Mass General Brigham

Individuals Who Can Obtain Informed Consent in Human Subject Research

Informed consent must be obtained from a research participant or the participant's legally authorized representative as described in an IRB-approved study protocol. Depending on the nature and details of the study, the IRB may approve the Principal Investigator and/or other study staff to obtain informed consent from participants. The tables below summarize the IRB's policy on who can obtain informed consent for different types of studies. In all circumstances, the PI is responsible for providing training and oversight of research staff involved in the consent process according to the IRB-approved protocol and institutional policies. Please refer to the *Informed Consent of Research Subjects* policy for additional information.

Who Can Obtain Informed Consent by Role:

Role on Study Staff	Can Consent for Which Types of Research Study?	Backup Needed?
➢ Licensed Physician Principal Investigators and co-Investigators ➢ Licensed Doctoral-level Nursing Principal Investigators and co-investigators	➢ More than minimal risk ➢ IND/IDE ➢ Minimal risk	➢ None
➢ Principal Investigators who are: ▪ Licensed Clinical Pharmacists ▪ Licensed Psychologists ▪ Other clinically licensed faculty members ▪ Other IND/IDE holders	➢ More than minimal risk ➢ IND/IDE ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Principal Investigators who are non-licensed or non-clinical faculty including: ▪ Non-licensed Physicians ▪ Statisticians ▪ Physicists ▪ Epidemiologist ▪ Other doctoral-level scientists	➢ More than minimal risk ➢ Limited Investigational Device studies: Only Non-significant risk or IDE exempt ➢ Limited Investigational Drug studies: IND exempt ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Other licensed advanced practice provider co-investigators including: ▪ Licensed Nurse Practitioners ▪ Licensed Physician Assistants	➢ More than minimal risk ➢ IND/IDE studies ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Other study staff including: ▪ Study Nurses ▪ Research Coordinators	➢ Minimal risk* *Consent for minimal risk studies involving drugs or investigational devices should be obtained by clinically licensed staff, including study nurses, co-investigators, and PIs.	➢ Principal Investigator/Co-Investigators listed on study staff

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Who Can Obtain Informed Consent by Type of Study:

Type of Study	Who Can Obtain Consent?	Backup Needed?
➢ Investigational drugs and devices, including under IND/IDE ➢ More than minimal risk	➢ Licensed Physician Investigators (PI and co-Investigators) ➢ Licensed Doctoral-level Nursing Investigators (PI and co-investigators)	➢ None
➢ Investigational drugs and devices, including under IND/IDE ➢ More than minimal risk	➢ Principal Investigators who are: ▪ Licensed Clinical Pharmacists ▪ Licensed Psychologists ▪ Other clinically licensed faculty members ▪ Other IND/IDE holders ➢ Other licensed advanced practice provider co-investigators including: ▪ Licensed Nurse Practitioners ▪ Licensed Physician Assistants	➢ Licensed physician investigator listed on study staff
➢ Limited Investigational Device studies: Only Non-significant risk or IDE exempt ➢ Limited Investigational Drug studies: IND exempt ➢ More than minimal risk	➢ Principal Investigators who are non-licensed or non-clinical faculty including: ▪ Non-licensed Physicians ▪ Statisticians ▪ Physicists ▪ Epidemiologist ▪ Other doctoral-level scientists	➢ Licensed physician investigator listed on study staff
➢ Minimal risk studies involving drugs or investigational devices	➢ Clinically licensed study staff including study nurses, co-investigators, and PIs.	➢ Principal Investigator/Co-Investigators listed on study staff
➢ Other minimal risk studies, including those involving non-invasive approved medical devices (e.g., standard MRI, EEG, EKG, etc)	➢ Study staff including research coordinators/assistants	➢ Principal Investigator/Co-Investigators listed on study staff