SOFTWARE AS A MEDICAL DEVICE
GUIDANCE FOR RESEARCHERS

• Regulations relating to software used for therapeutic purposes have been introduced by the Therapeutic Goods Administration (TGA)
• Products that use software to analyse clinical data, such as blood test results or ECGs, to assist with diagnosis or managing illness are considered to be medical devices and need to be listed with the TGA
• Questionnaires designed to indicate a level of risk to certain diseases or health conditions are not generally be considered to be diagnostic, regardless of the method of delivery

Medical devices:
• are used for humans
• have therapeutic benefits
• generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body

Definition of a device:
A medical device is: any instrument, appliance, material or other article (whether used alone or in combination, including the software necessary for its proper application) intended to be used for human beings for a medical purpose, ie one or more of the following:
1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
3. investigation, replacement or modification of the anatomy or of a physiological process;
4. control of conception; and/or
5. that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means

Examples - Classified as a medical device:
• medical device software products that use a source of electrical energy to perform therapeutic functions
• a software product that manages and presents information, such as medical records management system or a dosage calculator, if it also incorporates a therapeutic or diagnostic function
• products that have a role in diagnosing or managing illness using software that analyses clinical data, such as results of blood tests or ECGs
• smart phone apps that measure blood glucose levels and patient body temperature
• diagnostic software

Examples - Not classified as a medical device:
• a software product that is limited to managing and presenting information, such as medical records management system or a dosage calculator, unless it also incorporates a therapeutic or diagnostic function
• mobile apps that are simply a source of information or health advice
• questionnaires relating to health, administered on a tablet or other device

For further information, please contact Clinical Trial Governance (clinicaltrialgovernance.research@sydney.edu.au) or refer to the TGA website (http://tga.gov.au/industry/devices.htm)