Instructions for Incoming MTA Submission Form

In an effort to improve the quality of the information provided on our submission forms, the Office of Research has developed this submission form instruction sheet. Each question contained on the corresponding submission form is listed below in black text. Beneath each question, additional clarification is provided in red text.

General Tips:

- Please submit only fully completed forms with the requested supplementary materials attached. Incomplete forms/submissions will require the Office of Research to place your project "on hold" pending receipt of the remaining documentation.
- Please ensure the accuracy of the information provided on the submission form. Proper routing of the MTA and subsequent negotiation of appropriate contract terms is entirely dependent upon the information presented on the submission form.
- In the event you know of any specific execution procedures of the providing entity (e.g., requirement for original signatures on MTAs, ability to execute via PDF, etc), please provide this information in your submission email.
- Always try to obtain the proposed MTA as an editable Word file. As MTAs will often require negotiation of the terms, providing the MTA as an editable Word file will help to facilitate review/negotiation.
- All new submissions should be sent via email to orcontracts@offres.pitt.edu Please copy the appropriate corporate and clinical contract officer (CCO) on your submission emails. If you are unsure of who your CCO is, please refer to the constituency listing located at the following link: http://www.pitt.edu/~offres/cccs-const.html

  As a less preferable alternative to email, completed forms can also be faxed to 412/624-7414 or hand-delivered to the Office of Research.

Below please find the submission form questions in black text and additional helpful hints in red text (*).	
Left Column:	**Right Column:**
University Principal Investigator (PI) Name/Title/Email: *Please include the full name of the principal investigator including professional titles and academic title (i.e., Assistant Professor, Associate Professor, Professor, etc). Please also include the email address of the PI.	Company/Institution Providing Materials: *The Company/Institution providing the Material will be a party to the MTA.
PI's Departmental Administrative Contact for MTA Follow-up: (not Office of Research staff) *Please be sure to provide the complete name, phone number, and email address for contact purposes when the Office of Research needs to reach the University PI.	Company/Institution Legal Contact for MTA: *Please include the full name, email address and phone number of the individual with whom the Office of Research will negotiate the terms of the MTA. Please note that most MTAs will require negotiation and incomplete information may result in delays in completion of the MTA.
University Location/Lab(s) where Materials will be housed: *This is the physical location where the Material will be located while on University property.	Company/Institution PI/Scientific Name: *Name of the individual researcher (including any professional titles) who is sharing the materials. Oftentimes, the contact for MTA negotiation at the providing entity will need this information in order for

	them to complete their own internal processing procedures.
Will research use the Regional Biocontainment Laboratory (RBL)? Yes (attachment required)/No *In the event the Materials must be utilized in the RBL, the Office of Research requires evidence of approval from the RBL Director/Associate Director in the form of a letter.	List ALL Materials being provided under this MTA: *Please note that Office of Research staff will verify the Materials listed on the submission form match the Material referenced in the MTA. The Materials must be specifically listed with enough detail to ensure clarity of exactly what Materials are being transferred. Any discrepancy in the description of the Materials listed on the submission form and the MTA will result in inquiry with the PI for resolution and may result in delay in MTA processing.
General: Please attach a brief summary of the research and the intended use of the Material in your research or insert here: *Frequently referred to as a Scope of Work (SOW), this summary of your intended research using the Material may be needed for insertion into the MTA or attachment as an exhibit to the MTA. Please keep in mind that your use of the Material is limited to this Scope of Work. In the event you should desire to expand your Scope of Work, please contact your Office of Research Contracts Officer to discuss amendment of the MTA.	Is this a biological material? Yes/No *If the Material is biological and if the entity providing the Material is a signatory to the Uniform Biological Material Transfer Agreement (UBMTA), it may be possible for the University of Pittsburgh to utilize this expedited contracting mechanism. http://www.pitt.edu/~offres/ResContracts/UBMTAannouncement.pdf
What is the intended use of the Material in your research? Control/Tool Other (Please describe): *In the event the Material is being used as a research control or tool, it is less likely that your research will result in any new inventions related to the Material itself. If, however, you are intending to use the Material in some other way or for a new purpose, it is critically important to the Office of Research to be aware of these new uses to protect any downstream inventions and to comply with any funding requirements.	**Compliance:** Is the Material a live animal? Yes (attachment required)/No *If yes, please attach the corresponding IACUC approval letter governing use of the Material. Note: Live animals must be received in the DLAR onto an approved protocol.
Will the Material be modified? Yes/No *In the event the PI's research will modify the Material, the Office of Research must be aware of this intention to remove any limiting language contained in the proposed MTA and to ensure compliance with federal requirements.	Will the Material be used in animals? Yes (attachment required)/No *If yes, please attach the corresponding IACUC approval letter related to the use of the Material in animals.

Will the Material/modified Material become incorporated into a new research material? Yes/No *If the PI's research will modify the Material or cause the Material to be contained in some new material, the Office of Research must be aware of this intention to remove any limiting language contained in the proposed MTA.	Is the Material of direct human origin? Yes (attachment required)/No *Of "direct human origin" means collection of human tissue under an IRB approved informed consent form and generation of the Material from the human tissue here at the University of Pittsburgh. ** Investigators with incoming MTAs that transfer human biological specimens to the University of Pittsburgh should ordinarily complete the "OSIRIS Request for Determination of Exempt Status, or No Human Subjects Designation: Research with Biological Specimens" form located at the following weblink [http://www.irb.pitt.edu/exempt/bankedtiss.htm]. Once submitted through the OSIRIS system, the IRB will review your submission and will provide either an approval letter for the exempt research project or a letter indicating that the proposed research project does not constitute human subject research. Upon receipt, please forward the IRB letter to the Office of Research for inclusion in the contract file. If the to-be-studied biological materials constitute a de-identified, immortalized cell line and are being provided by a commercial entity or tissue repository such as ATTC, submission to the IRB is not required because the activity does not meet the definition of human subjects research according to 45 CFR 46.102(f).
What is the source of funding? (Response cannot be "none") insert details about funding source In addition, answer the following questions. Federal funds? Yes/No Are funds housed at Pitt? Yes/No PI Name on funding account: [enter information] *In the event federal funds or other external funds will support the research involving the Material (in whole or in part), the Office of Research will need to ensure that the language of the MTA permits the sharing of materials developed with federal funds and does not include restrictive invention language (i.e. Bayh-Dole implications).	Is the Material taken from a decedent (cadaver)? Yes (attachment required)/No *If the Material is taken from a cadaver, please attach the applicable CORID letter of approval or exemption.
Is this Material needed for a proposal under development or consideration for funding? Yes (name of funding agency)/No	Will the Material be used in human subjects? Yes (attachment required)/No *If the Material will be introduced into human beings,

*In the event the Material is being used in connection with a federal award, the Office of Research will need to ensure the proposed MTA is consistent with the NIH policy entitled "**PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES"** http://www.ott.nih.gov/policy/rt_guide_final.html or other federal requirements.	University of Pittsburgh IRB approval will be needed. If answering Yes, please attach the IRB approval letter corresponding to the pertinent research study.
What other agreements/funding/materials will be applicable to the Study? List all that apply, i.e., Sponsored Research Agreement, Government or Other Grant, CDA, License, MTA, Subcontract, Other Agreement (list Company/ies) Please provide Institution Number/Project Number or specific details of each. *If there are any other agreements which in any way relate to the research being conducted with the Material, the Office of Research must review the terms of these agreements to ensure that such agreements do not contain any contradictory language.	Does the Material contain human stem cells? Yes (attachment required)/No *As MTA signature requires evidence of hSCRO registration or approval, as appropriate for the given project, the Office of Research requires the submission in the form of a letter of such documentation for our records.
Is the Material commercially available? Yes/No	If human embryonic stem cells, are these cells on the NIH stem cell registry? Yes/No *Please note that the University can only process MTA transfer requests for human embryonic stem cells line approved by the federal government and listed on the NIH stem cell registry.
	Does the Material involve recombinant DNA? Yes (attachment required)/No *As MTA signature requires evidence of IBC/rDNA approval if the Material or use of the Material utilizes recombinant DNA, the Office of Research requires the submission of such documentation for our records.
	Is the Material hazardous? Yes/No *A hazardous material is any item or agent (biological, chemical, physical) which has the potential to cause harm to humans, animals, or the environment, either by itself or through interaction with other factors.

	Hazardous materials are defined and regulated in the United States primarily by laws and regulations administered by the U.S. Environmental Protection Agency (EPA), the U.S. Occupational Safety and Health Administration (OSHA), the U.S. Department of Transportation (DOT), and the U.S. Nuclear Regulatory Commission (NRC). Each has its own definition of a "hazardous material" and may have specific shipping and handling requirements. http://www.ehs.pitt.edu/
	Does the Material require Radiation Safety Officer approval? Yes (attachment required)/No *As MTA signature requires evidence of Radiation Safety Officer approval letter, as appropriate for any Material subject to Radiation Committee oversight, the Office of Research requires the submission of such documentation for our records.
	Is the Material on the federal Select Agent list? Yes (attachment required)/No *If Yes, please attach an approval letter from the appropriate Environmental Health & Safety (EH&S) officer. This is a list of highly regulated biologics and toxins. Please visit the EH&S link below for more information regarding the University's process for the use of Select Agents. Use and transfer of Select Agents requires written approval of EH&S. http://www.ehs.pitt.edu/assets/docs/select-agent-toxins.pdf

Signature Section:

*Principal Investigator must be a University of Pittsburgh faculty member.

This form can either (1) be signed by the PI and submitted on behalf of the PI; (2) be left unsigned if the PI himself/herself is submitting the form directly to the Office of Research; or (3) be left unsigned if the form is being submitted on behalf of the PI provided that the PI has indicated his/her approval of the contents of the submission form.