

BETA CELL BIOLOGY CONSORTIUM  
**POLICIES AND GUIDELINES**



April 27, 2011 – Version 4

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## A. DEFINITIONS

1. BCBC. The Beta Cell Biology Consortium.
2. BCBC CC. The BCBC Coordinating Center.
3. BCBC Affiliate. A non-investigator member of the BCBC who is directly employed by a BCBC Investigator. Affiliates can be research professors, postdoctoral fellows, graduate students, research assistants and other essential support staff. They may not be independently funded Principal Investigators.
4. BCBC Co-Investigator. An independently-funded investigator who (i) receives funding from a multi-investigator U01 grant awarded in response to [RFA-DK-09-011](#) but is not contributing at least 10% of his/her research effort to his/her BCBC project(s), or is not leading a project of major significance to the mission of the consortium, or (ii) receives funding from a BCBC special funding program.
5. BCBC Investigator. This is a designation that is conferred by NIDDK Program Staff and that carries special privileges within the BCBC. (i) BCBC Investigator status may be granted to an independently-funded investigator who receives funding from a BCBC grant awarded in response to [RFA-DK-09-011](#) or from a Seeding Collaborative Research in Beta Cell Biology (SCRBCB) award. BCBC Investigators must be leading a project of major significance to the consortium's mission and contribute at least 10% of his/her research effort to his/her BCBC project(s). On multiple-investigator awards, the principal investigator (PI) as well as project leaders (PLs) who meet the 10% effort requirement may qualify for BCBC investigator status. (ii) In rare occasions BCBC investigator status may be granted by NIDDK Program Staff to a Co-investigator whose expertise and/or contribution to the overall mission of the BCBC is seen as particularly significant.
6. Sponsoring Institution. The institution with which a BCBC Investigator, External Speaker or Consultant is affiliated.
7. BCBC Member. A BCBC Investigator, BCBC Co-Investigator or BCBC Affiliate.
8. NIDDK. The National Institute of Diabetes and Digestive and Kidney Diseases.

9. BCBC Resource. A chemical, antibody, genetically modified mouse, cell line, technology, method or dataset that is generated using funding obtain directly from the NIDDK, or indirectly through the BCBC Coordinating Center.

The following matrix provides a summary of what access is granted to the above roles, or definitions:

Role	Web access to private resources?	Signed Policies and Guidelines?	Responsible party?	Attend Fall Planning Meeting?	Attend Spring Retreat?	Steering Committee Member?	Can have affiliates?
BCBC Investigator	Yes	Yes	n/a	Yes	Yes	Yes <sup>1</sup>	Yes
BCBC Co-Investigator	Yes	Yes	n/a	No	Yes	No	Yes
BCBC Affiliate	Yes	No	BCBC (Co-) Investigator	No	Yes <sup>2</sup>	No	No
BCBC CC	Yes	n/a	n/a	Yes	Yes	No	No
NIDDK	Yes	n/a	n/a	Yes	Yes	Yes	No

1. Only U01 Principal Investigators (one for each U01).
2. The number of affiliates that a BCBC Investigator or Co-Investigator can bring to the retreat will be defined on a per-year basis.
3. n/a – not applicable

## B. OVERVIEW

### *Mission and Objectives*

The mission of the Beta Cell Biology Consortium (BCBC) is to facilitate interdisciplinary approaches that will advance our understanding of pancreatic islet development and function with the long-term goal of developing a cell-based therapy for insulin delivery.

The scientific goals for the third cycle of the BCBC, beginning August 1, 2010, are to 1) use cues from pancreatic development to directly differentiate pancreatic beta cells and islets from stem/progenitor cells for use in cell-replacement therapies for diabetes; 2) determine how to stimulate beta cell regeneration in the adult pancreas as a basis for improving beta cell mass in diabetic patients; 3) determine how to reprogram progenitor/adult cells into pancreatic beta-cells both in-vitro and in-vivo as a mean for developing cell-replacement therapies for diabetes; and 4) investigate the progression of human type-1 diabetes using patient-derived cells and tissues transplanted in humanized mouse models.

### *Introduction*

The Beta Cell Biology Consortium (BCBC) is a team science initiative and science consortium of cooperative agreements that was established by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in 2001 ([RFA-DK-01-014](#)), and competitively continued in 2004 ([RFA-DK-04-17](#), [RFA-DK-04-18](#)). During the second funding cycle, which ends on July 31, 2010, the BCBC consisted of over 50 scientists, the majority of whom participated as either Principal or Co-Principal Investigators on eight U-01 and two U-19 projects. In addition, scientists from two intramural NIDDK laboratories were involved.

Activities within the BCBC are overseen by both NIDDK staff members and participating scientists. A Steering Committee, which consists of all BCBC Investigators, meets on a semi-annual basis. An Executive Committee (EC) meets monthly by teleconference. An External Evaluation Committee (EEC) serves to provide objective scientific input and guidance. A Coordinating Center located at Vanderbilt University provides the organizational infrastructure for the BCBC.

As initially described in [RFA-DK-01-014](#) and restated in [RFA-DK-09-011](#), the BCBC is charged with bringing a team-based approach to the generation of new research tools, reagents, and technologies vital for developing new cellular therapies in diabetes. As a collaborative effort, the BCBC requires frequent interactions of awardees among each other and with the NIH. In their applications to participate, all BCBC Investigators were required to explicitly indicate their willingness to 1) participate in Steering Committee Meetings (two times per year) and regular telephone conference calls, 2) cooperate with other awardees in the development and design of research priorities, especially regarding resources, and 3) agree to the "Cooperative Agreement Terms and Conditions of Award" in [Section VI.2.A of RFA-DK-09-011](#). BCBC Co-Investigators are required to 1) cooperate with other awardees in the development and design of research priorities, especially regarding resources and 2) agree to the "Cooperative Agreement Terms and Conditions of Award" in [Section VI.2.A of RFA-DK-09-011](#).

The timely and unencumbered sharing of BCBC Resources and related information, both with BCBC Investigators and non-BCBC investigators, has contributed to the prior success of the consortium. Within the consortium a deep sense of trust was slowly established that has enabled meaningful collaborations and sharing to occur. To maintain these values more clearly defined policies and guidelines, and clarification of the penalties for noncompliance, are necessary to avoid confusion among an altered group of participating BCBC Investigators, BCBC Co-Investigators, and their Affiliates.

Thus, this document has been developed for this newest cycle of the BCBC beginning on August 1, 2010. As a condition of participation in the BCBC, as evidenced by their signatures at the bottom of this document, all BCBC Investigators (and future special funding program investigators) and their sponsoring Institutions acknowledge and agree that they have read and understood, and formally agree to adhere to these policies, guidelines and principles. Likewise, all BCBC Co-Investigators (U01 and other non-SCRBCB subcontract awards) acknowledge and agree that they have read and understood, and formally agree to adhere to these policies, guidelines and principles. It is understood that this document is a Statement of the BCBC's Policies and Guidelines effective as of August 1, 2010, regarding the conduct of all BCBC Investigators, Co-investigators and Affiliates; however, these Policies and Guidelines may be revised from time-to-time with such revisions being available at <http://www.betacell.org/about/policies/>.

### **C. THE BCBC WEBSITE AND ITS USAGE**

A website (<http://www.betacell.org/>) that supports the operations of the BCBC has been built and is continuing to be enhanced. The website provides an easy way for BCBC Members to both gain new knowledge and to fulfill their sharing obligations. This platform facilitates the confidential exchange of information, reagents and data between BCBC Members, the sharing of information and reagents with non-BCBC investigators, access to BCBC Core Facilities, registration for BCBC meetings and events, and management of the special funding programs of the BCBC. Accordingly, the BCBC website has a central role in the operations of the BCBC. BCBC Members are strongly encouraged to learn its features, visit the site frequently and recommend enhancements.

Usage of the website by BCBC Members includes the following expectations:

1. Member Profiles. To maintain good standing with the BCBC, all BCBC Investigators, BCBC Co-Investigators and BCBC Affiliates are required to establish and update their member profiles within the BCBC website on at least an annual basis. BCBC Members will be prompted to review and update their member profiles prior to registering to attend all regularly-scheduled BCBC meetings. BCBC Members who fail to update their profiles on an annual basis may have their access to information within the website restricted in addition to the restrictions in Section J.

2. Entry and documentation of new reagents. New reagents that have been conceived of, or that are in the process of being generated, must be documented on the BCBC website. Access to information describing these unpublished reagents will automatically be set to "BCBC Investigators and Affiliates". BCBC Investigators may petition the BCBC Executive Committee to restrict access to the information to "BCBC Investigators Only". If the generation of a new reagent involves the use of a BCBC Core Facility, then entry of information into the website must occur before work will be started by the core facility staff. Information about a resource described in the website must be made publicly accessible upon publication. While it is the responsibility of the BCBC (Co-)Investigator to make necessary status updates, BCBC (Co-)Investigators may always request assistance of the BCBC Coordinating Center. The BCBC CC, acting on behalf of the NIDDK, may implement features in the BCBC website in order to encourage compliance.

3. Scientific deliverables. BCBC (Co-)Investigators are required to enter into the website a brief description of scientific deliverables and time estimate for availability for each new reagent or dataset described in all U-01, Collaborative Bridging Projects, Pilot and Feasibility Awards, Seeding Collaborative Research in Beta Cell Biology Projects, and/or other yet-to-be-defined BCBC special funding programs, prior to the distribution of funds for these awards. This information will be viewable only by the NIDDK staff and BCBC Investigators within that project.

Since the generation of new resources may not always happen according to schedule, BCBC (Co-)Investigators will be provided with the opportunity at the time of the annual progress report to modify timeframes, to add new resources, or to remove resources resulting from changes in scientific direction or other circumstances. All changes in scientific deliverables will be visible to the BCBC Program Officer at NIDDK who may at times ask for additional information.

4. Annual meetings. Registration for annual meetings of the BCBC is managed through the website. The BCBC generally holds two annual meetings. In general, it is expected that all BCBC Investigators attend both the Spring and Fall meetings. BCBC Co-Investigators are required to attend the Spring Investigator Retreat but not the Fall Planning Meeting. Since attendance at these meetings is essential for the success of the collaborative efforts of the consortium, investigators who fail to attend may lose their good standing and some or all of the associated privileges.

5. Presentations from meetings. PowerPoint and/or Adobe PDF files of all presentations made at the semiannual meetings of the BCBC will be posted on the BCBC website where they can be viewed by other BCBC Investigators, and BCBC Co-Investigators in the case of the spring retreat. This information should be kept in strict confidence and only shared with BCBC Affiliates – by way of BCBC (Co-)Investigators - who are engaged in these projects after reminding them of their obligations to also maintain confidentiality.

6. Core Facilities. All resources developed utilizing the BCBC Core Facilities must be described in the appropriate database as the effort is underway. BCBC Core Facilities will not ship reagents to collaborating laboratories until the information describing the resource has been entered into the appropriate data resource on the BCBC website and made viewable to other BCBC Investigators and Affiliates. As work proceeds within a BCBC Core

Facility on a project, BCBC (Co-)Investigators may be periodically asked to review and update the scientific deliverables for each project that is under development.

7. Experimental datasets. Like other BCBC Resources, all genomic and other high throughput datasets that describe RNA expression, proteins, transcription factor binding and epigenomic regulation must be shared with other BCBC (Co-)Investigators and/or Affiliates prior to publication. This requirement can be satisfied by depositing the dataset into Beta Cell Genomics (<http://genomics.betacell.org/>) where access to this data, like other BCBC Resources and information can be securely managed.

## **D. CONFIDENTIALITY OF INFORMATION**

BCBC Members are obliged to maintain the confidentiality of unpublished information that is disclosed to them, either directly or indirectly, during the course of BCBC meetings and events. The main sources of unpublished information include the data and reagent descriptions posted on the BCBC website and unpublished data presented at BCBC meetings. However, unpublished information may also be gained by direct disclosure of one BCBC Member to another. Such information should not be shared with any third party without the consent of the original contributor(s) of such information, or until the original contributor(s) publishes or otherwise publicly releases such information.

## **E. SHARING AMONG BCBC INVESTIGATORS**

All BCBC (Co-)Investigators are expected to share information, reagents and data with other members of the BCBC prior to the initial peer-reviewed publication that describes the development of the resource or reagent, or research results. Since the willingness of BCBC (Co-)Investigators to share information and reagents depends on the responsible use of these reagents and appropriate scientific attribution, the following sections describe the general expectations for such exchanges in detail.

Sharing of information about experiments in progress is intended to minimize duplication and stimulate collaboration between BCBC (Co-)Investigators. However, at the same time BCBC Members must recognize that unpublished information may be incomplete, and sometimes even erroneous. Thus, BCBC Members are encouraged to directly discuss such data if experiments are being planned that are based on it.

1. Authorship. The use of an unpublished reagent or other key information that leads to a publication necessitates a discussion of authorship with the donating investigator. In general, the prepublication sharing of BCBC Resources should be dealt with through scientific collaborations in which the terms for the specific use of the BCBC Resource are agreed upon in advance. New functionality is being programmed into the BCBC Website to facilitate documentation of collaborative agreements involving the use of newly developed Resources. In general it is expected that BCBC Investigators and BCBC Co-Investigators maintain good scientific relationships with other BCBC Members. The failure of a BCBC Investigator or Co-Investigator to maintain good scientific relationships due to non compliance with the terms of a scientific collaboration may result both in a loss of Good Standing within the Consortium and a restriction of their privileges to access information on the BCBC Website (Section J.3).

2. Publications. All publications arising from collaborations that utilize unpublished resources or information from other investigators should include the donating investigator and key laboratory personnel as co-authors, unless explicitly agreed to otherwise. In general, the provider of the resource or dataset has the right to publish the description and use of the resource first. However, at the same time BCBC (Co-)Investigators must be willing

to commit to a reasonable timeframe that does not hinder other users of key resources the ability to publish their own results in a timely manner.

3. Third Parties. Unpublished reagents obtained from one BCBC (Co-)Investigator by another should not be transferred to a third party without the prior written consent of the originating contributor. BCBC Affiliates should always consult with their BCBC (Co-)Investigator before transferring reagents to other individuals including other individuals within the Institution the Member is associated with.

4. Documentation of collaboration. To facilitate collaboration between BCBC (Co-)Investigators, the BCBC website has functionality that enables the terms of use for unpublished reagents and datasets between collaborating BCBC Investigators to be documented and updated as needed.

5. Material Transfer Agreement. It is the responsibility of both parties to ensure that all MTAs or other institutional documents associated with this collaborative effort are submitted in a timely manner by using the Simple Letter Agreement found at [http://www.betacell.org/pdf/NIH\\_simp\\_ltr\\_agree.pdf](http://www.betacell.org/pdf/NIH_simp_ltr_agree.pdf).

## **F. SHARING BETWEEN BCBC AND NON-BCBC MEMBERS**

All published reagents such as mice, genetically modified ES cell lines, antibodies, and viruses that were made using BCBC funds, either in total or in part, must be freely distributed to investigators at academic institutions who request use of these reagents for non-commercial research. “Freely distributed” is defined as the unencumbered distribution patterned after practices of NIH-sponsored repositories, where distribution is carried out without regard to the requestor’s identity or experimental designs. Individuals found to be in breach of this policy may be subject to sanctions, including possible termination of their award.

1. Distribution. BCBC (Co-)Investigators who have generated a BCBC Resource will be responsible for distributing it to all requesting investigators prior to its submission to and distribution by a central repository. BCBC Members may ask the requesting investigator to reimburse the reasonable costs for preparing and distributing the reagent. If the expense of distributing reagents becomes burdensome, the BCBC Member may petition the BCBC Executive Committee for subsidization of distribution costs. A resource request mechanism is available on the BCBC website that assists in tracking and managing such requests. Guidelines for how requests for resources should be routed and managed through the BCBC website will be made available at <http://www.betacell.org/about/policies/>.

2. Repositories. BCBC (Co-)Investigators are encouraged to deposit all mouse strains that are likely to have continuing experimental value into a mouse repository, such as the NIH-supported Mutant Mouse Regional Resource Centers (<http://www.mmrrc.org>). At that time, all mice developed through the BCBC will be posted at the International Mouse Strain Resource (<http://www.informatics.jax.org/imsr/>). Similar obligations exist regarding newly developed ES cell lines, viral constructs, etc. These obligations can be satisfied by describing the resource on the BCBC website and setting accessibility to the public. Furthermore, all high throughput datasets that describe RNA expression, transcription factor binding and epigenomic regulation must be deposited into GEO (Gene Expression Omnibus - <http://www.ncbi.nlm.nih.gov/geo/>) following deposition into Beta Cell Genomics (<http://genomics.betacell.org/>), which has the capability to deposit the data into GEO. Preferred repositories will be described on the BCBC website and are subject to change.

3. Intellectual Property. BCBC (Co-)Investigators are expected to adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the “Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts” issued in December, 1999 ([http://www.ott.nih.gov/policy/rt\\_guide\\_final.html](http://www.ott.nih.gov/policy/rt_guide_final.html)). Specifically, all material transfers should utilize a Simple

Letter Agreement and not have any reach-through requirements ([http://www.betacell.org/pdf/NIH\\_simp\\_ltr\\_agree.pdf](http://www.betacell.org/pdf/NIH_simp_ltr_agree.pdf)). Moreover, should any intellectual property be patented the technology must remain widely available to the research community in accordance with the NIH Principles and Guidelines document.

## **G. BCBC AFFILIATE RESPONSIBILITIES**

BCBC Affiliates contribute to the atmosphere of collaboration and sharing by adhering to the operational procedures and guidelines outlined here. Not only does this facilitate the mission of the BCBC in accelerating the discovery process for developing beta cell therapies, it also promotes the BCBC Affiliate's scientific aspirations and goals by providing access to key reagents and resources.

BCBC (Co-)Investigators are responsible for determining their BCBC Affiliates, and are responsible for ensuring that these individuals both understand and comply with the Policies and Guidelines of the BCBC as described within this document.

BCBC Affiliates are encouraged to assist their BCBC (Co-)Investigator in entering relevant reagents and protocols into the appropriate database on the BCBC website.

1. Addition of BCBC Affiliates. In order to add BCBC Affiliates (via the website) and associate them to their (investigator) profile, BCBC (Co-)Investigators should login to the BCBC website and via their laboratory workspace, select the "Workspace Administration" menu option. A utility exists that allows affiliates to be added simply by providing the affiliate's name and email address. BCBC (Co-)Investigators should then communicate BCBC Affiliate Responsibilities to the affiliates (section G.3).

2. Removal of BCBC Affiliates. When a BCBC Affiliate needs to be removed, BCBC (Co-)Investigators can use the utility described for adding BCBC Affiliates, and clicking on the "Remove" link next to the BCBC Affiliate's name. Once the BCBC Affiliate is no longer associated with the BCBC (Co-)Investigator, the affiliation should be terminated by the BCBC Investigator. Both BCBC Affiliates and BCBC (Co-)Investigators are required to ensure the removal of affiliation status once the association is no longer deemed appropriate. Nonetheless, the termination of affiliation will not lead to removal of the user account. The users will be able to continue use their accounts on the BCBC website as a non-BCBC member (public status).

3. Responsibilities of BCBC Affiliates. BCBC Affiliates are required to have a member account for the BCBC website and to manage and maintain their own account profile which includes entering recent publications, contact information and a portrait-style photograph. Furthermore, BCBC Affiliates who attend BCBC meetings, such as the annual spring retreat, must have a completed member profile for meeting registration.

## **H. EXTERNAL SPEAKERS AND CONSULTANTS**

External speakers and consultants may be periodically invited to participate in BCBC meetings. These individuals are given privileged access to a breadth of information that is normally disclosed and discussed at these meetings. They will be expected to maintain confidentiality of this information, and to comply with the all Policies and Guidelines pertaining the Sharing of information (Sections E and F). External speakers and consultants and their Sponsoring Institution will be required to signing this document prior to their attendance at any BCBC event. External speakers and consultants will not be provided with BCBC Investigator-level website access.

## **I. BCBC EXECUTIVE COMMITTEE OVERSIGHT**

The BCBC Executive Committee (EC) consists of five voting members: the PI of the BCBC Coordinating Center who serves as chair, the NIDDK Project Scientist, the Associate Program Director, two other members of the NIDDK program staff, and three rotating members chosen among the BCBC Investigators that compose the Steering Committee. The EC reserves the right to request that a BCBC Investigator or BCBC Co-Investigator deposit resources such as mice, DNA constructs, monoclonal antibodies, genetically modified cell lines, viruses, data sets and other research results made using BCBC funds, to facilitate their distribution to the scientific community at-large. This request may occur prior to the initial publication of the resource.

## **J. FAILURE TO MAINTAIN GOOD STANDING**

In its oversight capacity, the EC can in its sole discretion take appropriate actions to ensure proper operation and implementation of the BCBC, including but not limited to the following: BCBC Investigators, BCBC Co-Investigators and BCBC Affiliates who fail to maintain good standing within the BCBC, particularly regarding the sharing of information and reagents, or inappropriately disclose confidential information, may be subject to sanctions, including having further NIH funding of the BCBC Investigator's grant restricted, as well as the following:

1. In general, the first restriction for failing to register for a meeting (Section C.4) or updating your list of sharable data resources or reagents (scientific deliverables – Section C.3) will be a restriction in access to the website.
2. A failure to update a member profile or to enter other required information into the BCBC website (Section C.1) will lead to an inability to register for the required BCBC meetings.
3. A failure to document new reagents (Section C.2), the inappropriate disclosure of unpublished data (Section C.5), or the failure to comply with the terms of a scientific collaboration (Section E.1), may lead to the inability to view and/or obtain other unpublished reagents.
4. A failure to maintain information about reagents being generated (Section C.2) may lead to the inability to apply to special programs of the BCBC.

BY SIGNING BELOW, I ACKNOWLEDGE AND AGREE, FOR MYSELF OR FOR THE SPONSORING INSTITUTION OF WHICH I AM A DULY AUTHORIZED OFFICIAL, THAT I HAVE READ, UNDERSTOOD, AND I/THE INSTITUTION SHALL ABIDE BY THE POLICIES, PROCEDURES, AND GUIDELINES OF THE BCBC.

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BCBC (Co-)Investigator, External Speaker or Consultant

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Date