner: first by the team leader and then followed by the POC. If the conflict is not resolved by the aforementioned scheme, the Scientific Advisory Committee will arbitrate the conflict and reach a binding decision.

Terms and Conditions

All members of the consortium agree to abide by the GCGH General Terms and Conditions (attached). In the event of a conflict between this memorandum of understanding the GCGH General Terms and Conditions, the latter will control.

The continuation of the MoU should be subject to the *written* consent of *all* parties. This memorandum of understanding will be effective upon signature by designated representatives from all organizations. This memorandum of understanding will be effective for a period of five years and will be renewed for the same period upon mutual consent of all parties.

All members of the consortium agree to abide by the general Terms and Conditions of the Global Access Strategy Agreement (attached).

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Donald Danforth Plant Science Center (DDPSC) Date

Attachment – A

Director, UPRM Department of Biology — Date

UPRM Dean of Arts & Sciences — 24-NOV-08 — Date

Director, UPRM R&D Center — 25/XI/08 — Date

International Center for Tropical Agriculture (CIAT) Date

International Institute of Tropical Agriculture (IITA) Date

Shanghai Center for Cassava Biotechnology at the Institute of Plant Physiology & Ecology (SIPPE) Date

Swiss Federal Institute of Technology Zurich (ETH Zurich) Date

University of Bath Date

University of Nebraska Date

University of Puerto Rico Nov 30, 2008 Date

Washington State University (WSU) Date

Washington University (WashU) Date

Global Access Strategy Agreement for BioCassava Plus

Improving Cassava for Nutrition, Health, and Sustainable Development

The innovations, products, and information generated by this project will be managed in a manner that ensures subsequent availability and accessibility at an affordable cost to African farmers and consumers who will benefit from nutritionally enhanced cassava. The main elements of our strategy are described below, following the outline suggested in the request for Expected Program Documents by the Grand Challenges Program.

Intellectual Property (IP)

The Project IP Team: The IP Team is directed by Dr. Paul Anderson and an assistant to be named. Their mandate is to facilitate all IP and Biosafety agreements. This team will work with the leaders of the six research focus teams to list and define the proprietary technologies necessary to achieve the research objective, to assess the current legal status of each of these technologies, and to approach third party owners of required intellectual property rights (IPR) in order to discuss options for "non assert" agreements and/or licensing for both research and deployment. Responsibility to obtain freedom-to-operate for enabling technologies will rest primarily with the Project IP Team. Responsibility to obtain freedom-to-operate for genes of interest will rest primarily with the researcher using the specific technology, but each researcher will turn to his or her institution's technology management office for assistance, with additional guidance and support provided by the Project IP Team. It is recognized that private companies holding IPR relevant to the project may in some cases be reluctant to grant final commercialization rights until the nutritionally-enhanced cassava products are more fully developed and targeted to specific markets through specific partners; however, companies can grant preliminary licenses stating that the company "will not unreasonably withhold the grant of a commercial license to the Institution for the purpose of granting commercial sub-licenses, upon request and demonstration that such sub-licenses are necessary to allow the deployment of improved cassava varieties for humanitarian purposes." Where necessary, we will pursue such licenses. More frequently, we will pursue the letters of "non assert" discussed earlier.

The members of the BioCassava Plus program agree to share and provide access to technologies through material transfer agreements required by their local institution. Access to technologies will be for research and development in cassava only. A non-compete agreement, as well as appropriate institutional material transfer agreements, will be exchanged between collaborators. All participants in BioCassava Plus agree to provide access to all relevant gene constructs, enabling technologies, and biological materials to BioCassava Plus collaborators according to the Humanitarian Purposes as defined by the Public Intellectual Property Resource for Agriculture agreement (PIPRA, http://www.pipra.org/index.htm). More specifically Humanitarian Purposes includes (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a

Developing Country. A list of developing countries approved by the World Bank is available at the PIPRA web site.

In order to ensure that Intellectual Property developed through the BioCassava Plus project is treated in a manner consistent with the Charitable Objective, the team members agree:

1. To disclose patentable discoveries made through the proposed research in a timely manner to technology management offices at their respective research institutes in accordance with institutional policies and procedures. Patent submissions will require prior consultation with the BMGF before publication.

2. To evaluate the advantages and disadvantages of pursuing a patent on a discovery-by-discovery basis, and consult with other team members and notify the GCGH Program Officer before taking decisions on protection.

3. To make provisions for preserving the availability of the intellectual property for the benefit of people most in need in the developing world (the .Charitable Objective.) when considering commercial licensing of any intellectual property generated through the BioCassava Plus grant.

4. To abide by those aspects of the GAS concerning commercialization, including plans to license freely inventions resulting from the Grant to other legal entities that will facilitate deployment of nutritionally-enhanced cassava, such as the African Agricultural Technology Foundation (AATF) and national agricultural institutions in Africa.

5. To report to BioCassava Plus, the home institution, and the BMGF annual IP events (including the creation of new inventions, the decision as to whether to seek IP protection, and negotiations to license or otherwise transfer IP rights) relating to the activities of this grant that continue after the funded project is concluded for a period of not less than 5 years in order to permit the BMGF to continue evaluating the intended health solution and understanding the related technologies and IP rights.

All Parties acknowledge their desire and aim that all materials and IP necessary for use in the Project be made freely available to other relevant Parties working on the Project and that the results of the Project be made both freely available to the scientific community working in not-for-profit institutions in general and affordably accessible to farmers in Africa (.the Charitable Objective.). However, each Party also acknowledges that certain materials and/or IP whose use in the Project may be necessary are owned by third parties and currently are not freely available for the desired use or dissemination. Accordingly, each of the Parties agrees that it shall use all reasonable endeavors to ensure that:

1. Relevant parties will include non-profit groups, institutions or corporations outside of BioCassava Plus who agree to the general terms and conditions and who contribute towards meeting the objectives of the program through research or other substantive contributions. Other Parties shall be able to use all such materials and IP as may be necessary in relation to the Project; the Charitable Objective in respect of results generated from the Project is achieved.

2. For the avoidance of doubt, as part of the above requirements, each party shall use its reasonable endeavors to procure, where necessary, the consents of third parties who own rights in materials and/or IP relating to the Project to enable the free use thereof for the Charitable Objective.

3. Where this is not possible, each Party agrees that it shall use all reasonable endeavors to find alternative materials and/or IP so as to be able to achieve the same. However, no warranty is given that the above-mentioned outcomes are achievable; therefore, provided each party shall use all reasonable endeavors as detailed above, no liability shall attach to any Party if it shall be unable to procure the achievement of such in respect of any particular material or IP.

Reporting of Inventions

The participating institutions anticipate that patentable discoveries will be made through the proposed research, and that team members will disclose these discoveries to technology management offices at their respective research institutes in accordance with institutional policies and procedures. Technology managers at each of the participating institutions will evaluate the advantages and disadvantages of pursuing a patent on a discovery-by-discovery basis, and consult with other team members before taking decisions on protection. Innovations that nutritionally improve cassava are not anticipated to be of commercial interest insofar as there is virtually no market for the sale of cassava planting materials in Africa -- cassava is mainly a subsistence crop and planting materials are multiplied and shared freely by farmers. Discoveries made in the process of cassava research may, however, have potential applications in other crops or contexts of commercial interest -- in these cases, patenting may be considered for crops other than cassava.

When considering commercial licensing of any intellectual property generated through this grant, each participating institution will make provisions for preserving the availability of the intellectual property for the benefit of people most in need in the developing world (the .Charitable Objective.). The DDPSC is a member of the Public Intellectual Property Resource for Agriculture (PIPRA) scheme -- an initiative by universities, foundations and non-profit research institutions to make agricultural technologies more easily available for the development and distribution of improved food crops for humanitarian purposes in the developing world.

Inventions generated through this project will be reported through publications and made known to our research collaborators through the BioCassava Plus Program Oversight Committee (POC) and the Scientific Advisory Committee (SAC) via our secure website. Per the Terms and Conditions of the Grand Challenges program, the Gates Foundation Program Officer will be notified in writing in the event of inventions arising out of the project and subsequent patent applications and awards. The Grantee (DDPSC) will report annual IP events relating to the activities of this grant that continue after the funded project is concluded for a period of five years, per the program requirements.

The consortium intends to make intellectual properties created through this grant freely available for licensing by public and/or private entities to use towards cassava improvement or to distribute improved cassava planting materials for the benefit of small-holder farmers and consumers in Africa. New varieties of cassava are currently distributed freely in Africa--

initially by public agricultural research systems and subsequently from farmer to farmer. Our plan is to use these existing systems to distribute nutritionally enhanced cassava resulting from this research. When technologies are ready, we plan to provide royalty-free licenses to interested African public agricultural research institutions, either directly or through a clearinghouse organization, for their use in helping farmers and consumers.

Transfer of Material between Collaborators

In agreement with the general MoU signed with the GCGH, and to the extent possible, the BioCassava Plus collaborating parties agree to share materials (DNAs, Agrobacterium strains, protocols, plants...) to be used in the project, with other members of the team upon request, both for materials obtained from third parties and for materials created in the course of this project, provided that the transfer of materials is not prohibited by the terms of a prior license agreement with a third party owner. Whenever possible, the collaborating institutes agree to attempt to negotiate Material Transfer Agreements for relevant technologies with owners that will allow for the transfer of specified materials to all members of the BioCassava Plus consortium. The consortium also agrees that any materials developed or discovered during the course of the BioCassava Plus project will be shared upon request to other members of the BioCassava Plus team.

Public Release of Printed Materials

Data generated by the research team will be made rapidly available to our research collaborators, the Program Oversight Committee (POC), and the Scientific Advisory Committee (SAC) on our secure website (in development) (http://www.BioCassava_Plus). Research summaries from each team leader will be posted on the website on a quarterly basis. This site will also be accessible to the GCGH Scientific Review Committee and designated representatives of the Harvest Plus program. Annual meetings of the main research collaborators will facilitate data sharing, discussion, and synergisms within the BioCassava Plus consortium.

As scientific research yields results, they will be published as rapidly as possible in peer-reviewed journals of the highest quality and impact. Members of each research team will be expected to review manuscripts prior to submission for scientific quality and completeness. Manuscripts will also be vetted prior to submission by the appropriate institutional technology management office and the BMGF Program Officer, per program requirements. All publications will include the acknowledgement: .Funded through the Grand Challenges in Global Health Initiative.. Preference will be given to publications in the rapidly growing network of Open Access publications of PubMedCentral, in journals participating in the Health InterNetwork Access to Research Initiative (HINARI) and the FAO-sponsored Access to Global Online Research in Agriculture (AGORA) online portal for scientific information. These journals are available free of charge to registered institutions in developing countries and many of these 2400 journals are open access (http://www.healthinternetwork.org/src/j_list.php). Research published in most journals on this list will be indexed in the US public databases PubMed (National Library of Medicine) and/or Agricola (National Agricultural Library) - both of which are freely accessible on the Internet.

In addition, whenever possible, team members will retain copyrights before publication to enable free distribution of their papers and, whenever necessary, seek permission to make published papers available freely for download in pdf format on the websites of the FAO.s Global Cassava Development Strategy, the Global Cassava Partnership, the international research centers IITA, and CIAT.

As field trial performance results are generated, these will be made available through the websites of IITA and CIAT, the participating National Agricultural Research Systems (NARS) and through outreach materials developed for dissemination to rural Africans in Nigeria and Kenya. We have included a budget line item in the proposal to cover these costs. Per the Terms and Conditions of the Grand Challenges program, the BMGF Program Officer will be notified in writing of the publication of results.

From time-to-time, original research papers and press releases will be published describing the goals and accomplishments of the BioCassava Plus program. In recognition of the programmatic effort, all investigators included in the BioCassava Plus Program will be listed as co-authors on these general publications.

In order to ensure that publications developed as a result of the BioCassava Plus project are managed in a manner consistent with the Charitable Objective, the team members agree:

- To coordinate with the DDPSC Public Relations Office on all public release of printed materials.

- That DDPSC Public Relations Office will designate an experienced public relations professional to serve as the central contact person for coordinating all media outreach.

- To designate a public relations professional from each of the BioCassava Plus institutes to serve as the single point of contact for public relations matters.

- That all media materials distributed to reporters will include the primary contact name from DDPSC and the designated contact person from each of the BioCassava Plus program institutions.

- That DDPSC will notify the BMGF Program Officer in writing of the publication of results along with advance notice of each media release and the date of release per the Terms and Conditions of the GCGH program.

- To acknowledge the funding supplied by the GCGH Initiative in all media releases and printed materials.

- To submit all proposed publications resulting from research by a given team to its team leader, the POC, and the SAC for review prior to submission to a journal. Authorship for research articles will be assigned on the basis of significant experimental or intellectual contributions. The POC and SAC will respond as rapidly as possible with comments.

- That the BioCassava Plus institution that develops a new technology is responsible for drafting the media release and associated media materials about the manuscript, and is responsible for sending these media materials to the POC. These materials will be posted to the secure Web site (in development) (http://www.biosci.ohio-state.edu/~plantbio/Faculty/Sayre/BioCassava_Plus/Index.htm). Prior approval will be necessary from the BMGF.

- That all BioCassava Plus program institutions will have seven business days to review media materials posted to the secure Web site and be able to provide input. A BioCassava Plus program institution that does not respond within this seven-day timeframe signifies acceptance of the materials. Final approval will be necessary from the BMGF.

- That the DDPSC Public Relations Department will manage a master list of reporters, with each BioCassava Plus program institution supplying names and contact details to compile this list. Final approval will be necessary from the BMGF.

- The parties will not distribute information on a formal or informal basis to members of the media without the prior written consent of DDPSC Public Relations Department. Final approval will be necessary from the BMGF.

- Promotional Materials for BioCassava Plus

It is to the advantage, and is the duty, of all the members of the BioCassava Plus team to maximally publicize the activities to be conducted within the consortium, but will have to be done in a coordinated manner to ensure fairness and accuracy of these promotional materials (websites, flyers, posters, movies, interviews, editorials...).

- All institutional websites should refer to and link with the public part of the BioCassava Plus website. BioCassava Plus members should refrain from creating new websites. However, if a need arose, the draft of the project should be proposed to the POC for approval.

- General BioCassava Plus flyers and posters should be done and generated by the PI, along with the input from other BioCassava Plus members, and should be made available to all institutions associated with the BioCassava Plus team. If needs arise to have more specific flyers and posters during the development of the BioCassava Plus project, and if it is best done by a team of the BioCassava Plus consortium rather than the PI, a draft of the projects should be submitted to the POC for approval before execution of the projects and products should be made available to other team members.

- Specific movies, interviews, editorials in direct relation to the activities of BioCassava Plus, and outside of PR activities will be best developed by consortium members, but will need to meet the Terms and Conditions of the grant. The POC will be informed and, whenever possible, a draft of the project will be provided to make sure that the obligations of the MoU signed with the GCGH challenge are respected.

Scientific Publications/Communications Note: All publications and communications are subject to the Terms and Conditions of the BMGF agreement.

Within the context of this grant we foresee two types of scientific publications:

- Those resulting directly from the activities of each team. As soon as a draft of a publication is made, the draft will be submitted, under the BioCassava Plus confidential agreement to the POC for information, if it abides by the individual institutional rules relative to protection of IPR. These draft papers will also be notified to the BMGF according the general MoU. These papers will be authored according to the general rules of scientific authorship and may include, in addition to BioCassava Plus team members, collaborators of other labs and institutions. Acknowledgment to the BMGF will be done according to the general MoU.

- Those resulting from a journal editor's invitation, a meeting organizer's invitation or any other type of review, report, where the BioCassava Plus project will be described, presented, reviewed in a more global manner. These requests, although suitable and welcome, should be forwarded to the POC for approval of content and determination of best authorship in order to represent not solely the lab or institute to which belong the requested team member, but the whole of the BioCassava Plus team instead.

Potential Post-Project Development Plans

The research plan outlined in this application is designed to genetically enhance a single model variety of cassava in order to make it: (1) richer in zinc and iron, (2) greater in protein content and quality, (3) richer in vitamin E and provitamin A, (4) lower in cyanide, (5) less prone to PPD, and (6) more resistant to CMD. The research plan goes beyond basic research to include human trials that test bioavailability and into field trials in Africa that assess performance of the new traits in the relevant environments. Each trait will be tested individually during this First Phase of the project (five years). Once traits have demonstrated good performance in terms of field trials and bioavailability, the process of stacking the traits will begin. The ultimate goal is to assemble the full range of nutrients in agronomically important cassava germplasm that has been enhanced further with traits to accelerate farmer acceptance. While some initial stacking of genes will begin during this First Phase of research, most of this work is scheduled to take place during a Second Phase.

During the Second Phase, as we move from upstream research into the downstream process of mass production of cassava transformants, we anticipate an expanded role for African institutions in the gene insertion and screening process. It will be necessary to produce hundreds of transgenic plants in order to select those with the optimal expression of the best combination of nutritional and agronomic traits - the best plants for commercialization/deployment. This process will need to be repeated for several of the most widely grown cassava cultivars.

Strategies Regarding Commercialization and Sustainability:

Member institutions of the BioCassava Plus team will sub-license the relevant technologies to the African Agricultural Technology Foundation (AATF), which will in turn sub-license

the set of technologies embodied in the enhanced planting materials to the National Agricultural Research Systems (NARS) NARS will then be responsible for securing regulatory approvals at the national level and arranging for multiplication and distribution of the improved planting materials to farmers.

Before any materials can be distributed to farmers, regulatory approvals must be obtained at the national level. In the case of conventionally-bred cassava varieties, regulatory approvals usually require only a demonstration of good agronomic performance. In the case of genetically-engineered crops, the regulatory requirements will be more demanding and it will be up to the NARS to take the lead in securing approvals based upon the submission and review of environmental and food safety data. The BioCassava Plus team will play an important role in generating this safety data working in cooperation with AATF. During Phase One, the BioCassava Plus team plans to conduct an initial biosafety assessment of the major technologies that are to be employed by the team in order to enhance cassava. These assessments will give us good preliminary assessment of the safety issues and allow us to focus our research on only those technologies that are safe and likely to be considered so by regulators. During Phase Two, more detailed safety assessments will need to be conducted to develop full biosafety dossiers for the final products flowing from this project, namely cassava varieties with .a full range of optimal, bioavailable nutrients in a single staple plant species.. These issues will be addressed as we reach year four and can effectively evaluate the progress of the program and individual team members.