



## **University of Massachusetts Medical School Clinical Research Patient Recruitment Methods**

Published on: June 13<sup>th</sup>, 2018

*Instruction: Please copy and paste this standard language based on your recruitment needs and included it in the ISP submission to UMMS IRB.*

1. **\*Recruitment using potential candidate list based on Clinical Data:** PI will submit a signed electronic request at the UMMS Clinical Data Portal ([www.umassmed.edu/it/cdp](http://www.umassmed.edu/it/cdp)) upon IRB approval of the protocol & approved HIPAA waiver to select a patient cohort that meets the inclusion and exclusion criteria and to retrieve identified patient data including upcoming appointments from the UMMS Data Lake / EPIC on the selected cohort. The UMMS Data Science & Technology Team will deliver the list of one or more individuals who meet the criteria securely to the study teams. The methods could include, for example, electronic lists or mobile alerts. For example, a text message would instruct the study team member to access patient information securely from a central location.  
This process may be repeated on a regular basis until the recruitment target is met. The study plan further describes the extent to which the study team will use the list to work with the treating physician/provider in advance and how / when the study team will approach patients to inquire about interest in participating studies.
2. **EHR alerts to care providers about patients in clinic who meet eligibility criteria:** Best Practice Advisory (BPA) is a functionality

available in Epic (UMMHC's Electronic Medical Record system). BPAs can be used to assist in patient recruitment. PI will submit a signed electronic request at the UMMS Clinical Data Portal ([www.umassmed.edu/it/cdp](http://www.umassmed.edu/it/cdp)) upon IRB approval of the protocol & approved HIPAA waiver to select a patient cohort that meets the inclusion and exclusion criteria and to retrieve identified patient data including upcoming appointments from the UMMS Data Lake / EPIC on the selected cohort. The UMMS Data Science & Technology Team will deliver the list of one or more individuals who meet the criteria securely to the study teams. Upon the verification by the study team, the UMMS Data Science & Technology Team will deliver the list securely to UMMHC EPIC builders. The patient list will then be securely uploaded to Epic.

- A. BPA will be implemented to send the message/alert to the treating provider during the patient encounter to enable the provider to alert the patient about the research and provide study team contact information. When the target recruitment is achieved, BPA will be stopped.
- B. BPA will be implemented to send the message/alert to the treating provider during the encounter to enable the provider to alert the patient about the research. The provider passes patient contact information via the authorization to contact form provided by the study team ([https://www.umassmed.edu/ccts/irb/forms\\_templates/](https://www.umassmed.edu/ccts/irb/forms_templates/)). When the target recruitment is achieved, BPA will be stopped.
- C. BPA will be implemented to send the message/alert to the study team. This process may be repeated on a regular basis until the recruitment target is met. The study plan further describes the extent to which the study team will use the list to work with the treating physician/provider in advance and how / when the study team will approach patients to inquire about interest in participating studies.

To avoid potential distraction for the physicians (physician fatigue), 2A & 2B will be used only in very difficult to recruit studies or studies that require real time recruitment.

**3. \* Use of EHR patient portals to notify patients of research opportunities:**

MyChart is Epic's patient portal where the patient may sign up and participate in managing his/her health care. MyChart can also be used in assisting in patient recruitment. PI will submit a signed electronic request at the UMMS Clinical Data Portal ([www.umassmed.edu/it/cdp](http://www.umassmed.edu/it/cdp)) upon IRB approval of the protocol & approved HIPAA waiver to patient cohort that meet the inclusion and exclusion criteria and retrieve identified patient data including upcoming appointments from the UMMS Data Lake or using EPIC tools on the selected cohort. The UMMS Data Science & Technology Team will deliver the list securely to UMMHC EPIC builders. Potential patients will see the following message in their MyChart portal:

*Dear (Patient Name),*

*I would like to let you know about a research study being offered at the UMASS Medical School. The purpose of this study is (Study Purpose in about 6 words- no jargon). My study team will be reaching out to (eligibility gender) who are (eligibility age range) years of age to see if they are eligible and if they choose to participate in the research study.*

*If you DO NOT want to be contacted about this research study please contact (Study Team Contact Name) at (Phone Number) OR (E-Mail Address).*

*If you do not call or e-mail (in time frame or by actual date), my study team member may call you to describe the research study in more detail and answer any questions you may have. Participation in research is always voluntary, and you do not have to participate unless you want to.*

*If you are interested in learning more about the research study or have any questions, please e-mail or call the telephone number listed above to speak with a member of my study team.*

*Thanks for your consideration, (PI Signature)*

When the target recruitment is achieved, the message will be removed.

**(Please note: Exact MyChart recruitment language needs to be submitted and approved by UMMS IRB.)**

4. **Opt-in Recruitment using Conquering Diseases Volunteer Registry:** The UMMS Volunteer registry allows patients to express interest in being contacted by study teams when a study that suits the condition that they have expressed interest in opens in the future. The system facilitates automated consenting for future contacts.