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AND MASSACHUSETTS GENERAL HOSPITAL

MEMORANDUM TO: Principal Investigators, Research Staff, and Department/Research Administrators **DATE:** 4/11/18

FROM: Anne Klibanski, MD, Partners CAO
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SUBJECT: European Union (EU) Data Protection Laws – **New Privacy Requirement**

We are writing to give you a heads-up on new EU privacy requirements, the *General Data Protection Regulation* (GDPR), that, beginning May 25, 2018, will affect Partners research collaborations with EU entities (e.g., hospitals acting as clinical trial sites or data coordinating centers or universities collaborating on a Partners hospital basic science project) and may affect some Partners educational activities.

Background: The GDPR replaces existing EU privacy laws and expands personal privacy rights for EU residents and non-EU residents located in the EU. It applies to institutions with no physical EU presence if that institution works with what the regulation defines as Personal Data. There are correlations between HIPAA and the GDPR, but the GDPR is broader, extending to areas and information not covered by HIPAA.

New - GDPR Review: When you submit any of the agreements listed below through Insight, the applicable contracting office (Research Management, Clinical Trials Office or Innovation) will forward the agreement to the Office of General Counsel (OGC) and Partners Information Security and Privacy (ISPO) for a GDPR review.

Agreements subject to GDPR review

- Collaboration with an EU organization;
- Human subjects/patient/personal data or materials sharing agreement (e.g., Data Use Agreement, Material Transfer Agreement, Clinical Trial Agreement or industry Sponsored Research Agreement) with an EU organization; or
- New agreement from a sponsor (industry, federal or non-federal) or EU entity with GDPR/privacy terms.

Following the GDPR review by OGC/ISPO, you will be notified by the appropriate contracting office if you need to take additional steps to bring the project into compliance with GDPR.

If you are developing a government or foundation proposal/grant application that involves **an EU entity**, please work with your Pre-Award Grants Administrator to develop an Insight record, as you would for any new proposal/grant application, and let them know of EU involvement, e.g., if the project includes a subcontract to an EU entity. If and when the proposal/application is funded, you will need to take additional steps to vet the activity through your contracting office and bring the project into compliance with GDPR. The Pre-Award office will contact you at JIT to begin this process.

Existing EU Collaborations: PIs of existing EU collaborations will be contacted individually when we have completed an assessment of current research projects. Other than as noted above for new agreements or applications/proposals, you do not need to do anything immediately.

Partners Activities: Partners Information Security/Privacy, Research Compliance, and the Office of General Counsel are working together to understand what GDPR will mean for Partners research and educational activities. This group, convened by Jigar Kadakia and Mary Mitchell, will work with Partners research contracting groups (Research Management, CTO and Innovation), Human Research Affairs, TBD hospital offices and PIs. It will take time for us and other US AMCs and universities to understand and determine GDPR implications and compliance requirements.



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Please watch for more information from us or the Partners GDPR group. The goal is to develop templates (e.g., informed consent template language) and tools to streamline the process as much as possible. When available, this information will be posted on the Research Compliance page of the Research Navigator and communicated in Research News.

Please share this information with your research group.

Copies to: Monica Baggio-Tormey, Kris Betres, Robert Birnbaum, Andrew Chase, Chris Coburn, Robert Damiano, Kim Durniak, Mary Gervino, Lisa Griffin, Jigar Kadakia, Maureen Lawton, Jen Mahoney, Peter Markell, Rob Martin, Fabio Martins, Scott McNeal, Mary Mitchell, Allison Moriarty, Suzanne Morin, Shawn Murphy, Pearl O'Rourke, Emily Sobiecki, Stephanie Stone, Dave Waldron, Beth Watters, Deborah Weinstein, Steve Wiviott