



Management of Incidental Findings At The EXPLORER Molecular Imaging Center

¹Ofilio Vigil, ¹Lorenzo Nardo, ²John Tupin, ¹Denise Caudle, ¹Cameron Foster,
^{1,3}Simon Cherry, ^{1,3}Ramsey Badawi, ¹Dana Little

¹Department of Radiology, UC Davis, ²Institutional Review Board, UC Davis,

³Department of Biomedical Engineering, UC Davis

Introduction: The world's first total-body PET scanner, EXPLORER, is operating at UC Davis Health (UCDH). It is utilized for research purposes and routine clinical PET/CT scanning. Given EXPLORER's long axial field-of-view (194 cm) and ultrahigh physical sensitivity, allowing for simultaneous imaging of the entire body, the discovery of incidental findings (IFs) related to clinical problems in research volunteers is likely, potentially requiring follow-up procedures exposing research participants to additional risks.

Methods: Lacking clear guidance in the context of this first-in-the-world scanner, we developed a plan to address IFs. We relay to participants, via the informed consent form (ICF), the possibility that findings related to a medical problem may be discovered. When an IF is identified, our clinical research team works with the Study Radiologist to contact participants within 8 weeks of the scan to discuss it. However, if the IF requires urgent action, participants are contacted according to the UCDH Department of Radiology guidelines related to emergency findings. During consent, we ask all participants to provide contact information for their medical provider. If a participant requests, we provide them with a subset of their images to share with their medical provider. The research team will send a letter (see Fig 1) to their provider stating the purpose for the scan, the discovery of a potential problem, and the contact information for the Principal Investigator/Study Radiologist.

Conclusion: The method for dealing with IFs is described in all EXPLORER protocols with appropriate language included in the ICF. Our goal is to mitigate risks due to unnecessary follow-up while capturing benefits from important clinical findings obtained during cutting-edge research on EXPLORER.