Human Research Protection Program

Announcement

Feb 22, 2017

Subject: Revised Electronic Research Enrollment Form

In compliance with JCI standards regarding the safety and welfare of patients enrolled in Research clinical trials at AUBMC (whether sponsored or PI-initiated), the Human Research Protection Program (HRPP)/IRB and in joint efforts with the Medical Records Department and the Information Technology Department at AUBMC have launched a revised Electronic version of the "Research Enrollment Form".

The "Research Enrollment E-Form" **MUST** be completed for each patient enrolled in any clinical trial/ interventional research study at AUBMC. The form can be easily accessed on the main HIS page (https://his.aub.edu.lb/), under "Quick forms" section, with icon shown hereby:

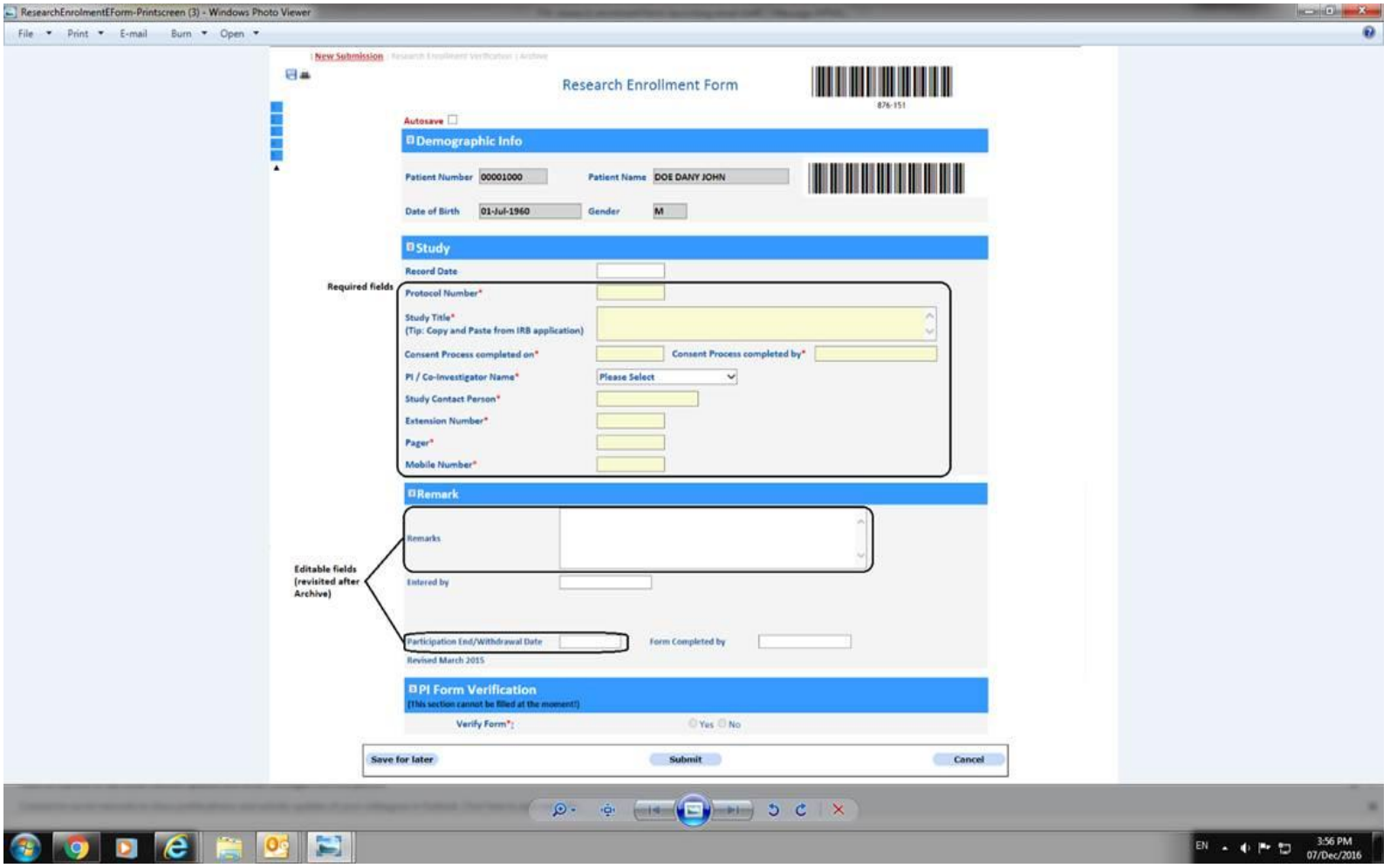
It is a mandatory **JCI requirement** to have this form completed and verified as soon as a patient is enrolled in a clinical trial. Audits will be made as required to ensure full compliance with this safety standard. Failure to comply will jeopardize JCI accreditation in relation to Human Research Protection chapter and others, and will be cited as a non-compliance finding by the HRPP/IRB. This requirement is already highlighted in all IRB approval letters when indicated.

All AUB/AUBMC academic and non-academic faculty and staff who have an AUB user account have been granted access to complete this form, per the following steps:

- When a patient is **recruited and enrolled in a clinical trial/interventional research study**, the person assigned by the Principal Investigator (PI) should adequately and fully **complete the Research Enrollment E-Form** (sample below) online and then submit it for the Principal Investigator (PI) to verify.
- The PI shall receive an email notification (Titled: **Action Required: Research Enrollment Form for verification**) of a submitted form which can be easily accessed through a link within the notification email; the **PI can then review the content and verify (or don't verify) the submitted form**. The PI is responsible to ensure the all patients enrolled in a clinical/interventional research study/trial at AUBMC have each had a form adequately completed.
- Once verified by the PI, the completed form shall become a part of the patient's Electronic Health Record (EHR).
- Once the **subject participation comes to an end or once the subject chooses to withdraw from the study**, the PI or his/her designated person, needs to **complete the field in the E-form that requests for the date of End of Participation or withdrawal**, along with the name of the person completing this section. In order to have the research records complete, The PI is kindly invited to ask his/her research team/delegate to complete the "**Remarks**" section of the form and state the reason of ending the participation and any other remarks found appropriate by the person completing the form. Once the "**Participation End/Withdrawal Date**" field is completed, the patient will no more appear as enrolled in a clinical/interventional research study/trial within a period of 30 days after the recorded end of participation date. The information will remain accessible in an archived fashion under Research Section of EHR.
- A pop up alert showing that a patient is enrolled in a research study whenever a patient presents to AUBMC and his/her EHR is accessed, has been made functional too. This will alert the caregiver that the patient is enrolled in a specific research study, permitting coordination of care with the PI and thus securing the patient safety.

Print Screen of the Research Enrollment E-Form found on the following link:

https://his.aub.edu.lb/https://his.aub.edu.lb/



Print Screen of the pop up appears in the EHR view:

If you have any questions regarding this form, you can kindly contact:

Mrs. Carol Haddad at the Medical Records Department at 6460/6461 or Mrs. Jamale Eid at the HRPP office at 5456.

If you encounter any technical issues related to this form, please contact the IT help desk.

Thank you for helping us meet this required standard in a timely fashion.

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Professor of Medicine

Director, Human Research Protection Program