

International Data Sharing: Participant Data Flow Guidance

The direction of the flow of data between UMN and international collaborators determines what authorization forms and additional consents are required for compliance with applicable privacy laws and regulations. Please refer to this chart, and the following page of details, to better understand what forms are required based on the type of international collaboration your study is engaging in:

When data from **non-US** participants is collected in another country and/or is shared **from** International Collaborator **to** UMN:

- Up-to-date HIPCO training is **Required**¹
- International Consent Form is **Required**²
 - *GDPR Countries: "EU/EEA International Consent"*****
 - *Non-GDPR Countries: "General International Consent"****
 - *UK DPA International Consent****
- HIPAA Authorization is **Not Required**

When data from **US** participants is shared **from** UMN **to** International Collaborator:

- Up-to-date HIPCO training is **Required**
- HIPAA Authorization is **Required**
- International Consent Form is **Not Required**³

***Exception: HIPCO's international consent addendums are not required if the sponsor of the study and/or study-affiliated, non-US-based clinical sites:

1. Collect study data outside of the US;
2. Own the rights to the study data; and
3. Have a valid consent and authorization form distribution process allowing UMN involvement with research non-US participants.

¹ HIPCO training is mandatory for anyone whose study/studies involve international collaboration (applies to both GDPR and non-GDPR countries) in which UMN will be *receiving* Personal Identifiable Information (PII) from participants who are citizens of another country, regardless of HIPAA applicability. This requirement ensures study teams are familiar with baseline privacy standards and best practices.

² Since GDPR and other international privacy laws are different from—and can be stricter than—HIPAA privacy laws, the applicable International Consent Form is required in alignment with international privacy laws. Note that these International Consent Forms *do not replace* the standard IRB consent form and need to be provided to international participants *in addition to* the standard consent form.

³ The HIPAA Authorization Form is required in this instance, as HIPAA *does* apply to US citizen data (PHI), even PHI that is shared with international collaborators. The GDPR and non-GDPR consent forms are *not* required in these circumstances.