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June 30, 2011

The Honorable Mark Leno
Chair, Joint Legislative Budget Committee
1020 N Street, Room 553
Sacramento, California 95814

Dear Senator Leno:

Pursuant to Health & Safety Code 1627, enclosed is the University of California's plan to the Health and Fiscal Committees of the California State Legislature for the establishment of the Umbilical Cord Blood Collection Program (UCBCP).

Sincerely,

Mark G. Yudof
President

Enclosure

cc: The Honorable Ed Hernandez, Senate Health Committee
The Honorable William W. Monning, Assembly Health Committee
The Honorable Mark DeSaulnier, Subcommittee No. 3 on Health and Human Services
Mr. Gregory Schmidt, Secretary of the Senate
Ms. Jody Martin, Joint Legislative Budget Committee
Ms. Tina McGree, Legislative Analyst's Office
Ms. Sara Swan, Department of Finance
Mr. Dotson Wilson, Chief Clerk of the Assembly
Ms. Amy Leach, Office of the Chief Clerk of the Assembly
Ms. Diane Anderson, Legislative Counsel Bureau
Executive Vice President Nathan Brostrom
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Associate Vice President Debora Obley
Associate Vice President Cathryn Nation
Executive Director Jenny Kao

Plan for Establishment of the Umbilical Cord Blood Collection Program (UCBCP)

Submitted to the Health and Fiscal Committees of the California State Legislature
Prepared by the University of California Davis Health System
Submitted by the University of California, Office of the President

July 2011

An investment in UC pays dividends far beyond what can be measured in dollars. An educated, high-achieving citizenry is priceless.

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EXECUTIVE SUMMARY

This document reflects the University of California plan, pursuant to California Health & Safety Code § 1627, to establish and administer the Umbilical Cord Blood Collection Program (UCBCP).

Mission: The mission of the UCBCP is to serve the residents of California through: (1) collection of umbilical cord blood units (CBUs) representative of the state's unique and genetically diverse population, (2) storage of these CBUs in public cord blood banks (CBBs), licensed by the Food and Drug Administration (FDA), that are searchable and accessible to those in need of a transplant, and (3) distribution to qualified research laboratories of CBUs that are not suitable for transplant.

Vision/Aims: The UCBCP will work to expand access to cord blood stem cell therapies for Californians by targeting current inventory deficiencies to increase the likelihood that people of any race or ethnicity can be matched to an appropriate CBU in the National Cord Blood Inventory (NCBI). To do so, the UCBCP will:

- Promote targeted education programs for health professionals
- Promote directed outreach to under-represented people of California
- Utilize best practices for cord blood collections
- Facilitate provision of high quality deliverables for transplantation
- Be funded with revenue from birth certificate fees and other sources
- Promote research and development of effective treatments utilizing cord blood stem cells
- Distribute high quality CBUs not suitable for transplant to qualified researchers
- Develop a Sustainability Fund to enable the program to continue after December 31, 2017
- Develop a collection and education program that will be self-sustaining by January 1, 2018

Strategies: The UCBCP will leverage the intrinsic value of California CBUs to facilitate collection and storage of as many high-quality, genetically diverse CBUs as possible, while promoting clinical translation of novel or improved cord blood-based therapies and leading the program to be financially self-sustaining. By combining several approaches for restricting or recouping costs with effective use of existing resources and infrastructure, the UCBCP will strive to maximize the benefit to California residents and patients throughout the United States, and thereby to achieve the goals of the legislature reflected in the 2010 Umbilical Cord Blood Collection Program (§§ 1627-1630 of the California Health & Safety Code, as amended).

Program Structure: The UCBCP plan has been developed to make the most of public dollars made available under the enabling legislation for the program, Chapter 529 (AB 52, Statutes of 2010), by leveraging the value of California's high birth rate and ethnic diversity and by making effective use of existing resources and infrastructure. The UCBCP will focus its efforts on improving collections rather than on burdensome administrative and banking costs. For personnel, the UCBCP will operate with the fewest possible administrators for complete coverage of duties and compliance with applicable law. Under the current plan, the UCBCP Fund will cover the costs of designated staff at hospitals serving as collection sites and of cord blood maternal blood collection materials. UCBCP funds may be used to support or expand ongoing collections occurring throughout the state and to develop new collection sites. Financial and procedural oversight will be provided by designated UC campus officials.

Growth and Sustainability: To ensure its longevity, the UCBCP intends to extend and leverage the money outlaid for collections by requiring that approximately 75% of costs for banking each qualified unit of cord blood be assumed by CBB(s) contracted by UC to process and store the program's CBUs. The program is also mounting a detailed campaign to reach self-sustainability by: (1) recovering the cost of collected CBUs that are not clinical grade by charging research centers to which they are provided, on a cost-recovery basis; (2) pursuing public and private funding opportunities; (3) developing productive and supportive relationships with philanthropic organizations that could potentially support UCBCP operations; (4) exploring federal sources; and (5) exploring revenue sharing opportunities with other CBB partners when they retrieve UCBCP-collected CBUs for transplant. The UCBCP will create a UCBCP Sustainability Fund from these sources of revenue, to continue the program upon the sunset of the current revenue source ($2 per certified copy of a birth certificate), as of January 1, 2018.

Section 1627 of the California Health & Safety Code reads in part:

> (a) (1) On or before July 1, 2011, the University of California is requested to develop a plan to establish and administer the Umbilical Cord Blood Collection Program for the purpose of collecting units of umbilical cord blood for public use in transplantation and providing nonclinical units for research pertaining to biology and new clinical utilization of stem cells derived from the blood and tissue of the placenta and umbilical cord. The program shall conclude no later than January 1, 2018.

I. MISSION

The mission of the Umbilical Cord Blood Collection Program (UCBCP) is to serve the residents of California, through: (1) collection of umbilical cord blood units (CBUs) representative of the state's unique and genetically diverse population, (2) storage of these CBUs in public cord blood banks, licensed by the Food and Drug Administration (FDA), that are searchable and accessible to those in need of a transplant, and (3) distribution to qualified research laboratories of CBUs that are not suitable for transplant.

This mission stems from the many tragic stories of Californians who have watched a loved one die as a result of deficiencies in the National Cord Blood Inventory (NCBI) and the national registry of bone marrow donors. Umbilical cord blood and bone marrow contain life-saving 'adult' hematopoietic stem cells that are capable of re-establishing healthy blood and immune systems in transplant recipients provided that a closely matched source can be identified. The genetic diversity of California is not well represented in the NCBI, meaning that many Californians are less likely than others to find an appropriate match. The state of California is uniquely suited to reverse this inequity by collecting high quality CBUs that target NCBI deficiencies in CBUs from ethnically diverse births. In fact, harvesting this California resource could offer the world's best chance for improving the probability that all patients in need of a transplant will find a suitable match. In response to AB 52, UC proposes to establish and administer the UCBCP, to begin in summer 2011, and to conclude no later than January 1, 2018, unless further action is taken by the legislature or the UCBCP becomes self-sustaining.

II. VISION/AIMS

The UCBCP will strive to expand access to cord blood stem cell therapies for Californians, by substantially improving probabilities for people of any race or ethnicity to find an appropriately matched CBU in the NCBI. A guiding principle for the UCBCP will be that the program is open to donation from all Californians, regardless of race or ethnicity. The purpose of this program is to collect units of umbilical cord blood for public use, which as defined will be both for clinical use in transplantation and for specified research as permitted by the enabling legislation. To meet the intent of the legislature, the plan consists of the following aims:

II.A. AIM 1: UC will utilize UCBCP funds to develop a state-of-the-art system that promotes targeted education programs for health professionals and directed outreach to under-represented people of California. The defined system will draw on best practices for cord blood collections and facilitate consistently high quality deliverables for transplantation.

II.B. AIM 2: The UCBCP will support and promote the research and development of effective treatments utilizing cord blood stem cells by distributing high quality CBUs that are not suitable for banking to qualified researchers.

II.C. AIM 3: The UCBCP will work to develop a collection and education program with a goal of becoming self-sustaining by January 1, 2018.

II.D. AIM 4: Consistent with the enabling legislation for the program, the UCBCP will also consider how a contingency response program might benefit from the program's activities and resources.

III. STRATEGIES

The UC plan for establishing and administering the UCBCP has been designed to leverage the intrinsic value of California CBUs to facilitate collection and storage of as many high quality, genetically diverse CBUs as possible, while promoting clinical translation of novel or improved cord blood-based therapies and leading the program to become financially self-sustaining. Assuming a $3 million annual budget, an estimated 5,000 high quality, pre-screened CBUs could potentially be offered to CBBs for processing, storage, and potential transplantation. By combining several approaches for restricting or recouping costs with effective use of existing resources and infrastructure, the UCBCP will seek to maximize the benefit to the people of California and patients throughout the United States.

III.A. LEVERAGING OWNERSHIP

To help maximize the number of CBUs collected through the program, UCBCP operations will be limited to collections, such that costs invoiced to the UCBCP Fund will be restricted to those for administration, collection personnel, collection materials, and CBU shipping. The UCBCP will then transfer to partnering CBBs ownership of the CBUs – and, with that, all responsibility for preparing, testing, and banking the units, and furnishing them to health care facilities for transplantation (approximately 75% of the total cost per unit). The distribution of research CBUs that fail to meet the

minimal criteria for banking to research institutions will provide an additional mechanism for the UCBCP to help recoup program costs.

III.A.1 Ownership of banked CBU: Historically, collection costs make up approximately 25% of the approximate $2,000 total cost per clinical grade banked CBU. UCBCP projected costs of $193.00 for each collected CBU fall just below the current average calculated by the National Marrow Donor Program (NMDP) of $212.00. Thus, it is estimated that 2.6 units ($500/$193 = 2.6) will be collected for every 1 unit that will have sufficient cells to be considered "clinical grade" (see Appendix A for calculations of UCBCP projected costs). Qualified banks will be required to fund the remainder (~75%) of the costs for shipping, screening, processing, storing, listing and retrieving the units, in exchange for ownership of the CBUs and the right to seek additional reimbursement as appropriate for CBB services and to make negotiated payments into the UCBCP fund.

III.A.2. Ownership of research CBUs: Research CBUs are a valuable resource for California researchers and for residents who may later benefit from that research. Those CBUs will be distributed to UCBCP registered researchers for a cost-recovery price consistent with the limitations specified in AB 52 (see Appendix B for list of requirements for registration to receive research CBU). The recharge rate will be established through standard institutional procedures (see Appendix A for an initial estimate).

III.B. LEVERAGING DIVERSITY

Many CBBs (currently ten in the US, www.hrsa.gov), contract with the Health Resources and Services Administration (HRSA) to be reimbursed for collection and storage of CBUs that fulfill contract-specific quotas based on race or ethnicity. Addressing deficiencies in the NCBI for under-represented ethnicities is important for increasing usage of CBUs for transplantation, which in turn enhances CBB revenue and sustainability. This fact provides the UCBCP with leverage to request that the CBBs and/or HRSA fund the majority of the costs of banking clinical-grade units.

III.B.1. Targeting Hospitals for Collections: The UCBCP will focus its initial collections efforts on hospitals with high rates of births in NCBI-designated priority populations. The program will use information furnished by the NMDP, the California Department of Public Health, and other organizations and agencies to target appropriate collection sites. Another strategy will be to work with OB/GYN practices that have an ethnically diverse patient population to disseminate information in a targeted fashion. A guiding principle for the UCBCP will be, however, that the program is open to donation from all Californians, regardless of race or ethnicity. To adhere to that principle, the UCBCP will work to inform all Californians of the opportunity to donate cord blood units, and will accept all eligible donations through participating hospitals. Expansion to additional hospitals will be pursued if and as funding permits.

III.C. LEVERAGING EXISTING RESOURCES AND INFRASTRUCTURE

Efficient utilization of existing resources and infrastructure will be required for the UCBCP to become self-sustaining. By focusing on collections, the UCBCP will not be required to establish an

appropriately licensed and certified CBB, but instead can rely on existing public CBBs that meet standards specified in AB 52 to provide these services. Collection centers will be set up within facilities that have the infrastructure to support collection center activities, such as the UC medical centers and other interested hospitals and systems. California is home to hundreds of clinics and hospitals that provide pre- and peri-natal care services to residents, which can also serve as sites for community outreach, health professional education, donor recruitment and/or collections. Additionally, there are several California hospitals where cord blood collections are occurring or set to begin soon that could expand their programs with additional funding. The UCBCP intends to provide funding for personnel and supplies for collections at sites where collections for public banking are underway, and developing sites at targeted hospitals to cover under-represented areas. Care will be taken to avoid duplicating or hindering collections for private or public banking that are ongoing in the state.

IV. PROGRAM STRUCTURE

IV.A. PERSONNEL

The UCBCP intends to function with a small number of highly productive personnel. Directors are responsible for the long-range planning, daily oversight and all logistics regarding the implementation of the UCBCP. The Medical Director position is required by the Foundation for the Accreditation of Cellular Therapy (FACT) standards for a collection center. The plan limits the number of administrative and laboratory personnel, so that the majority of personnel costs will go toward collections, including related outreach. A projected five-year budget is included as Appendix C.

IV.A.1. Directors: Program personnel listed below have decades of combined experience in cord blood collections, translational cord blood stem cell research and selection of clinical-grade stem cells from cord blood. This group was assembled to generate the UC proposal for administration of the UCBCP, and with the exception of the Administrative Directorship, a temporary position which will be eliminated with implementation of the plan, the indicated Directors will continue in their designated positions until further notice. The Medical Director is a licensed FACT inspector of CBBs and is the only position required by FACT for umbilical cord blood collection centers. The Scientific Director is a pioneer in hematopoietic stem cell transplantation research and serves as scientific director for clinical trials involving cord blood products. The Co-Directors bring expertise in neonatal stem cell collections, including cord blood collections, and clinical lab technical and managerial experience with a focus in hematological analyses and good manufacturing practices/FDA compliance. The Administrative Director ran a clinical marrow and cord blood transplantation laboratory for ten years. Biosketches for all Directors are available upon request from UCDHS.

IV.A.1.a. *Medical Director*: Leonor Fernando, MD, MSP. Staff Physician, UC Davis; Director of Apheresis, Department of Pathology and Laboratory Medicine; FACT CBB Inspector.

IV.A.1.b. *Scientific Director*: Jan A. Nolta, PhD, Professor, UC Davis; Director, Institute for Regenerative Cures (IRC); Director, Stem Cell Program, UC Davis; Scientific Director, Good Manufacturing Practices (GMP) Facility, IRC.

IV.A.1.c. *Co-Director*: Suzanne Pontow, PhD, Staff Research Associate V, Supervisor; Faculty Project Scientist V (Pending); Stem Cell Program, IRC, UC Davis.

IV.A.1.d. *Co-Director*: Jon E. Walker, CLS, Quality Assurance/Quality Control (QA/QC) Testing Lab Supervisor, GMP Facility, IRC, UC Davis.

IV.A.1.e. *Administrative Director*: Geralyn Annett, CLS, Stem Cell Program Manager, UC Davis.

IV.A.2. Administrative Positions: Administrative duties within the UCBCP will be restricted to a single (1.0 FTE) Business Manager and a single Contracts Analyst (1.0 FTE). The business manager will be responsible for UCBCP communications, administrative paperwork, budget, coordination of research CBU disbursement, fee collection, maintenance and tracking of the UCBCP Sustainability Funds. The contracts analyst will prepare, submit and track IRB and other hospital documents, material transfer agreements, and legislative, HRSA, and regulatory agency reports. The employee will also maintain training documents for each site and perform additional duties as assigned.

IV.A.3. Quality Control Testing Lab Technician (1.0 FTE): This technician will perform complete blood cell counts on collected CBUs to determine if collected units meet the minimum criteria for banking or are better suited for non-clinical use. This individual will coordinate shipment of bankable units to the CBB, facilitate transfer of high quality non-bankable units to qualified research scientists, keep accurate records, prepare and provide CBU statistics to the Business Manager for the purpose of tracking disposition of units as well as supplying data for monthly, quarterly and annual reports.

IV.A.4. Collection Site Personnel (16 part-time FTE projected): The UCBCP will provide funding for hiring and training UCB collections staff to be placed in up to 8 hospitals throughout the state. Funding could be provided to hospitals to hire collection staff or to offset a portion of the salary for an existing position on a birthing floor to assure time is allocated to collection efforts. Collectors must have at least phlebotomy experience and may require other skills or training depending on local hospital practices. These individuals will also provide coverage of UCBCP administrative duties at the hospital, which includes obtaining informed consent, providing the maternal screening questionnaires and documentation required, coordinating collections, and coordination of CBU transport to the designated collection center.

IV.B. POLICIES

IV.B.1. Regulatory Issues: UC Davis (UCD) as the proposed administrator of the UCBCP will comply with applicable regulatory standards (or, as applicable, require its contractors including CBBs to comply), as further specified below.

IV.B.1.a. *Regulatory Guidance*: In California, a clinical laboratory performing diagnostic laboratory tests must have and maintain a California Clinical Laboratory License or an Out of State License issued by the California Department of Public Health (CDPH) Laboratory Field Services. In addition to the clinical laboratory license, any CBB processing, storing and distributing umbilical cord blood for the purpose of transplantation must maintain a California Biologics License, also issued by the CDPH.

IV.B.1.b. *Compliance*: The UCD Institute for Regenerative Cures Quality Control Testing Lab will maintain both a California Clinical Laboratory License and a California Biologics License. To ensure

that partner CBBs are in compliance with all applicable regulations, standards and laws, UCD will require contracted CBBs to maintain and document ongoing FACT or American Association of Blood Banks (AABB) accreditation as well as all applicable federal and state licenses. In addition to AABB or FACT documentation, UCD will require collection sites to maintain and document Institutional Review Board (IRB) approval of UCBCP activities and facilitate on-site audits by applicable regulatory agencies, CBBs, and other organizations with oversight responsibilities.

IV.B.1.c. *Laboratory Operations*: FACT and AABB both mandate a list of tests to be performed on all CBUs that are suitable for banking, as well as any maternal testing to ensure the safety of the cord blood supply in the national inventory. The CBB is responsible for either performing or facilitating (through the contract laboratory) all mandated screening tests. Documentation that a CBU has been listed in the NMDP database provides assurance that all applicable tests have been performed and found to be negative. Laboratories performing the screening tests must have the appropriate personnel, utilize current approved Standard Operating Procedures (SOPs), and participate in a Proficiency Testing Program. Current documentation of laboratory accreditation through the College of American Pathologists (CAP) and/or appropriate state licensure provides assurance that laboratories are operating under the above guidelines.

IV.B.1.d. *Training and Documentation*: UCD will develop a training program for umbilical cord blood collectors and include any specialized requirements stipulated by partner CBBs and consistent with UCBCP goals. UCD will provide initial training upon activation of a new UCBCP collection site and document the training. Collection site supervisors will conduct ongoing training. As part of collection site training, a proficiency testing program will be developed for collection sites. CBBs and Clinical Laboratories are required to have training and proficiency testing programs. As part of the accreditation process, CBBs are required to provide documentation that collection sites are staffed with trained personnel. UCD will provide documentation of its training activities to partner CBBs for accreditation purposes. In addition, collection sites may be audited as needed to ensure that training and proficiency is adequate to collect and transport high-quality umbilical CBUs. Accreditation by FACT, AABB, CAP and/or a State Biologics License provides assurance that the CBB or Clinical Laboratory has training and proficiency testing programs and that the documentation is current. UCD will require that partner CBBs and Clinical Laboratories maintain current accreditation and licensure and will document these qualifications.

IV.B.1.e *Banking*: UCD will contract only with CBBs that meet the high standards specified by the legislature in AB 52.

IV.C. PLANNING AND PROGRAM DEVELOPMENT

IV.C.1. <u>UCBCP Planning Phase</u>: External oversight and direction has been included throughout the planning phase of the UCBCP through meetings with the leadership of the NMDP, the CDPH, HRSA, BloodSource blood bank, the Joanne Pang Foundation, the Dean's Office of the UCD School of Medicine (UCDSOM) and the UC Office of the President (UCOP). Additional guidance was provided by the AB 52/UCBCP Proposal Advisory Group that was assembled from nominations gathered by the UCDSOM office of Vice Chancellor and Dean and by UCBCP program personnel through communication with UC medical school deans and prominent members of the cord blood banking field, respectively. Advisory group meetings were convened four times during the course of proposal

planning, and interested parties were allowed to present to the group. Meeting rosters and agendas are provided in Appendix D.

IV.C.1.a. *Principles*: As a guiding principle, the UCBCP will strive to meet and exceed public expectations and will pursue excellence by adhering to all federal and state regulations pertaining to the collection, processing and storage of umbilical cord blood. Program operations will be developed in accordance with FACT and AABB standards, as well as applicable regulatory requirements.

IV.C.2. UCBCP Program Development: In support of future program development, UCD intends to convene an expert panel of individuals with knowledge of the use of cord blood for unrelated allogeneic transplantation to help inform and advise the University in regard to program development. A report template is included in Appendix E, and a schedule of regular reporting has been developed and includes the following:

- Monthly Reports: On a monthly basis, program activities will be summarized in table form, and reviewed by the Directors of the UCBCP.
- Quarterly Reports: Every three months, UCD leadership will be sent an accounting and summary of that quarter's activities.
- Annual Report: An annual report will be made publicly available.

IV.C.3. Financial Oversight: Financial oversight of the program will follow usual procedures. To the extent state funds are utilized to support the program, responsible state agencies will assure relevant requirements are met prior to release of funds. Internal oversight bodies will provide additional financial oversight.

IV.D. COLLECTION LOGISTICS

IV.D.1. UCBCP Collection Site Operations at UC Davis: UCD is prepared to serve as a collection center for the Northern Central Valley, and as a facilitator and supporter of ongoing and expanding collections throughout the state. The UCD Collections Center will be located in the licensed Quality Control Testing Laboratory, Institute for Regenerative Cures, UCDHS, and will receive CBUs for screening from fixed collection sites that the UCBCP will oversee in the Sacramento region and surrounding areas. The UCD Collections Center Laboratory has highly trained Good Manufacturing Practices Facility and Quality Assurance/Quality Control staff, and the instrumentation for screening CBUs are already in use for assessing CBUs. Staff trained in cord blood collections and distributions of CBUs for research are available at UC medical centers in northern and southern California. See Appendix C for the UCBCP proposed budget. This budget includes the administrative costs of running the UCBCP, with distribution of funds to other sites for collections staff and UCBCP collection supplies.

IV.D.1.a. *UCD Collections and Administrative Center*: The UCD Collections Center is proposed as the hub for collections starting with four proposed hospitals in the Sacramento region, including UCDHS, Sutter Memorial, Mercy General and Mercy San Juan hospitals. In 2008, these four hospitals had more than 12,000 births, with 34% from ethnically diverse or multi-racial mothers. Collections at two Sacramento Kaiser Foundation Hospitals, with over 2,000 ethnically diverse births out of 5,000, could be valuable partners and inquiries are being made to these facilities.

IV.D.1.b. *Bay Area Collections*: The potential to increase ongoing collections at Children's Hospital of Oakland, through the UCBCP fund will be explored. Providing funding for collections that are scheduled to begin shortly at Stanford University, for banking at MD Anderson (a HRSA-contracted CBB), offer further options to increase total collections without the cost of creating new infrastructure. Additional sites in the San Francisco Bay area are already operating or nearly operative and these sites may receive funding to expand their collections in this region.

IV.D.2. Southern California Collection Site Operations: Other partnering sites are proposed for collections in Southern California, with funding provided through the UCBCP Fund. UCD will oversee planning and implementation of collection sites in Southern California.

IV.D.2.a. *Southern California Permanente Medical Group*: Potential collection sites may be based at Kaiser Foundation hospitals, and administered by Southern California Permanente Medical Group at a unifying collection center. With 13 hospitals in the Los Angeles and surrounding areas, and approximately 33,000 total births last year, this could be a productive partnership for the UCBCP and a rich source of diverse CBUs for the NCBI. A Memorandum of Understanding allowing discussions to proceed between UCD and the Southern California Permanente Medical Group as representatives for Kaiser Foundation Hospitals in Southern California has been signed by both parties. Dr. Robert Cooper, MD, made a presentation to the AB 52 Proposal Advisory Group as a representative. Issues to be negotiated include choice of partnering CBBs that will have an IND or FDA Biologics License in place, approved methods for collections, processing and storage, and types of funding required.

IV.D.2.b. *Southern California UC Medical Centers*: Talks are underway with colleagues for potential collections at UCLA. A CBB, previously in operation at UCLA, provides the infrastructure and personnel expertise to support rapid development of a collection program that already has a mechanism in place for distribution of research CBUs. Also under consideration is funding for ongoing collections at UCI, with a suitable banking partner to be determined by the UCBCP. Additional sites for collections are potentially present at UCSD and elsewhere in Southern California. As the proposed administrative home for the UCBCP, UC Davis will facilitate and pursue these discussions, with funding provided through sub-awards to participating sites (subject to availability of resources and mutual agreement).

IV.E. EDUCATION AND OUTREACH

The issues to be addressed in educating and engaging the public and their healthcare teams are critically important to the longevity and sustainability of the UCBCP. Without the support of the general public and the medical community, the mothers wanting to donate and the patients needing transplants would be left with few options. This is the serious situation that California now faces. Once the UCBCP is operational, ongoing efforts will be made to assure sustainability to meet continuing public needs. An important aspect of educational efforts will be informing the public about the diseases that umbilical cord blood transplantation can potentially treat.

IV.E.1. Targeted Education Programs: To maximize the benefit of education programs that will promote understanding of and best practices in cord blood collections, informational resources will be tailored to specific audiences. UCDHS personnel in several departments have pledged to participate in planning best strategies and practices for education programs and community engagement. Bioethics and Health Disparities divisions are available at UC Davis to assist with outreach to community members who are under-represented in the NCBI. Mothers are often eager donors when well informed, and an immediate impact will be felt in California as information spreads about a widely accessible public banking system for the state. Thus, the medical and birthing communities will need to be well educated and enthusiastic about taking part in this important program.

IV.E.1.a. *For Health Professionals*: OB/GYN practitioners, nurses and midwives will each have different needs for training, and will be approached in a variety of ways to meet those needs. For hospitals, in-service meetings with nurses, residents and/or attending physicians on a monthly basis are a highly productive way to build relationships and to improve the quality of collections. Visibility on the labor and delivery floors of participating hospitals is essential to creating and maintaining a supportive environment for donating mothers and their families. Web-based training is provided and required by some CBBs to ensure that CBB protocols are followed. For the Sacramento area, UCBCP personnel are and will be traveling to potential partner CBBs to learn each bank's procedures and regulations. What is applicable to the UCBCP will be disseminated to all the UCBCP-associated collection sites and centers through training sessions, implementation of best practices, communication opportunities and employee fairs. Additionally, the UCBCP will encourage medical education programs in California to include training in CBU collections and uses.

IV.E.1.b. *For the Public*: Targeted information dissemination will also be a priority for educating and engaging the general public and specified patient populations. Community health-related events provide venues for reaching a broader public base. Information placed in OB/GYN offices, Labor and Delivery floors, hospital information booths, blood banks, clinical labs and clinics statewide will be a primary avenue for reaching more targeted audiences. The Stem Cell Dialogues held quarterly at UCD is another method by which the UCBCP plans to reach out to the Sacramento area residents interested in cord blood banking.

IV.E.2. Recruitment: Donor recruitment will be performed consistent with applicable regulations and IRB requirements. The type of consent secured often is determined by the way a donor was recruited. If a woman is first approached during labor, she can give consent to collect her CBU, but not to bank her CBU, as this important decision should never be made under duress. In this case, a two-step consent may be required, with the consent for banking obtained after the baby is delivered and the mother is rested. If a woman provides consent earlier in her pregnancy, when she has plenty of time to understand the process and her donation, then her consent is simply affirmed at the birthing hospital. Once approval is obtained from the UC Davis IRB of a consent form and process, the approval can be shared among participating UC campuses and other collection sites upon request and review.

IV.E.3. Community Engagement: Fundamental issues that affect the potential longevity of the UCBCP include ways to educate the public and create the trust necessary to reach out to under-represented groups that might feel a distrust of scientific research and its purposes. UCD experts in the Department of Bioethics and Division of Health Disparities are considering the best methods for community engagement projects. Current recommendations for promoting the mission of the UCBCP through community engagement are presented below.

IV.E.3.a. *Building Relationships*: The UCBCP will use the Clinical and Translational Science Research and Education Community Advisory Board to identify community-based people who would be interested in working with UCBCP personnel to learn about the cord blood collections program and developing a community outreach and education plan. Individuals should be well connected to specific communities to be targeted by the outreach and educational activities to be developed by the group. These specific communities would be comprised of audiences most interested in cord blood collections opportunities, (e.g., organizations working with groups of new mothers, many of whom are minorities; service organizations (e.g., Rotary, Kiwanis) that reach a broad audience; ethnic-based organizations such as Hmong Women's Heritage Association; and youth development organizations such as Roberts Family Development Center). Community members of the planning group might also include representatives of organizations with websites, which could serve as dissemination channels for information about the UCBCP and cord blood collections. Once recruited, community members and staff from the UCBCP would engage in the Community Stakeholder Planning Process followed by the UC Davis Center for Reducing Health Disparities in their community needs assessments. Deliverables might include a document detailing a plan for engaging community members and community-based organizations around cord blood collection efforts, videos of parents who made the decision to bank their babies' cord blood, transplant recipients who had received a lifesaving treatment for sickle cell anemia, leukemia, or other devastating diseases, and researchers talking about what diseases might be addressed with cord blood transplants.

IV.E.3.b. *Reaching Out*: There are myriad ways to get the private and public sectors informed, enthused and engaged in the mission to collect cord blood. The UCBCP has already been approached by groups excited at the prospect of a state-based public banking option for their particular constituencies. While the NMDP provides free informational materials to CBBs that are for use by collection centers, additional ways of reaching the public will be considered. For example, professional sports teams could participate through "Cord Blood Awareness Game Days," and corporations that have a customer base of pregnant women, infants and young parents could be targeted to support cord blood collections, statewide or at specific sites. A Stroll-a-thon sponsored by each participating hospital that has a fixed-site program in place would be a way to advertise the UCBCP. Identifying celebrity spokespersons for the UCBCP should also be a priority, especially those with links to cord blood banking, such as a transplant recipient, or someone who has banked their baby's CBU. The leadership of the Joanne Pang Foundation has offered to work with the UCBCP leadership to develop these exciting public outreach efforts. Any of these efforts will need to target geographical areas where the collections are actually occurring.

IV.E.4. Reports: Deliverables from any plan for education and outreach strategies should include an evaluation of the project and suggestions about how to improve or expand operations. Reports by participating entities will be requested annually.

IV.F FUNDING

IV.F.1. UCBCP Fund: The state has set up the UCBCP Fund (Fund 1017) for UC to invoice expenses for reimbursement. Access to this Special Fund money is restricted to the State Controller's Office. The responsible state agency will give approval for the release of funds from the Office of the Controller to the UCBCP. The Office of the Controller will work in conjunction with UCOP officials, who will request funds and allocate them to the UCBCP.

IV.F.1.a. *UCBCP Fund Assets*: The CDPH Office of Vital Records collects fees ($2/certified copy of birth certificate). The increased fees for a certified copy of a birth certificate have been collected and deposited into this Fund since December 2010. In the current Governor's Budget for UC (under the Fund Condition Statement section), the Legislature has authorized a budget for UC for this program in the amount of $4.618 M ($1.931M in 2010-2011, and $2.688M in 2011-2012), and will continue to adjust that budget based on the actual revenue collected. After this proposal is submitted and approved, the UCBCP will be given an annual budget figure authorization level, and will submit claims consistent with that assigned annual budget to the State Controller's Office, drawing down funds on a reimbursement basis from the UCBCP Fund. The overall cord blood collection budget for any given year, defined as the annual amount the state collects and deposits into the UCBCP Fund, will be estimated by the state as the annual budget is finalized, and that figure will be adjusted throughout the year based on actual revenue from the birth certificate fees. That money will be authorized annually to UC under Special Funds by the Legislature in the Governor's Budget. In turn, UC's Office of the President will then annually assign a budget authorization figure to the UCBCP. UC will contact the Department of Finance to coordinate any actions needed regarding the funding.

IV.F.1.b. *UCBCP Fund Debits (Budget)*: A projected budget has been developed by UCBCP personnel and is included in Appendix C. Expenditures include personnel for administration and collections, courier and shipping contracts, small allowances for travel for personnel training, IRB submissions and outreach/public education, and supplies for CBU and maternal blood collections. Implementation can be scaled up or down in future years depending on available UCBCP funds.

IV.F.2. Sustainability Fund for Research CBU: Collections for research are already ongoing at UC Davis and UCLA, with distribution to the most highly qualified cord blood stem cell researchers now occurring. This is another important mission of the UCBCP. For distribution of research cords, centralized inventory software will be used to track intake, screening, requests for and distribution of CBUs. Additional information on each CBU will be maintained securely with certain de-identified data utilized for reports to designated UC officials and other applicable organizations and regulatory agencies. UC rate committees are available to determine the fair price of cost recovery for staff time and supplies (Appendix A). The cost recovery funds recouped from the distribution of research cords will be deposited to the UCBCP sustainability account at UC Davis. The sustainability account will be accrued to permit ongoing collections and other programmatic purposes after the UCBCP program fee accruals end in 2018 (see section V on sustainability).

IV.F.2.a. *Principles and Standards*: The cost to researchers will be the same for higher and lower quality CBUs because the actual costs for collections do not vary, which is a reality faced by all cord blood investigators. Open communications between researchers and the UCBCP Collections Center supplying those investigators will facilitate determinations of CBU quality, and some flexibility will be built into the distribution network to allow replacement of very low TNC CBU that may be distributed. Distribution will only be allowed to qualified investigators as further described in Appendix B.

IV.F.2.b. *Recharges*: See Appendix A for projected calculation, as identified by the UCD Rates Committee schedule, of reimbursement value of the cords for cost recovery. Assuming a 50% consent rate with 50% of collected CBU eligible for banking, approximately 5,000 CBUs per year could be available to California researchers for material transfer at approximately $200/CBU. Therefore, $1M could be deposited into the UCBCP Sustainability Fund from the research CBU recharges, per year. Thus, research CBUs have high value for Californians, contributing to the sustainability of the UCBCP and providing a rich source of cells for translational research to improve cord blood transplantation methods and disease applicability.

IV.F.3. Sustainability Fund/HRSA Reimbursement: The UCBCP proposes to recoup collection costs of HRSA-reimbursed CBUs from CBBs when they are reimbursed by HRSA. The UCBCP has assurance from Robert Baitty, Director, Blood Stem Cell Transplantation Program, Division of Transplantation, HRSA that this strategy is allowable and should be a component of any contract with a HRSA-contracted CBB. HRSA-reimbursement funds shall be deposited into the UCBCP Sustainability Fund.

IV.F.4. Sustainability Fund/Fees charged to CBBs: The processing, screening, storing and retrieving of CBUs for transplantation is expensive and represents for CBBs an investment that is realized only if the unit is selected for clinical use. The price that a CBB can charge for a CBU is set through negotiation with NMDP, and is generally within a range between $20,000 and $35,000/unit. The UCBCP recognizes the expense of running a quality public CBB and will work to promote their efforts. In an effort to become self-sustaining and to continue providing high quality and genetically diverse CBUs to the NCBI beyond January 1, 2018, a negotiated fee will be charged to CBBs for units selected for transplantation.

IV.G CONTRACTS AND PARTNERSHIPS

UC will partner with existing California collection sites and American CBBs that have an IND or FDA Biologics License, provided that certain qualifications are met as specified in the law. UC will seek additional guidance from AABB, FACT and FDA standards and recommendations when selecting partners for cord blood services. For collections, priority contracts will be negotiated with hospitals that have high birth rates, serve patients of under-represented ethnicities and that are not currently performing cord blood collections.

IV.G.1. Hospital fixed-sites and collections centers: During the first year of operations, several agreements will have to be negotiated between UC and the sites chosen for initial collections. In addition, partnering CBBs will need to have agreements in place with each hospital where collections for that CBB might take place. All negotiations will be handled through the Contracts Office of UCDHS.

IV.G.1.a. *Selection of collection sites*: To expedite contract negotiations and signings, selection of potential sites will be highly focused. Priority will be given to hospitals with high birth rates and an ethnically diverse patient population. Also taken into consideration will be whether the hospital leadership is interested in participating in the UCBCP and whether the infrastructure exists to support collection of high quality CBUs. HRSA and the contract quotas that HRSA has established with CBBs will determine racial and ethnic collections targets. Although CBUs originating in California are not required to be HRSA-reimbursed, there are several reasons why HRSA-reimbursed status is preferred. First, CBBs want to fulfill their contracts with HRSA, which allow for reimbursement only if the race/ethnicity of the donor is named in the contract and the quota has not been met. Second, the UCBCP will require reimbursement for costs of collection from CBBs that receive HRSA reimbursement for a California-derived CBU. Finally, HRSA reimbursed CBUs are being retrieved faster for transplantation than non-HRSA CBUs (HRSA 2012 Budget Report, www.hrsa.gov).

IV.H. PRIVACY AND INFORMATION SECURITY

The UC system complies with the California Information Practices Act and other laws, regulations, and institutional policies protecting the privacy of patients and other individuals served through UC programs. The UCBCP will, prior to program implementation, develop any additional policies that may be needed to comply with the confidentiality provisions of the enabling legislation.

V. UCBCP GROWTH AND SUSTAINABILITY

The expansion of collections and public banking in California are important to the missions of HRSA, the NMDP, and the NCBI, and are life-saving for Californians, which should make the UCBCP an invaluable public resource. To promote its longevity, the UCBCP is extending and leveraging the money outlaid for collections by requiring that approximately 75% of costs required for banking each qualified unit of cord blood to be shouldered by the CBBs. Cost recovery for research CBUs is a second mechanism for sustainability, and reimbursement of a portion of the costs for transplanted units as permitted by law is a third. In addition, the program will strive toward self-sustainability, pursuing public and private funding opportunities as appropriate, and developing productive and supportive relationships with philanthropic organizations and philanthropists that could potentially support UCBCP operations through establishment of critical endowments. In addition, the UCBCP will explore a variety of strategies for reimbursement of collection costs, from federal and banking sources. To interest hospitals in participating, the UCBCP would offset costs incurred by sharing outreach and collections materials, funding and training for Labor and Delivery personnel, and CBU for research. It is the success of the UCBCP that will ultimately determine its ability to thrive and become self-sustaining.

V.A. UCBCP SUSTAINABILITY FUND

The UCBCP will, consistent with the enabling legislation, accept private and public monies from a variety of sources including recharge funds from the distribution of research-grade CBUs and any fees charged to CBBs for the purpose of administering the program. The University of California Davis plans to develop a UCBCP Sustainability Fund to keep the program viable beyond January 1, 2018. Funds expended prior to 2018 will be derived from the UCBCP Fund and the special fee on certified copies of California birth certificates being collected by the Office of Vital Records, and under the administration of the Office of the Controller. The UCBCP must agree to set up a Sustainability Fund

with any realized revenues stemming from the UCBCP collections and banking to be used for cord blood collection purposes and program sustainability only.

V.B. UCBCP EXPANSION

It is the intent of the UCBCP that all Californians have the opportunity to donate their babies cord blood and to participate in the life-saving technologies that these donations support, whether through patient transplantation or research. As the UCBCP develops, revenues are realized for sustainability, and public support for the project is gauged, the ability of the UCBCP to expand will be explored. One potential mechanism to cover less populated areas, especially those in outlying areas with pockets of unique ethnicities, is the 'kit collection' model, which is currently under pilot study by HRSA. In this scenario, mothers receive information during their pregnancy, and if wishing to donate, the mothers call for information, provide consent and receive a collection kit that is brought to the hospital for the birth. With this model the UCBCP becomes a facilitator, with all agreements occurring between the mother and the CBB that will receive the shipped unit after the OB/GYN or midwife collects it. It is hoped that as the program expands, hospitals will also become more interested in participating and assist with subsidizing collections for banking and research.

Any amendments to this plan made in connection with its implementation and operation will be consistent with the requirements of AB 52 and other applicable law.

Contact information:
UCOP Budget and Capital Resources
1111 Franklin Street, 6th Flr.
Oakland, CA 94607-5220
Office website: http://budget.ucop.edu
Report website: http://budget.ucop.edu/legreports/

Appendix A

Appendix A

Rate Calculation per Units Produced

Note: shaded cells and rows are either fixed or calculated.

Rate Name (enter in cell C4):

Research Cord Blood

POSITION TITLE:	CLS	Assoc ProjSc	Collect/Consent	TOTAL
BILLABLE HOURS CALCULATION on full-time annual basis				
Hours in year (always 261 days = 2,088 hours)	**2,088**	**2,088**	**2,088**	
Subtract hours not at work: (use actual data if available)				
Vacation (example: 15 days = 120 hrs)	120	120	0	
Sick Leave (example: 12 days = 96 hrs)			0	
Holidays (13 days = 104 hrs)	104	104	0	
Hours at work (= row 8 minus rows 10 thru 12)	1,864	1,864	2,088	
Subtract hours at work but not billable:				
Prep, consults, meetings, breaks, admin	900	900	0	
Training & Conferences	40	40	0	
Billable hours on full-time annual basis (= row 13 minus rows 15+16)	**924**	**924**	**2,088**	
For information only: billable hours as % of hours in year (= row 17/row 8)	44%	44%	100%	
For information only: billable hours as % of hours at work (= row 17/row 13)	50%	50%	100%	
PERSONNEL-RELATED EXPENSES on full-time annual basis				
Benefits rate (use actual data when available - PPS 92)	40.2%	30.0%	30.0%	
Full-time annual average salary (including Oct 1 adjustment)	$ 104,410	$ 98,000	$ 90,000	
Full-time annual benefits (including Oct 1 adjustment) (= row 22 * row 23)	$ 41,973	$ 29,400	$ 27,000	
Full-time Supplies & Expense associated with positions	$ -	$ -	$ -	
Total personnel-related expenses on full-time annual basis (= sum rows 23 thru 25)	$ 146,383	$ 127,400	$ 117,000	
Personnel-related expenses per hours in year on full time annual basis (= row 26/row 8)	$ 70.11	$ 61.02	$ 56.03	
Personnel-related expenses per billable hour (= row 26/row 17)	**$ 158.42**	**$ 137.88**	**$ 56.03**	
PROJECTED NUMBER OF UNITS THAT WILL BE SOLD & CALCULATED FTE				
Calculated FTE dedicated to rate (hours on rate/billable hours) (= row 34/row 17)	0.01	0.01	0.05	0.07
Number of units that will be sold (projection)				1000.00
Number of hours worked on each unit	143.00	0.00	0.00	
Number of hours worked on this rate (= row 34 * row 32, column H)	10	-	-	
EXPENSES CALCULATION adjusted for FTE				
SB0% Academic Salaries (= row 23 * row 31)	$ 1,044.10			$ 1,044
SUBS Staff Salaries (= row 23 * row 31)		$ 980.00		$ 980
SUBG General Assistance (= row 23 * row 31)			$ 4,500	$ 4,500
SUBG General Assistance (overtime or stipend expense)			$ -	$ -
SUB6 Benefits (= row 24 * row 31)	$ 420	$ 294	$ 1,350	$ 2,064
SUB3 Supplies & Expense associated with positions (= row 25 * row 31)	$ -	$ -	$ -	$ -
SUB3 Supplies & Expense (enter $ per unit in column D)	$ 185.00			$ 185,000
SB74 Improvements Reserve (enter $ per unit in column D)	$ -			$ -
SB75 Depreciation (enter $ per unit in column D)	$ -			$ -
Other - Not Listed Above (specify)				$ -
Total Expenses (= sum rows 37 thru 46)				$ 193,588
Deficit Reduction (+) / Surplus Return (-) or Subsidy (-)				$ -
TOTAL $ (= row 47 + row 48)				$ 193,588
Material Pass-Through costs not in rate calculation				$ -

RATE & REVENUE CALCULATIONS		
Recharge rate calculations (SUB9):		
Recharge rate (calculated) (Total $ / # of units) (= row 49/row 32)	$	193.59
Recharge rate (= row 54 rounded)	$	194.00
Units sold to recharge clients (projection)		600
SUB9 -- TOTAL RECHARGE REVENUE (= row 56 * row 55)	$	116,400.00
Non-University client calculations (INC0):		
Recharge rate (= row 55)	$	194.00
NUD @ 28.5% for 2009/2010 and 2010/2011 (= row 59 * 28.5%)	$	55.29
Charge (w/o mark-up) to non-university client (= rows 59 thru 60 rounded)	$	250.00
Mark-up (object code 006M) (enter a dollar amount)	$	-
Total charge to non-university client (=row 61+ row 62 rounded)	$	250.00
0066 NUD assessment transferred out (= row 60 * -1)	$	(55.29)
0076 NUD assessment returned to department (= 14.5% * row 59)	$	28.13
Income for the department per unit (= sum rows 63 thru 65)	$	222.84
Units sold to non-university clients (= row 32 **TOTAL** minus row 56) (projection)		400
INC0 -- TOTAL INCOME (= row 66 * row 67)	$	89,136
Revenue from Pass-Through costs (not included in rate calculation) = row 50	$	-
TOTAL REVENUE = SUB9 & INC0 & Pass-through Rev (= row 57 + row 68 + row 69)	$	205,536
Balance = Total Rev minus Total Exp minus pass-through costs (= row 70 - row 47-row 50)	$	11,948

OTHER INFORMATION:

ORMP, Doc III: Spreadsheets, Rev. September 2009

Appendix B

Appendix B

Research Requirements to Receive Umbilical Cord Blood Under CA HSC 1627-1630

The California Health and Safety Code Section 1627 list the requirements for researchers to receive Umbilical Cord Blood Units that do not meet the criteria for banking.

HSC 1627 (b) (2) (C): In order to qualify to receive appropriate cord blood units and placental tissue to advance the research goals of this program, an entity shall, at a minimum, be a laboratory recognized as having performed peer-reviewed research on stem and progenitor cells, including those derived from placental or umbilical cord blood and postnatal tissue.

HSC 1627 (b) (3): A medical provider or research facility shall comply with, and shall be subject to, existing penalties for violations of all applicable state and federal laws with respect to the protection of any medical information, as defined in subdivision (g) of Section 56.05 of the Civil Code, and any personally identifiable information contained in the umbilical cord blood inventory.

In order to ensure that researchers meet the above criteria, UCD will require anyone requesting research cords to submit the following documentation:

1. Curriculum Vitae (CV) or NIH-style bio-sketch for the principle investigator and any collaborators.

2. A summary of the proposed research planned with the cord blood.

3. Documentation of Institutional Review Board approval for Cord Blood Research.

4. A signed attestation of compliance with CA Code HSC 1627.

5. A release of liability for the University of California.

Appendix C

Appendix C

Umbilical Cord Blood Collection Program (UCBCP)

Projected Five Year Budget, Last Revised June 2011

**The University intends to operate the program within available revenue sources, and will annually reassess their budget projections, and scale the program implementation to utilize actual fee revenue realized.*

	Year 1 2011-12	**Year 2** 2012-13	**Year 3** 2013-14	**Year 4** 2014-15	**Year 5** 2015-16
Personnel (Salary & Fringe Benefits)	1,265,126	1,300,536	1,310,112	1,313,659	1,313,659
Outreach	20,000	20,000	20,000	20,000	20,000
Equipment	111,000	0	0	0	0
Collection Supplies	471,000	721,000	721,000	721,000	721,000
Travel	45,000	45,000	45,000	45,000	45,000
Other Expenses (IRB Costs & Shipping)	511,400	491,400	491,400	491,400	491,400
Additional Program Sites (TBD)	2,186,000	422,064	412,488	408,941	408,941
TOTAL Projected Annual Program Costs	**4,609,526**	**3,000,000**	**3,000,000**	**3,000,000**	**3,000,000**
TOTAL Anticipated Annual State Special Appropriation^	$4.61 M~	$3 M	$3 M	$3 M	$3 M

^ The Legislature will annually authorize an appropriation to UC through the normal state budget process. State special funds will expire in 3 years beginning at the year of allocation. The University will submit claims to the State Controller's Office for actual program expenditures, drawing down funds on a reimbursement basis from the UCBCP Fund.

~ Year 1 funding combines anticipated birth certificate fee revenue in 2010-11 and 2011-12. CA Department of Finance projects $1.931M in 2010-11, and $2.688M in 2011-12).

Total Projected Program Costs - All 5 Years*	$16,609,526
Total Anticipated State Special Revenue - All 5 Years**	$16,610,000

** CDPH Office of Vital Records is currently collecting a $2 fee from each certified birth certificate issued for deposit in the UCBCP Fund. $16.6M over 5 years is an estimate only. Actual revenue available to UCBCP will depend on the number of certified birth certificates issued.

Appendix D

AB52 Proposal Advisory Group

Members

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UCDAVIS STEM CELL PROGRAM

Meeting Agenda

AB52 Proposal Advisory Group

Monday, April 25, 2011

Education Building - 4610 X Street, Sacramento
Conference Room 3227

3:30 PM | **3:40 AM**	Welcome, Introductions and Agenda Overview Jan Nolta, PhD Director, Stem Cell Program and IRC Institute for Regenerative Cures
3:40 PM | **3:50 PM**	AB52 Overview and Proposal Requirements Suzanne Pontow, PhD SRA V, Supervisor Stem Cell Program
3:50 PM | **4:00 PM**	Available Models for Umbilical Cord Blood Collections and Banking Suzanne Pontow, PhD SRA V, Supervisor Stem Cell Program
4:00 PM | **4:10 PM**	Regulatory Bodies, Recommendations and Standards Jon Walker, CLS GMP QC Testing Lab Supervisor Stem Cell Program
4:10 PM | **4:15 PM**	Required Oversight Committees and Nominations Jon Walker, CLS GMP QC Testing Lab Supervisor Stem Cell Program
4:15 PM | **4:25 PM**	Budget and Umbilical Cord Blood Collection Program Fund Geralyn Annett Program Manager, Stem Cell Program Institute for Regenerative Cures
4:25 PM | **4:35 PM**	Program Future, Expansion and Sustainability Suzanne Pontow, PhD SRA V, Supervisor Stem Cell Program
4:35 PM | **4:50 PM**	OpenDiscussion
4:50 PM | **5:00 PM**	Presentation from StemCyte, Covina, CA Calvin Cole President StemCyte

UCDAVIS HEALTH SYSTEM

UCDAVIS HEALTH SYSTEM

Agenda

AB52 Proposal Advisory Group Meeting

May 11, 2011 9:00-11:00am

Location: **Institute for Regenerative Cures Conf Rm 2A**

Conf Call-in: **(218) 895-4640 Passcode 1671810**

Webinar: **http://www.anymeeting.com/UCDHS1**

Greetings: Meeting will follow the outline of the proposal

I. Missions Statement

II. Vision Aims

III. Strategy

IV. Program Structure

V. Privacy and other information security issues

VI. Contracts

VII. Administration of the Umbilical Cord Collection Fund (Budget)

VII. Alternative and additional funding mechanisms to support self-sufficiency of the program

IX. Comprehensive education and community outreach proposals

Further Discussion

UCDAVIS HEALTH SYSTEM

Agenda

AB52 Proposal Advisory Group Meeting

May 18, 2011 2:30 – 4:30pm

Location: **Institute for Regenerative Cures Conf Rm 2A**

Conf Call-in: **(218) 895-4640 Passcode 1671810**

Webinar: **http://www.anymeeting.com/ucdhs1**

Greetings: Meeting will follow the outline of the proposal

I. Family Cord Blood Services - Alyssa Ziman

2. Conference call in from Bob Cooper re: Collections at Kaiser Hospitals in Southern California

3. Continue discussion

UCDAVIS HEALTH SYSTEM

Agenda

AB52 Proposal Advisory Group Meeting

June 6, 2011 11:30am – 1:30pm

Location: **Institute for Regenerative Cures, Conf Rm 2B**

Conf Call-in: **(218) 895-4640 Passcode 1671810**

Discussion of Draft Proposal

Appendix E

CBU Tracking Report - DRAFT

	No. Info Given	No. Objecting	No. Consenting	No. Consented Deliveries	No. Collections	No. Sent	No. Banking Ineligible	No. Banked	No. Banking for Research	No. Distributed for Research	No. Distributed for Transplant	No Cost Recoveries
Chinese	2	0	2	2	2	2	0	2	0	0	2	2
Hmong	3	0	3	3	3	3	0	3	0	0	3	3
Japanese	2	0	2	2	1	1	0	1	0	0	1	1
Korean	2	0	2	2	2	2	0	2	0	0	2	2
Pacific Islander	1	0	1	1	1	1	0	0	0	0	0	0
Vietnamese	5	0	5	5	5	5	0	4	1	1	2	1
Total for Asian	**15**	**0**	**15**	**15**	**14**	**14**	**0**	**12**	**1**	**1**	**10**	**9**
African American	6	1	5	5	2	2	0	2	0	0	2	2
Caucasian	2	0	2	2	2	2	1	1	0	0	1	1
Hispanic (non-white)	4	0	4	4	4	4	0	2	1	1	2	1
Mixed Race	1	0	1	1	1	1	1	0	0	0	0	0
Unknown	4	1	3	3	3	3	0	3	0	0	3	3
Total for Other than Asian	**17**	**2**	**15**	**15**	**12**	**12**	**2**	**8**	**1**	**1**	**8**	**7**
Grand Total	32 No. Info Given	2 No. Objecting	30 No. Consenting	30 No. Consented Deliveries	26 No. Collections	26 No. Sent	2 No. Banking Ineligible	20 No. Banked	2 No. Banking for Research	2 No. Distributed for Research	18 No. Distributed for Transplant	16 No. Cost Recoveries

Reasons CBU Ineligible for Banking

9/1/2011 Shipment breach	Mixed Race
9/1/2011 Quota filled	Caucasian

CBU Tracking *DRAFT*

Mother Information Entry Form

Enter New Mother

Mother: Jennifer ID: 1

Consenter: Jane Doe

Demographic: Hmong

DOB: 3/12/1980

City of Birth: Modesto

MotherID: 1

CollectorID: John Duffy

Date Entered: 4/28/2012

Enter New Donation Opportunity from this Mother

For time fields, use 24hr clock. e.g., write 2:00pm as "14:00".

4/23/2011 Date educated mother CBU ID: 1 Date Entered: 5/27/2011 4:51:50 PM

4/23/2011 Date Consented/Objected Collector: Jane Doe

Pre-Natal Eligible? Eligible to Collect

Consented/Objected? Consented

Enter Reason for Ineligibility

Enter Objections

Details of Cord Blood Unit

Collection Site: 2531 Stockton Bldv - Obstetri City of Collection: Sacramento

5/1/2011 Date of Birth Collection

21:45 Time of Birth Collection

Eligible at Birth ?

Eligible to Send

Enter Reason for Not Collecting

5/2/2011 Date Sent to CBB ABC Cord Blood Banking - UT Cord Blood Bank

5:00 Time Sent to CBB FexEx SentVia

To be filled out by CCB

5/3/2011 Date Received at CBB

11:00 Time Received at CBB

Eligible to Bank?

Eligible to Bank

Enter Reason for Not Banking

5/3/2011 Date Banked

13:30 Time Banked

2032 BankUnitID No

6/23/2011 Date Distributed:

13:45 Time Distributed:

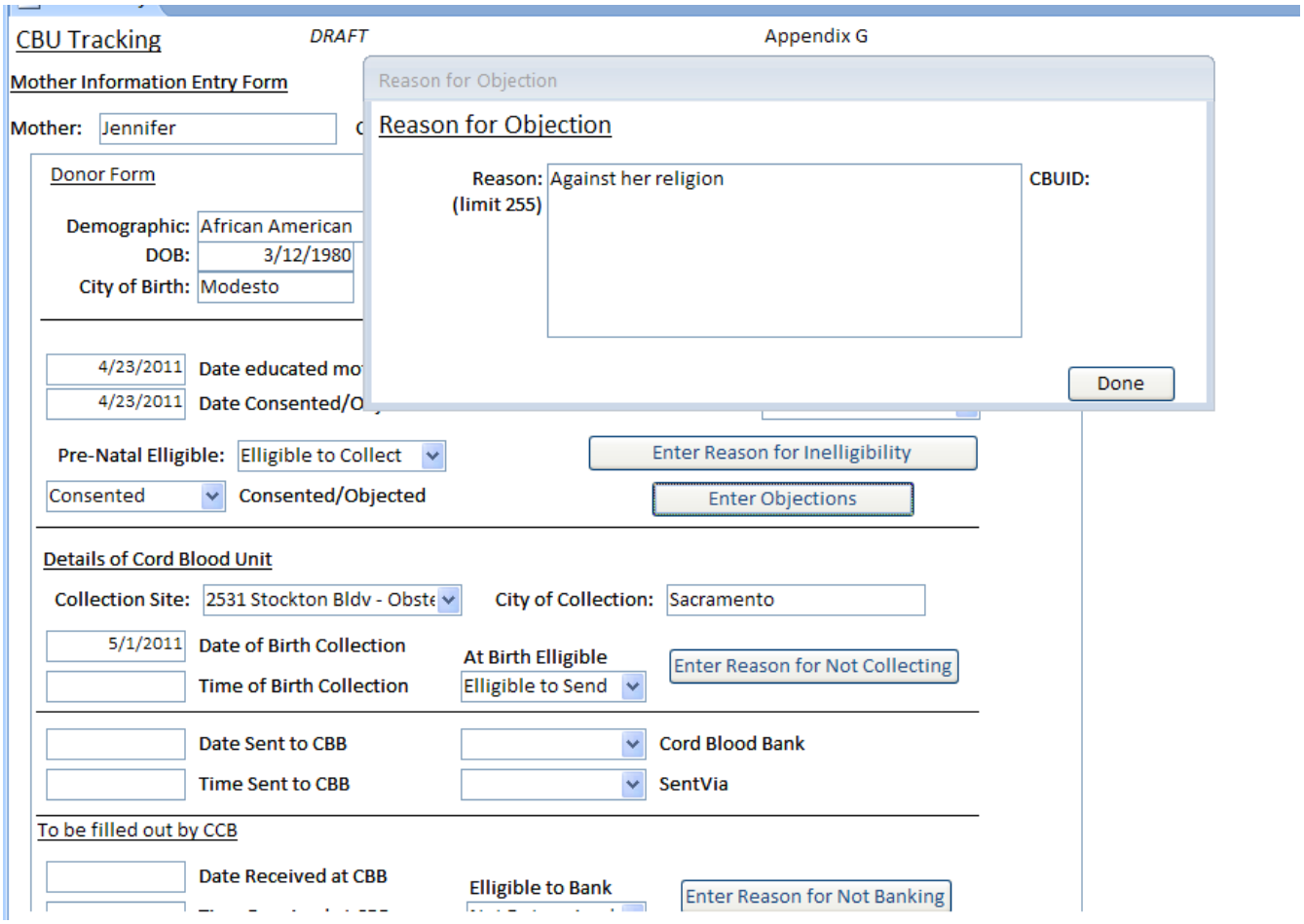
For Research or Transplant?

For Transplant

Enter Transplant Outcome

☑ Check here if there was cost recovery.

Example of Reasons tracking pop up form:



Example of Transplant Outcome tracking form: