From: irb@umassmed.edu
To: Blodgett, Allison
Subject: Investigational Drug Service Support for Clinical Trials
Date: Thursday, August 23, 2018 12:00:27 PM

TO: UMMS Research Community

FROM: Katherine Luzuriaga, MD, Vice Provost, Clinical and Translational Research
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DATE: August 21, 2018

SUBJECT: Investigational Drug Service Support for Clinical Trials

We are writing to remind the community that all investigational agent use in human subjects research across UMass Medical School (UMMS) and UMass Memorial Medical Center (UMMMC) must utilize the Investigational Drug Services (IDS). This includes investigational agents used for compassionate use. Even an FDA-approved drug may be considered investigational in the context of human subjects research; cases that qualify for IND exemption under FDA regulations remain within the scope of IDS. IDS pharmacists play a key role in facilitating subject safety for clinical trials. IDS fees should be built into clinical research budgets accordingly. As indicated in UMMMC Pharmacy Department Policy 4.1.0, exceptions to requirements will be considered by IDS on a case-by-case basis following a formal written request from the Principal Investigator. IDS policies may be accessed on the intranet:
https://inside.umassmed.edu/ccts/human-research/ids-policies

Any investigators currently using clinical pharmacy services for research activities should contact the IDS to arrange for dispensing and apprise the IRB as soon as possible.

Please feel free to contact us with any questions or concerns.