VUMC International Privacy Office (IPO) Project Review Process

VUMC – Principal Investigator (PI)/ Study Team

- ❑ PI submits request to OCM via PEER request and/or a Material Transfer Agreement (MTA) via MTA Share
- ❑ PI completes PEER/MTA submission indicating international data/materials in scope
- ❑ PI completes IPO REDCap survey
- ❑ PI submits Pegasus request for International Project Security Review by VECPC
- ❑ PI/study team attends VECPC meeting to review project/study
- ❑ PI/study team reviews draft Security Overview report from VECPC, and provides updates or approves draft
- ❑ PI/study team receives final copy of Security Overview report
- ❑ PI participates in Contracts Optimization meeting if project risk is high
- ❑ PI/study team completes International Privacy training
- ❑ PI/study team notifies VECPC of any changes to the project data flow or technology during the study lifecycle, if applicable
- ❑ PI will receive annual follow-up email from VECPC, and must complete process again for any renewals/amendments for projects more than 2 years old

Office of Contracts Management (OCM)

- ❑ OCM contract analyst receives PEER request
- ❑ OCM contract analyst opens a Xakia request to OLA
- ❑ Once contract is finalized, OCM contract analyst will trigger emails in PEER for approval from associated groups (OLA & IPO are last to approve for completion)

APPROVAL NEEDED

VU Center for Technology Transfer & Commercialization (CTTC)

- ❑ CTTC contract analyst receives MTA Share application
- ❑ CTTC contract analyst identifies if material is sourced from international location
- ❑ CTTC contract analyst emails notification of international MTA to IPO
- ❑ CTTC contract analyst emails international MTA draft to OLA for review
- ❑ CTTC sends MTA to CTTC authority for signature once IPO approval has been provided

Achieved Compliance/International Privacy Office (IPO)

- ❑ IPO assesses whether project is in IPO's scope of work
- ❑ If project is in scope, IPO tracks matter and IPO # is assigned
- ❑ IPO adds project to PEER IPO Dashboard
- ❑ IPO sends email to PI to complete IPO REDCap survey, VECPC Pegasus request, and International Privacy training
- ❑ IPO reviews REDCap survey to assess risk and assign risk score
- ❑ If study is assessed as high risk, the project is sent to Contracts Optimization Committee with recommendations and International Project Security Overview report. Contracts Optimization Committee may provide conditional approval with requirement of additional training or security controls to approve the project to move forward in PEER
- ❑ If study is not high risk, and International Project Security Overview, International Privacy training and IPO REDCap have all been completed, then IPO signs-off project
- ❑ IPO reviews International Project Security Overview and completes the Standard Contractual Clauses (SCCs) based on details within the Overview, if applicable

APPROVAL NEEDED

Office of Legal Affairs (OLA)

- ❑ OLA receives Xakia request or email from CTTC contract analyst with international MTA draft for review
- ❑ OLA receives Xakia request from OCM
- ❑ OLA negotiates contract until all parties are satisfied
- ❑ OLA requests IPO to complete appropriate cross-border transfer documentation
- ❑ OLA provides project approval in PEER

APPROVAL NEEDED

VUMC Enterprise Cybersecurity Policy & Compliance (VECPC)

- ❑ VECPC receives Pegasus request
- ❑ VECPC reviews data in Pegasus request & IPO REDCap survey
- ❑ VECPC schedules meeting with PI/study team
- ❑ VECPC meets with PI/study team to review project/study
- ❑ VECPC documents the international data in scope, handling of associated data, and data flow
- ❑ VECPC drafts initial International Project Security Overview w/ data flow diagram
- ❑ VECPC sends draft International Project Security Overview to PI for review/update/approval
- ❑ VECPC updates draft International Project Security Overview, if needed, until PI/study team approves draft
- ❑ Draft approved by PI is sent to VECPC management for approval
- ❑ VECPC management approves International Project Security Overview report
- ❑ Final version of International Project Security Overview is published and provided to IPO and PI/Study team, and retained in VECPC archives
- ❑ VECPC provides project approval in PEER IPO Dashboard
- ❑ VECPC completes associated Pegasus request
- ❑ NOTE: If international data is being saved to a system not previously approved by VEC SAAS, the PI/delegate is instructed to submit a Pegasus request to Request Coordination. This review must be completed before VECPC can draft International Project Security Overview
- ❑ If other issues are identified during the PI interview process, (use of external consultant, waiver of consent, use of non-compliant systems) those items must be resolved before the International Project Security Overview draft can be completed and released to PI for review/approval
- ❑ VECPC follows up with PI/study team annually to confirm project is still active and that there are no changes to the data flow or security environment

APPROVAL NEEDED

Request Coordination (when applicable)

- ➢ As part of the Request Coordination process, the VUMC Enterprise Cybersecurity Security Architecture and Assurance Services (VEC SAAS) & Business Resilience Services (BRS) team is engaged to review the security/compliance of the associated system(s). This review must be completed before VECPC can draft Security Overview, if applicable.
- ➢ See linked PowerPoint outlining the Request Coordination Process - https://pegasus.vumc.org/ViewKnowledge.aspx?id=15041