Mandatory Form

Educational Grant Request

In order for the grant to be considered you must complete all applicable sections in their entirety.
Please sign, date and upload to the "Mandatory Form" spot on the online application.

Event & Contact Information:

Organization Name	
Event Title	Event Date(s)
Please specify the type of support that you are requesting below: ○ Monetary Request ○ Product/In-kind Request ○ Monetary and Product/In-kind Request	

For Non-Accredited Programs Only

☐ Yes ☐ No	Will your course include any content that references reimbursement/ billing of J&J company products?
If "Yes", you must submit this content for further review by the J&J Law Department 30 days prior to course.	

For Accredited Programs Only

☐ Yes ☐ No	Has the CME provider been found to be in partial or non-compliance, or placed on probationary status, by an accrediting organization in the past 12 months?
☐ Yes ☐ No	Has the educational provider had acceptable results from the fair balance and commercial bias assessments/ratings of their last 3 educational activities?

Grant Requestor Qualifications

☐ Yes ☐ No	Are there any activities or agreements between the educational provider (requestor) and any Johnson & Johnson company or key J&J staff members that could cause a real or perceived conflict of interest or commercial bias?
☐ Yes ☐ No	Does the educational provider have a Compliance Officer/ Ethics Officer (or equivalent) and a formally documented compliance program?
If you answered "No" to the question above, please answer the following question ☐ Yes ☐ No Are there corporate compliance policies in place at your institution with someone entrusted to ensure those policies are current and enforced?	
☐ Yes ☐ No	Are you seeking additional financial support from other sponsors?
☐ Yes ☐ No	Are you a Medical Education Communication Company (MECC) that provides content development support or logistical support to the educational provider putting on the event?
If you answered "Yes" to the MECC question above, please answer the following question ☐ Yes ☐ No Is the educational provider responsible for the design and content of the educational event?	

Needs Assessment

☐ Yes ☐ No	Are you submitting a separate needs assessment document that provides an analysis of the bona fide need that this educational activity will cover? (May included but is not limited to: Educational Gap Analysis; Learning/ Program Objectives; Targeted Audience and Reasoning; Proposed Educational Methods)
If you answered "No" to the question above, please enter a needs assessment below: (Limited to 300 characters. If you need more space, please attach a separate document and input "See Attached" in the field below)	

Lab (Complete for Lab or Hands-on Training)

Does your program include a lab or hands-on training session?	
○ No Lab	○ Yes, LIVE ANIMAL LAB ○ Yes, SIMULATION, INANIMATE LAB ○ Yes, HUMAN CADAVER LAB
If you answered "No Lab" to the above question, you do not need to complete pages 2 and 3.	

Live Animal Lab Required Information

Lab Site	
☐ Yes ☐ No	**Conventional Setting:** Those settings where animal laboratories are routinely performed. These settings include universities/colleges, contract labs and teaching hospitals.
If you answered "**NO**" to the above: Please be advised that the company no longer provides support via educational grants for live animal labs at nonconventional settings.	If "**YES**" to the above: The following documentation must be submitted for review in order to determine support of live animal training laboratories in a conventional setting:
○ I have included	Copy of your IACUC approved protocol with documentation of the date of approval. Approval date documentation can be contained on the protocol or can be separate from the protocol in the form of an approval letter that references the IACUC protocol number.
○ I have included	Copy of your USDA registration
○ I have included	Acknowledgement of the AAALAC, international status. (Please note this certification is preferred but not required.)

Simulation, Inanimate Lab Required Information

Lab Site	
☐ Yes ☐ No	**Conventional Setting:** Those settings where simulation labs are routinely performed. These settings include universities/colleges, contract labs and teaching hospitals.
☐ Yes ☐ No	**Non-conventional Setting:** Those settings where simulation laboratories are not routinely performed. These settings include hotel, convention centers, and mobile units.
If you answered YES to SIMULATION, INANIMATE LAB, the grant requestor agrees that it is in compliance with the following parameters in order to determine support of simulation training in nonconventional settings. (Contractors are also responsible for assuring compliance with any relevant state or local regulations.)	
○ Agree	An authorized party at the nonconventional location has granted permission to run a simulation or inanimate lab at that location.
○ Agree	Access to the lab area will be controlled so that only individuals who are registered for the lab or who have been otherwise approved by the instructor will be allowed access.
○ Agree	If tissue is used it will be fit for human consumption and/or sourced from a supplier that is USDA registered. Tissue from condemned animals is prohibited.
○ Agree	The lab area will be cleaned after the training is completed and all waste including tissue, sharps and product will be safely disposed of.

Human Cadaver Lab Required Information

Lab Site

The grant requester agrees that it is in compliance with the following parameters in order to determine support of cadaver training specific to the specimens:
Specimens will be tested for the following at a CLIA Licensed laboratory pursuant to current FDA approved cadaveric specimen testing as described at the FDA Web site http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm095440.htm approved prior to delivery to Facility

Please be advised if you do not comply with the following serology requirements, the Company *cannot* provide in-kind support.

○ Agree	Human immunodeficiency virus (HIV) types 1 and 2
○ Agree	Hepatitis B surface antigen (HbsAg)
○ Agree	HBV
○ Agree	Hepatitis C virus (anti-HCV)
○ Agree	Only Specimens with results of the initial and subsequent confirmatory tests that are negative will be used
○ Agree	Specimens donors will not be known to be infected at the time of death with any highly communicable or contagious disease

☐ Yes ☐ No	**Conventional Setting:** Those settings where cadaver laboratories are routinely performed. These settings include universities/colleges, contract labs and teaching hospitals.
☐ Yes ☐ No	**Non-conventional Setting:** Those settings where cadaver laboratories are not routinely performed. These settings include hotel, convention centers, and mobile units.

If you answered "Yes" to Non-conventional Setting question above, the grant requestor agrees that it is in compliance with the following parameters in order to determine support of cadaver training: (Contractors are also responsible for assuring compliance with any relevant state or local regulations.)

○ Agree	An authorized party at the nonconventional location has granted permission to run an animal or cadaver lab at that location.
○ Agree	Access to the lab area will be controlled so that only individuals who are registered for the lab or who have been otherwise approved by the instructor will be allowed access. The doors to the lab area will remain locked at all times.
○ Agree	The lab area is separate from public areas and cadaver entry/removal in and out of building is discrete.
○ Agree	The lab area will be cleaned after the training is completed and all waste including tissue, sharps and product will be safely disposed of.
○ Agree	Lawful and informed written consent has been obtained of the donors or individuals having authority under applicable state law to consent to the donation. All personal and medical information relating to the anatomic specimens and their donors shall remain confidential except as necessary to ensure the safety of individuals that come in contact with the specimens.
○ Agree	(i) Documented processes are in place regarding the sourcing, transportation, handling, use, and disposition of anatomic specimens which are in compliance with all applicable laws and regulations, and (ii) all necessary permits, licenses and approvals required under such laws and regulations have been obtained and maintained.
○ Agree	All personnel handling the anatomic specimens are trained and will comply with all applicable standards for protection from blood-borne pathogens.
○ Agree	The disposition of all anatomic specimens complies with all applicable laws and is in accordance with the informed consent given by the donor and/or the donor's legally authorized representative.
○ Agree	All anatomic specimens will be treated with dignity and respect.

Signature Required For All Grant Requests

Today's Date	Organization or University sponsoring event	
Course Coordinator (Name and Title):		Email
Phone	Cell	Fax
Requesting Organization		
Authorized Signature	Print Name	Date

Internal Company Use Only

Name of On-site Contact	Email

Johnson & Johnson MEDICAL DEVICES COMPANIES