3D Bioprinting Core at IUSM / IUPUI (3DBPC) Core Policies

Confidentiality Policy:

IU Users

For users within the IU system, confidentiality is regulated by existing University polices in this regard (e.g. https://compliance.iu.edu/compliance-areas/index.html and http://researchcompliance.iu.edu/index.html). The University Policies on intellectual Property and on Research Misconduct establish that research and research data at IU is to be protected from intentional and unintentional disclosure. Thus, all samples, products derived from samples, data obtained from the analysis of samples, and data or analyses obtained from a Core user shall be treated as confidential.

Non-IU Users

For Core users from outside of IUSM, such as corporate partners, investigators from government, other universities, or any other institution, the same confidential treatment of constructs and data shall be applied in the Core. However, in this case the confidentiality is assured through execution of a specific ***Material Transfer Agreement*** (http://www.researchadmin.iu.edu/GrantContract/gc-award/award_mtas.html). External users may contact the Office of Research Administration at IUPUI. Assistance in establishing such agreements will be provided by Core Manager and/or the Core Director.

All Users

The Core will not share data or privileged research information with any other parties. Since the constructs and data generated by the Core are owned by the respective investigator, all data generated in the Core is provided back to the User. Specifically, the Core will not provide access to the printed tissue constructs, or to information about them, to anyone except the owner (the PI or a person designated by the PI). Permission from the PI is required to release any remaining samples or data from the Core. Concepts related to the process of bioprinting (i.e., placing spheroids on Kenzans) and biofabrication (tissue fabrication perfusion or other culture methods developed by the Core) not already protected by the bioprinter manufacturer will be considered Core owned information.

However, the School of Medicine requires periodic reports on billed and partially completed projects; the information provided includes the investigator's name, department, percent complete, account number and total cost. As we become a CTSI-designated Core, we are also required to indicate the general service provided (e.g. 3D BioPrinting, perfusion, spheroid production) as well as the list of publications resulting from Core use. However, this information will be treated as confidential and not shared with a third party.

To track instrument and overall Core performance and to inform future customers about tissue fabrication techniques and tissue production parameters, the Core may collect and use quality control information from all experiments. For this reason, the Core may request information regarding spheroid or tissue generation at any stage of the activity, and may ask permission to

use this information (de-identified, if not specifically permitted by the User) for guidance of other investigators and to develop a catalog of fabrication parameters.

Whenever it applies, digital copies of a user's activity or pertinent information about it will be archived in a secure server (encrypted, password-protected), which access is restricted to the authorized Core personnel only. However, although we may archive copies of generated data, it is the responsibility of the user/investigator to maintain all data for their own records. The Core is not responsible for the loss of archived data.

Equipment and Supply Care Policy

Core Personnel will ensure the Regenova Bio 3D printer and Kenzans are in working order prior to being released for use by a user. If any questions arise during use, please contact Core personnel before performing an unfamiliar operation. Principal Investigators are responsible for any damage to the Regenova or Kenzans used by users in their lab.

Recovery/Payment Policy:

Payment is expected for any material service rendered by the Core, beyond the initial consultation. A list of the specific fees will be provided to the users at the beginning of their project. An IU account number or a purchase order number (PO#) must be provided before service is provided. In addition to the account number and expiration data, the PI or the PI designated person responsible for payment, must sign and date the agreement.

Full payment is expected if data are obtained, regardless of whether or not it represents the result expected by the investigator. No 'partial payments' are considered at this time, for any of the Core's services.

Our mechanism for initial quality control is to perform free spheroid scanning to achieve optimized spheroid and test print for a nominal fee to determine if your spheroids can be printed. Our guidelines for sample submission include quality control information. If an investigator wishes to attempt a print without performing scans or a test print, we will do our best to print a competent construct from the spheroids provided in the time allotted. However, if the samples fail at any stage of our print, we will stop the process (or suggest that users stop the process) and consult with the investigator (who should be present) about how to proceed. In any case, we will expect partial payment to recover the costs associated with the aborted experiments (time used and/or percentage of project complete).

The Core bills at the end of every month. For experiments which are comprised of multiple batches for processing, billing may occur as each batch is completed. Work cannot be billed before it is completed (e.g. to meet a grant expiration date); it is investigator's responsibility to get a no-cost extension or schedule work in a manner that it can be billed before your grant expires. We will let you know at submission time if there is a possibility that we will not be able to complete your project before expiration of your grant.

Prioritization of Work Policy:

Core service requests are initiated through email with the Core Director. These requests are honored on a 'first come, first served' basis. However, a negotiable priority will be applied to the Major Users vs. Minor users, as defined by the Shared Instrument Grant proposal. Requests for urgent attention are considered by Core personnel on an ad hoc basis, upon consultation with the already scheduled users.

Researchers communicating their new interest in using the Core services will then be sent a Consultation Form (see attached draft) to fill out. Following consultation, all requests are approved by an authorized representative of the Core, and the financial account is set up in the system. Only then will the bioprinter be reserved using the online calendar. Minor rearrangements of this scheduling may be made when reagents or supplies are backordered from our supplier or if a minor shift in schedule can make better use of the equipment.

We reserve the right to break up larger experiments into batches if it will make better use of the equipment and allow us to minimize delays to small experiments. Delays can happen when the equipment fails or when there is high traffic on the instrument. The customer will be notified by email when this occurs.

Publication, Authorship, and Acknowledgement Policies:

Expectations of authorship for Core personnel will be discussed at the beginning of the project with the Core Director and/or the Manager. In general, authorship is not required and will be considered inappropriate for Core personnel that provides only material assistance with the project,

However, if there is significant intellectual and/or organizational effort of Core personnel to the work described in the manuscript, authorship is warranted and expected. For example, expert spheroid production, or tissue fabrication by the Core personnel that is required in support of claims in a manuscript or patent, warrant authorship.

It will be made clear to investigators utilizing the Core that the recovery of Core expenses through the Core cost recovery system does not exclude the possibility for authorship for Core research personnel, when justified. Similarly, authorship does not substitute for payment of Core expenses for services rendered.

In publications that describe research that took place at the Core facility, authors should include a statement acknowledging the use of the facility and the 3D BioPrinting Core. Examples of acknowledgements:

1) Methods section of publications: ‘Data/Tissue Constructs were acquired at the IUSM/IUPUI 3D BioPrinting Core facility using the Cyfuse Regenova 3D BioPrinter’.

2) Acknowledgement section of publications: ‘Data were acquired at the IUSM/IUPUI 3D BioPrinting Core facility using the Cyfuse Regenova 3D BioPrinter’.

3) Acknowledgement section of oral presentations: ‘Cyfuse Regenova 3D BioPrinter at the IUSM/IUPUI, 3D BioPrinting Core facility’.

If specific personnel in the Core were very helpful, acknowledgement of those personnel would be also appropriate.

Conflict Resolution Policy:

Should issues such as scheduling disputes, technical problems with the equipment, quality of work, questions about charges, authorship, and conflict of interest, etc. arise, first the Core Manager or Director will discuss the issues with the investigator in order to resolve them.

If the issues cannot be resolved in this manner, the disagreement or dispute will be presented to the Core Advisory Committee for assistance in conflict resolution. If a mutually agreeable solution is not achieved within 30 days of the dispute notification to the Core Director, the Core Advisory Committee will be convened ad-hoc to mediate the dispute. If invention rights or claims are involved, a technology transfer manager will be consulted and included in the deliberations.

If the solution is not accepted by all of those involved even after Advisory Committee mediation, the matter will be referred for resolution to the Office of the Vice Chancellor of Research at IUPUI, as the final instance with arbitrating authority. In this event, all Core projects related to the disupute will be suspended until the dispute is resolved.

These policies were adapted from the Indiana University School of Medicine Center for Medical Genomics (CMG), the Indiana University School of Medicine Angio BioCore (ABC) and the Purdue University Transgenic Mouse Core Facility (TMCF).