## Overview of study protocol and ethics documents

- Ethics approval was sought as an **amendment to** a larger Breast Screen Ophelia study within which these RCTs were conducted (see '1. Study Protocol', which describes this amendment). Please note, this Study Protocol initially included 3 study arms, with the third arm receiving both a letter and a phone call. This Study Protocol was approved by Deakin University Human Research Ethics Committee (DUHREC) as an amendment on 22/05/2017.
- Prior to registration of the trial with ANZCTR, BSV informed us that due to an overestimation of
  the number of women who were forecast to receive their 2-yearly reminder letter, they
  considered that it was not achievable to also include the third arm (letters and phone calls). This
  group was therefore dropped from the trial, and was not included in the information provided
  to ANZCTR. The trial was submitted to ANZCTR on 28/07/2017 and registered on 8/8/17.
- We notified DUHREC that the third arm of the trial was not included (see 2. Ethics Modification\_Application and protocol). This modification was approved on 16/1/18.
- The original protocol also includes a secondary outcome being the source of referral as selfreported by women when booking a screening appointment; however, this data was never collected as BreastScreen Victoria decided the data were unlikely to be reliable.