

UHN-REB Guidance on Submitting an Investigator's Brochure / Product Monograph

July 25, 2017

An **Investigator's Brochure (IB)**, or **Product Monograph (PM)**, or other **Investigational Product Documentation** is required documentation for an Initial Clinical Trial Submission to UHN REB. Updated IBs, or PMs, or other Investigational Product Documentation need only be submitted to UHN REB along with other pertinent documents, via an **Amendment** submitted through CAPCR, when they reflect a change to:

- 1) the currently approved protocol and/or
- 2) the existing risk for participants and/or
- 3) any participant-presented documents

Please note that the UHN REB reserves the right to request a copy of any version of the IB or PM or other Investigational Product Documentation at any time.