

## **30.2-7 Grants and Charitable Donations**

### **Policy**

Wright Medical Group N.V. (the “Company” or “Wright”) is committed to fostering charitable donations and giving, and encouraging research and education, based on the principles of transparency and accountability by ensuring compliance with applicable laws and regulations, and preserving the integrity of the physician-patient relationship.

This policy is intended to be consistent with the principles set forth in the Company’s Code of Business Conduct, the Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”), Accreditation Council for Continuing Medical Education (“ACCME”) Essentials and Standards for Commercial Support, and all applicable laws and regulations.

The Company’s Grant Review Committee (“GRC”) is the administrative body that reviews and approves all grants and donations including, but not limited to, scholarships, fellowships, education grants, and all other charitable donations to organizations that are affiliated with HCPs (as defined below). The GRC is a cross-departmental group of Wright employees that meets, as needed, to review submissions of grant requests. Departments represented in the GRC include, but are not limited to, Compliance, Legal, Medical Education, Finance, and Clinical Affairs.

The Human Resources Department identifies community organizations and/or causes to charitably support. It reviews charitable donations to organizations that are not affiliated with HCPs. Human Resources must consult with Compliance on all charitable donations to determine if an HCP affiliation is present.

### **Scope**

This policy applies to all global Company employees, Company representatives, members of the Board of Directors, independent contractors, consultants, sales agents, distributors, distributor employees, sub-distributors and all others performing service on behalf of the Company.

“Health Care Professionals” (“HCPs”) include individuals and entities that are (1) involved in providing health care services and/or items to patients and (2) in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Wright’s products in the United States. The phrase Health Care Professional is to be interpreted broadly and includes both persons providing services (such as physicians, doctors of podiatric medicine (“DPMs”), physician assistants, nurses, operating room staff or consultants) and persons who do not provide services directly (such as administrative hospital or office staff), but who may be involved in the decision to purchase, lease, or recommend Wright products. HCPs also include purchasing agents, physician’s practice managers and management within General Purchasing Organizations (“GPOs”).

## Allowed and Excluded Requests

### **The Company will only provide grants and donations to support and encourage:**

- the advancement of medical science or education;
- indigent care or medical missions;
- patient and public health education; and
- events where the proceeds are intended for charitable purposes.

### **Wright will not provide grants or donations:**

- for research unless there is a written agreement defining the required procedures and protocol, which is reviewed and approved by the SRC (Strategic Review Committee);
- where the budget for a proposed program appears to be unreasonable under the circumstances;
- to directly fund any fellowships in the United States. Fellowship funding may be provided to and administered through legitimate medical education foundations or institutions;
- to non-profit organizations that are controlled by, or appeared to be controlled by, an HCP or an immediate family member of an HCP, or if there appears to be any inappropriate influence by the HCP on the organization;
- to fund scholarships unless the recipients are medical students, residents, fellows, or others who are HCPs in training;
- where the circumstances are likely to improperly influence, or appear to improperly influence, medical judgment;
- where one purpose is to influence an HCP to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe the Company's products.
- when the funds would be used to defray the HCP requestor's ordinary operating expenses or overhead; when funds would pay for travel, housing expenses or time spent for doctors attending third party educational events;
- to fund educational events whereby social events or activities such as golf outings, leisure time, or other recreational activities, take precedence over the educational component or are not considered high quality programs of significant educational value;
- when the funds would be used to directly fund payments for exhibit space, consulting or other services or goods provided to the Company, Company promotional activities or events, or any program where any of the speakers are Company employees; or
- when the funds would be in support of or to offset entertainment or recreational activities.

## Administration

Product Donations: The Company may donate product for charitable missions and/or the benefit of indigent patients. Requests for product donations will require certification by the requestor that the patient's physician(s) and/or the hospital or other facilities will not bill the patient, Medicare, Medicaid or any other person or third-party payor for the cost of any of the health care services for which donated Company products will be used.

Product Leases/Loans: If a product donation request for a bona fide medical mission or indigent care case is approved by the GRC, the Company may lease or loan instrumentation necessary for donated product to be implanted as part of the charitable case(s). The value of the approved donation will be calculated to include the value of the leased or loaned instrumentation. Once the Compliance Department confirms that the loaned/leased instrumentation has been returned, the value of the grant will be adjusted accordingly.

Grand Rounds: The Company may provide funds to support programs for the bona fide education of fellows/residents/interns. These programs are therapeutic area specific, but not specific to a company's product. Company representatives may not attend Grand Rounds events that Wright has funded.

Exhibits, Booths and Meeting Sponsorships: Exhibits, booths and meeting sponsorships are not considered grants or donations and must be approved through the Company's Compliance Department and/or Arrangements Review Committee.

## Recipients

Except in the case of medical missions, the Company will only award funds to (1) non-profit organizations or (2) entities that have been recognized as qualified providers of continuing medical education ("CME") by the ACCME, providers of podiatric medical education ("CPME") accredited by the Council on Podiatric Medical Education, or by state or territory medical societies approved by ACCME to accredit CME or CPME providers.

Except in the case of medical missions, grants and donations must not be provided (1) to any individual; (2) to any "for-profit" physician practice or group; (3) to any patient; (4) on behalf of any patient or HCP; or (5) to non-CME or non-CPME accredited "for-profit" providers.

## Wright Medical

## Proprietary Information

Doc. Type: Policy/Procedure

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Title: **Grant and Charitable Donations**

Effective Date February 28, 2014

Document Owner/Dept: **Professional Affairs**

Last Revision Date: January 1, 2019

Status: **Issued**

Issued Date: January 1, 2019

## Procedure

Responsible Department	Steps
Requestor Organization/Business Unit	<p>Submit required documentation to grants@wright.com:</p> <ul style="list-style-type: none"> <li>• The requestor's name, address, IRS tax identification number and a copy of the IRS tax-exempt determination letter (or other appropriate tax-exempt status documentation)</li> <li>• A letter and a description of the organization's charitable, educational, or scientific purpose</li> <li>• A description of the specific educational or charitable event or other purpose for the grant</li> <li>• A detailed agenda of the event, outlining location, dates, time, speakers and topics</li> <li>• A detailed budget, outlining the event and speaker expenses</li> <li>• A completed W-9, signed by the organization</li> <li>• For medical missions, a list of the requested products to be provided by Wright, along with the purpose and ultimate destination for the use of the products; and/or a description of the requested equipment to be provided by Wright, along with the purpose and ultimate location of the equipment</li> <li>• Completed Certificate of Compliance from the organization, including confirmation that requestors and their respective institutions are not persons or organizations excluded from participation in Medicare, Medicaid or other federal healthcare programs by the Department of Health and Human Services Office of Inspector General and are not barred from federal contracting by the General Services Administration. In the case of fellowships, these requirements are also applicable to the attending physician and the proposed fellow. (Appendix A)</li> </ul>
Wright/Professional Affairs	Provides confirmation of request receipt to requestor

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Monetary Grant/Donation	
GRC	Reviews and approves (or rejects) request
Grants Administrator	Provides voucher and supporting documentation to GRC Chair
GRC Chair	Reviews and approves request, including completion of the Grant Documentation Summary (Appendix D)
Finance	Processes payment ( <b>wire or check only</b> ) from voucher. <b>Funds must be paid directly to the recipient.</b>
Grants Administrator	Receives check or wire notification from Finance and sends notification of approval and payment to recipient.
Grants Administrator	If denied, sends email notification to the requestor
Grants Administrator	Maintains all approved grant request documentation in electronic file on the shared drive with access by the GA, GRC Chair and CCO
Product Donation	
GRC Chair, Compliance, Legal, Regulatory	Reviews and approves (or rejects) request
Grants Administrator	Sends approved request, Product Donation Request form (Appendix B and C) and other supporting documentation to Customer Service
Grants Administrator	If approved, sends notification of approval to the requestor
Grants Administrator	If denied, sends email notification to the requestor
Customer Service	Obtains proper paperwork and pulls product for donation
Customer Service	Ships requested products directly to the requestor
Grants Administrator	Maintains all approved grant request documentation in electronic file on the shared drive with access by the GA, GRC Chair and CCO

*Wright reserves the right to deny a grant or charitable donation request for any or no reason, in its sole discretion. Wright is under no obligation to provide an explanation for its decision.*

*The GRC cost center will be billed for Wright's standard product cost.*



## Grant Request Form

Requesting Institution:	
Institution Address:	
Contact Name:	
Contact Address:	
Contact Phone:	
Contact Email:	

### Wright Certificate of Compliance

This certification is intended to comply with all applicable laws, rules and regulations regulating the subject matter of this request for funding and the relationship to the parties, including the federal anti-kickback status 42 U.S.C. 320a-7(b), as well as the related safe harbor regulations. Wright reserves the right to modify this certification for such reasons as Wright deems appropriate to maintain compliance with federal, state, local laws, rules, and regulations. I, the undersigned, certify that to the best of my knowledge, all of the following statements are true with respect to this request:

1. The receiving organization, its personnel, and I have not, implicitly or explicitly, solicited the requested donation in exchange for an agreement to purchase, use, order, or recommend Wright products.
2. No Wright representative implicitly or explicitly offered a donation to the receiving organization, its personnel, or me to purchase, use, order, or recommend Wright products or to reward prior purchases, uses, orders, or recommendations of Wright products.
3. The requested donation will not result in any private benefit to a health care provider who uses, orders, or recommends Wright products.
4. The receiving organization, its personnel, and I are not a person (or persons) or organization excluded from participation in Medicare, Medicaid, or other federal healthcare programs by the Department of Health and Human Services Office of Inspector General and is not barred from federal contracting by the General Services Administration.
5. The receiving organization, its personnel, and I are not a person (or persons) or organization identified on the U.S. State Department's Terrorist Exclusion List on the U.S. Treasury Department's list of Specially Designated National or Blocked Persons
6. I have read and accepted Wright's Code of Business Conduct

[http://www.wright.com/wp-content/uploads/2015/04/014026A\\_11-May-2016-Code-of-Bus-Conduct-Manual\\_EN\\_LR\\_LE.pdf](http://www.wright.com/wp-content/uploads/2015/04/014026A_11-May-2016-Code-of-Bus-Conduct-Manual_EN_LR_LE.pdf)

Submitter's Name	
Submitter's Organization & Title	
Signature	
Date	

Attached Documentation		
W-9 <i>(required)</i>	501(c)3 <i>(required)</i>	Request on Company Letterhead <i>(required)</i>

### Request Details

*(Please include specific details as to what program(s) this grant would support along with the amount requested)*



## Product Donation Request Form

Requesting Institution:	
Institution Address:	
Contact Name:	
Contact Address:	
Contact Phone:	
Contact Email:	
Shipping Name/Address for Donation:	

### Wright Certificate of Compliance

This certification is intended to comply with all applicable laws, rules and regulations regulating the subject matter of this request for funding and the relationship to the parties, including the federal anti-kickback status 42 U.S.C. 320a-7(b), as well as the related safe harbor regulations. Wright reserves the right to modify this certification for such reasons as Wright deems appropriate to maintain compliance with federal, state, local laws, rules, and regulations. I, the undersigned, certify that to the best of my knowledge, all of the following statements are true with respect to this request:

1. The receiving organization, its personnel, and I have not, implicitly or explicitly, solicited the requested donation in exchange for an agreement to purchase, use, order, or recommend Wright products.
2. No Wright representative implicitly or explicitly offered a donation to the receiving organization, its personnel, or me to purchase, use, order, or recommend Wright products or to reward prior purchases, uses, orders, or recommendations of Wright products.
3. The requested donation will not result in any private benefit to a health care provider who uses, orders, or recommends Wright products.
4. The receiving organization, its personnel, and I are not a person (or persons) or organization excluded from participation in Medicare, Medicaid, or other federal healthcare programs by the Department of Health and Human Services Office of Inspector General and is not barred from federal contracting by the General Services Administration.
5. The receiving organization, its personnel, and I are not a person (or persons) or organization identified on the U.S. State Department's Terrorist Exclusion List on the U.S. Treasury Department's list of Specially Deisgnated National or Blocked Persons
6. I have read and accepted Wright's Code of Business Conduct

[http://www.wright.com/wp-content/uploads/2015/04/014026A\\_11-May-2016-Code-of-Bus-Conduct-Manual\\_EN\\_LR\\_LE.pdf](http://www.wright.com/wp-content/uploads/2015/04/014026A_11-May-2016-Code-of-Bus-Conduct-Manual_EN_LR_LE.pdf)

Submitter's Name	
Submitter's Organization & Title	
Signature	
Date	

Attached Documentation		
W-9 <i>(required)</i>	501(c)3 <i>(required)</i>	Request on Company Letterhead <i>(required)</i>

### Request Details


*(Please include specific details as to what is the purpose of the product donation, what products are needed (must include part numbers and quantities)*

**Product Donation Request and Approval Form**

<b>Date of Request</b>	
<b>Date Product Needed</b>	
<b>Organization</b>	
<b>Requester's Name</b>	
<b>Contact information</b>	<b>Name:</b> <b>Email:</b> <b>Phone:</b>  <u>Shipping Address:</u>
<b>Description of Need</b>	
<b>Products Needed (Part #s and Description)</b>	
<b>Estimated Costs</b>	
<b>Within Grant Budget (Yes/No)</b>	
<b>See Attached</b>	

<b>Review and Approval Table</b>			
	<b>Name</b>	<b>Signature</b>	<b>Comments</b>
<b>Compliance</b>			
<b>Legal</b>			
<b>Grant Committee Chair</b>			



	<p>Grant Documentation Summary</p>	<p><b>Grant Request ID:</b></p> <p><b>Request Date:</b></p>
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<input type="checkbox"/>	Grant requestor's name, address, email address, and phone number	Comments	
<input type="checkbox"/>	A letter or email describing the organization's charitable, educational, or scientific purpose	Comments	
<input type="checkbox"/>	A description of the specific educational or charitable event or other purpose of the grant	Comments	
<input type="checkbox"/>	A detailed agenda of the event, outlining location, dates, time, speakers, and topics	Comments	
<input type="checkbox"/>	A detailed budget which outlines the event and speaker expenses	Comments	
<input type="checkbox"/>	For medical missions or indigent care: A list of requested products or list/description of requested equipment to be provided by the Company, and the purpose and ultimate destination of the requested products/equipment	Comments	
<input type="checkbox"/>	A completed W9, signed by the organization	Comments	
<input type="checkbox"/>	IRS tax identification number and copy of the IRS tax-exempt determination letter (or other appropriate tax-exempt status documentation (for grant monetary requests)	Comments	
<input type="checkbox"/>	Exclusion Check(s) Performed	Comments	
<input type="checkbox"/>	Signed Certificate of Compliance Form	Comments	
<input type="checkbox"/>	Completed Grant Documentation Summary Form	Comments	
<input type="checkbox"/>	Other Supplemental Documentation	Comments	



Grant Documentation Summary

Grant Request ID:

Request Date:

Committee Review Date:

Final GRC Decision Date:

Committee Decision:  Approved  Denied  Postponed

Decision date back to requester:

Communication Type:  Approval letter/email product donation  Approval letter/email grant check  Denial letter

Date of check or product shipment:          Amount:

Code of Business Conduct accepted:  Via email  Via mail          Date Accepted:

Verification by Grant Administrator Signature:

Verification by Committee Representative Signature: