IRBMED Statement of Practice
Remote Study Procedures

I. BACKGROUND

Since March 2020, there has been increased use of remote study procedures in human subject research activities due to the restrictions on in-person research activities. While the in-person restrictions have been relaxed, IRBMED has noted continued use of remote study procedures. The following are some of the most common remote study procedures:

- Remote recruitment activities
- Electronic informed consent process
- Remote data collection activities through surveys or phone calls/telehealth visits
- Performing study assessments (labs, imaging, etc.) at external (non-UM) facilities
- Shipping investigational products directly to subjects' home

IRBMED issued several guidance documents to address these scenarios (linked in the resources below). In addition, the FDA's guidance on this topic, "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency", was also extensively utilized by UM researchers. According to the FDA, this guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. Through this document, IRBMED intends to update the research community on this information and clarify the IRB submission procedures for remote study activities.

II. STATEMENT OF PRACTICE

1. Per federal regulations, IRB approval is required before implementing any change to IRB-approved human subject research unless the change is to eliminate apparent immediate hazards to the subjects. The procedures outlined in the IRBMED's "Reporting Time-Sensitive Modifications" guidance are still applicable and should be utilized by researchers. They outline scenarios when an Amendment (for study-wide changes) or an ORIO (one-time changes) should be submitted to seek IRB approval of a change.
2. Since March 2020, many researchers have submitted contingency plans for their IRB applications in order to conduct remote study procedures. Unless a specific end date is indicated in these contingency plans, IRBMED acknowledges that these contingency plans remain in effect.
3. Any remote study procedures conducted by the study teams that were not approved by IRBMED (via an ORIO or an Amendment) are considered deviations and must be reported to IRBMED via the ORIO reporting process per the IRBMED ORIO guidance.
4. Electronic/remote informed consent: If a research team would like to use remote consent and/or e-consent for their study, the consent plan must be described in Section 10 (question 10.1.2) of IRB application. As with any changes, IRB approval must be obtained for any change to the consent process. For additional information, review IRBMED's guidance on Informed Consent Procedures Using Electronic Systems and Remote Use of Paper Documents and the FDA guidance on electronic informed consent.
    a. If an IRB application is FDA regulated, the FDA compliant version of SignNow must be utilized. This is the only system available through U-M and currently recognized to be 21 CFR Part 11 compliant which is required for FDA regulated studies. See IRBMED's guidance on SignNow.

b. For all other non-FDA regulated studies, various tools (Redcap, Qualtrics, DocuSign, etc.) are currently available which allow for electronic signatures to address the informed consent signature/documentation requirements. Note that not all e-consent systems contain the ability to document legally effective signatures. When a signature is not being obtained, there has to be an approved waiver of informed consent documentation from IRBMED.

c. For HIPAA authorization, a signature is still required. See the IRBMED Guidance: Waiver or Alteration of HIPAA Authorization