



PLACEMENT OF A RESEARCH CONSENT FORM IN THE PARTICIPANT'S MEDICAL RECORD

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The Duke University Health System (DUHS) Institutional Review Board (IRB) has adopted the following policy regarding the placement of a signed research consent form in the research participant's medical record (Maestro Care) at Duke.

I. Definitions

"FDA-regulated" means any study that is subject to review by the U.S. Food and Drug Administration (FDA). FDA-regulated studies include all research studies that involve an Investigational New Drug (IND or BB-IND), biologics, in vitro diagnostic product (IVD) or an Investigational Device Exemption (IDE). In addition, FDA-regulated studies include all research studies evaluating the safety and/or efficacy of drugs, biologics or devices for which an IND, BB-IND or IDE is not required.

"Study activities" means drug administration, device implantation or administration or any other activity that is required by the research protocol.

"Clinically relevant" means any study-related activity that could have an effect, adverse or otherwise, on the clinical treatment of the subject. This definition includes investigational drugs, devices, or biologics that could, separately or in combination with other substances or activities, interfere with the clinical treatment of the subject or place the subject at greater risk of harm.

"Sensitive" means any consent form whose disclosure outside of the study team or outside of Duke could result in financial, social, or personal harm to the subject. Financial harm includes, but is not limited to, adverse effects on employment or study status, adverse effects on the ability to maintain medical insurance, adverse effects on credit standing, or harm to career opportunities. Social harm includes, but is not limited to, damage to either friendships or memberships in social groups. Personal harm includes, but is not limited to, adverse effects on personal or familial relationships.

II. Requirements

A research consent form must be placed in the subject's medical record if it meets the definition of 'clinically relevant' as described above. The research consent form must always be placed in the participant's medical record in the case of FDA-regulated research studies. In all other cases, it is left to the discretion of the Principal

Investigator (PI) whether to place a copy of the consent form in the subject's medical record or to maintain it in the regulatory binder for the study.

It is the responsibility of the PI of a research study to determine whether or not study activities are considered clinically relevant. Likewise, it is the responsibility of the Principal Investigator to ensure that the consent form template for the study accurately describes whether or not the document will be placed in the medical records of study participants.

III. Sensitive Consent Forms

A consent form that meets the definition of 'sensitive' should not be placed in the subject's medical record unless it is determined to also be 'clinically relevant'.

IV. Studies with a Certificate of Confidentiality

A clinically relevant consent form for a study governed by a Certificate of Confidentiality (C of C) should be placed in the subject's electronic medical record. At the discretion of the PI, if there is information contained in the consent form that should be further restricted from view (i.e., information that is not contained elsewhere in the medical record), the PI should mark the consent form as "sensitive".

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