Standard Operating Procedure

Guidelines for Management of Incidental Findings

PC-SOP-GA-011-v04

Revision History

Version	Reason for Revision	Date
04	To reflect the change from the PERFORM Centre to the School of Health.	Nov/20/2023

Summary

This document provides guidelines for handling and communicating any suspected incidental findings of potential clinical relevance during any activities at the School of Health.

1. Introduction

1.1. Background

Incidental findings (IFs) are unexpected discoveries or observations of potential clinical significance (i.e., having potentially significant welfare implications for the participant) detected during an activity, that is outside the scope, or unrelated to the purpose or variables, of the activity.

The potential for IFs is inherent in all activities that observe, measure, or analyze the status or responses of human participants (and human-derived materials). IFs must be discussed in the context of research and addressed through ethical review and participant informed consent (refer to Concordia Policy VPRGS-3: Policy for the ethical review of research involving humans). However, the inter-disciplinary variety of human participant activities at the School of Health which might reveal IFs leads us to pursue a comprehensive framework to deal with IFs in all instances.

1.2. Purpose

These guidelines are intended to assist both School of Health users (researchers, laboratory workers, employees, educators, students, etc.) and participants in adopting a consistent approach to considering the possibility for IFs before undertaking their activities, and how to deal with them should they arise. This process should make clear to all users and participants that they should expect no diagnostic report on the finding (if outside either the user's professional scope of practice or the activity mandate), and that the participant will be referred elsewhere to seek a medical opinion if they so desire.

1.3. Scope

This SOP applies to people operating at the School of Health in activities involving human participants.

The scope of this SOP covers a minimum set of guidelines for demonstrating a deliberate process to consider and address IFs in activities undertaken at the School of Health, for the purpose of observing, measuring, or analyzing the molecular, physiological, or psychological status or responses of human participants (and human-derived materials).

Each individual research study, protocol, teaching activity or community service could include additional requirements, conditions, and processes (such as those imposed by a particular research ethics board) for recording and reporting on activity-specific factors including IFs outside the scope of this SOP.

1.4. Responsibility

All those working at the School of Health with human participants are responsible for acting within their mandate and within the defined scope of their activity/study, which includes being able to distinguish what lies outside of scope for a given measurement. At all times, it is the responsibility of the user to ensure they act in a manner which respects any demands of their professional order or designation.

It is the Directors responsibility to ensure a program is in place to communicate the School of Health's SOP on IFs to users.

It is the PI's responsibility to ensure anyone under their supervision is:

- trained on this SOP
- understands the scope of their activities
- knows how to respond to an IF and respond to it in concordance with this SOP and any other ethical consideration which would apply.

Any School of Health employee observing a suspected IF while providing support to research teams, will report the suspected IF to the PI. PIs are responsible for reporting IFs which have been properly assessed and are considered to potentially represent a health hazard (whatever the nature or severity of this) to participants and follow up as outlined in their protocol.

1.5. Relevant Documents

This SOP is governed by the following Concordia University policies and School of Health SOPs and PODs:

- Concordia Policy VPRGS-3: Policy for the ethical review of research involving humans.
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.
- Zawati, MH et al. Incidental findings in data-intensive postgenomics science and legal liability of clinician-researchers: ready for vaccinomics? OMICS 15(9):615-625, 2011.
- Suspected Incidental Finding Record
- Approval to share participant data

NOTE: This SOP defers to Concordia Policies at all times

2. Guidelines for addressing incidental findings

Activities at the School of Health which are not intended as clinical or medical investigations can still reveal unexpected observations of potential clinical significance for the participant.

These guidelines do not cover professional responsibility or liability, but instead provide guidance for anyone conducting activities at the School of Health who determines they have sufficient cause to suspect an IF. PIs or project leads articulating their IF plan of action shall consider the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans on IFs which states:

- PI's have an obligation to disclose IFs that have been interpreted as having significant implications to the participant whether health related, physiological, psychological, or social.
- In some cases, PI's may have good reasons to question whether reporting a suspected IF to a certain participant may cause more harm than good. In such a situation PI's should consult colleagues and their ethics board (see Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010; p.34)

As most activities at the School of Health will not involve interpretation of IFs, a general consideration for all should be simply to notify the relevant PI by completing the Suspected Incidental Finding Record. The PI will be responsible for deciding whether further action is necessary (outside evaluation, contacting the subject, etc.).

All activities can follow three simple steps to deal effectively with IFs: inform, assess, and act.

2.1. Inform

Each responsible PI should ensure that they or users on their teams communicate, the activity/study's scope (limitations and exclusions), the possibility of IFs, and the process for communicating IFs with potentially significant welfare implications to participants prior to them continuing the activity. It should be clear to the participants not to expect a medical interpretation of the findings outside the requirements of the professional scope of practice of the user or outside the scope of the activity/study.

2.2. Assess

Anyone conducting an activity with participants or reviewing participant data is exposed to situations where they may encounter what they suspect to be an IF (with potentially significant welfare implications), that lies outside the scope of the study/activity. Before acting upon such an observation, it is expected that users of the School of Health

exercise sound judgment while considering the participant's immediate safety as well as providing information within the limits of their scope of practice.

2.3. Act

In the event of a suspected IF, the user should immediately inform the responsible PI by emailing the suspected incidental finding record. If the situation is one of immediate physical threat to the participant, it is understood the PI may deem it necessary to communicate to the participant that a suspected IF has been detected and that the participant is advised to rapidly seek a medical opinion.

- The PI will ask the participant to provide their approval in writing before School of Health sends their health service provider the data that gave rise to the suspected IF in any case where an IF has been deemed worthy of further follow-up (see Approval to share participant data with medical professional form).

In cases where the PI has decided that an observation is indeed an IF and that such a finding must be communicated to the participant, follow up should be according to what the participant stipulated in the consent form for such a situation. However, after having initially consented to have information transferred to their primary physician, the participant could still decide not to transfer information to a medical professional; then School of Health users will fill out the Suspected Incidental Finding Record stating that the PI has ethically acted upon the suspected IF. (see Suspected incidental findings record form)