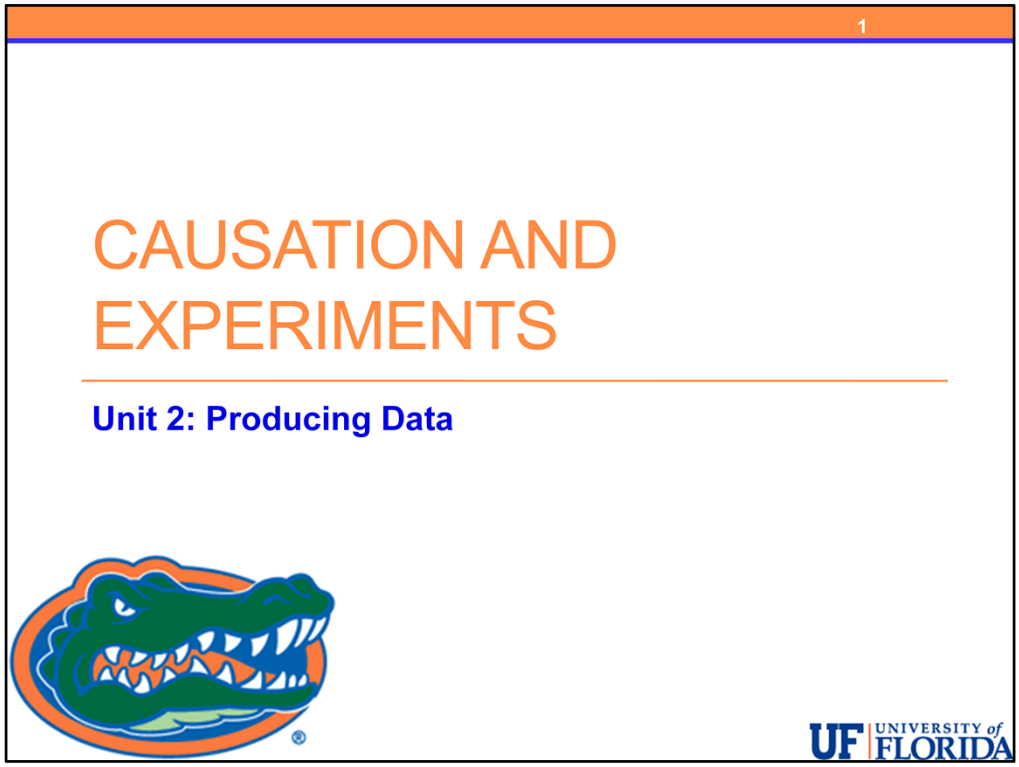
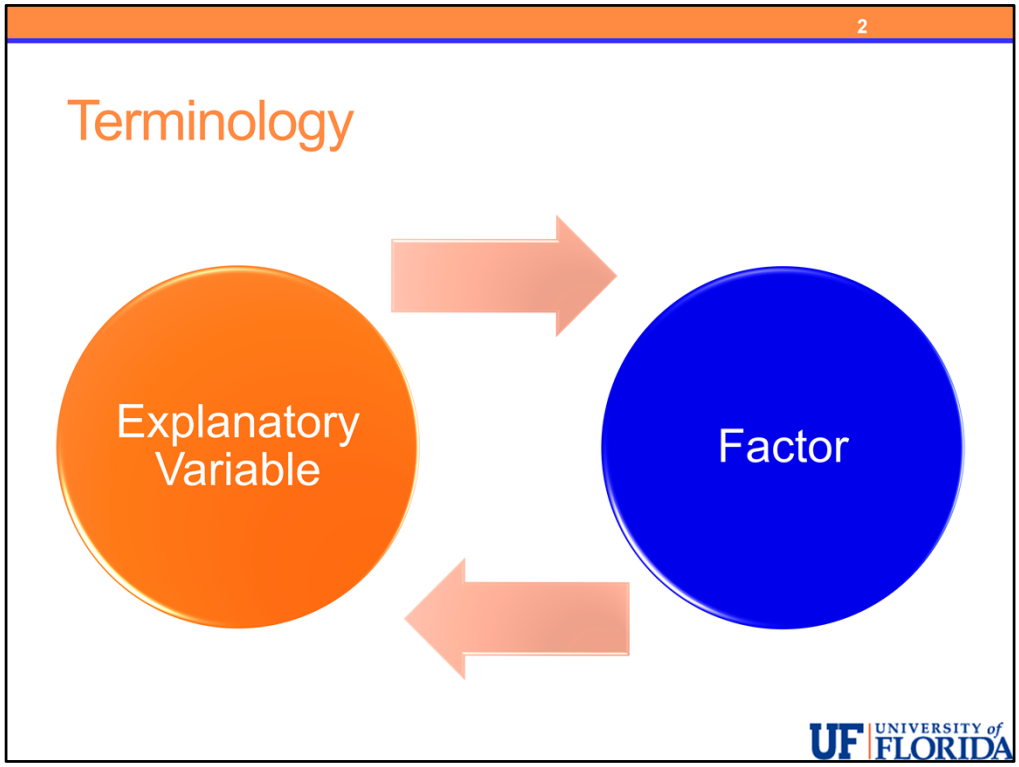


When we wish to show a causal relationship between our explanatory variable and the response variable, a well designed experiment provides the best option.

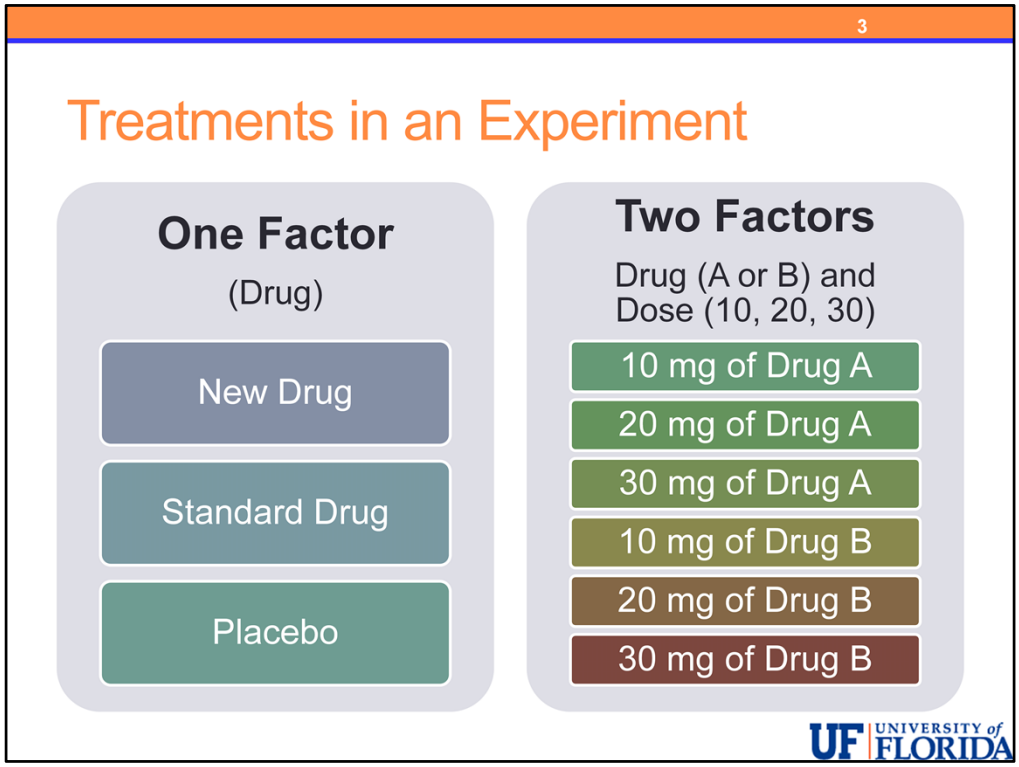
Here, we will discuss a few basic concepts and definitions associated with experiments and talk about the strengths and limitations of using an experiment in practice.



Designed Experiments have developed their own terminology. The individuals in an experiment are often called “subjects.”

And the explanatory variables in an experiment are called factors.

Sometimes we may have more than one factor in a particular experiment – for example, drug and dose might be two factors in an experiment to compare a new drug to an older one. In our course, we will focus on one factor but we will briefly discuss how multiple factors are addressed in an experiment.



The different possible values the subjects can receive are called treatments. The treatments in an experiment can represent the levels of one factor or combinations of levels of two or more factors.

Let's discuss a few examples to clarify.

When there is only one factor – then the treatments in our experiment will simply represent the levels of our single factor – for example – suppose we have a new drug and we wish to compare it to the standard drug and to a control group – which is given a placebo (which contains no drug, possibly in the form of a sugar pill). In this case, we would have three treatments corresponding to the three possible values which could be assigned to participants in the study – New Drug, Standard Drug, and Placebo

If there are two factors (or more), the treatments usually represent all possible combinations of the two factors – if we wish to study both the drug (A or B) and the dose (say 10, 20, and 30 mg), then there would be 6 treatments (two drugs times three doses). Each representing one combination of drug and dose.

We would have 10 mg of Drug A, 20 mg of Drug A, and 30 mg of Drug A and the same for Drug B (10, 20, and 30 mg).

Control groups may or may not be included in an experiment. A control group receives no treatment, sometimes in the form of a placebo that looks exactly like the actual

treatment(s).

Notice also that the word “control” is used in different contexts –

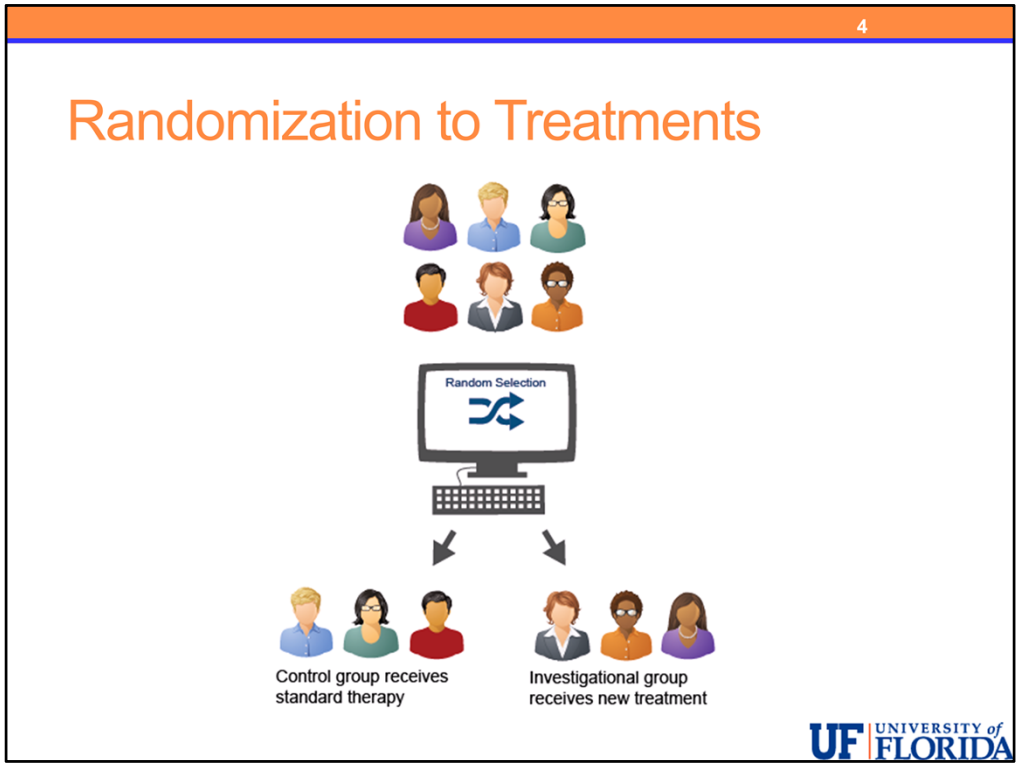
- We can control for a confounding variable by stratifying our analysis in an observational study.
- We can perform a controlled experiment where researchers assign the treatments as opposed to having them occur naturally.
- We can have a control group in a designed experiment for the purpose of comparison to the treatment under study.

Sometimes it is not ethical to provide “no treatment” to individuals in the study and sometimes a study of the effect of one particular treatment may be all that is of interest.

Ideally, the subjects in each treatment group should differ from those in the other treatment groups only with respect to the treatment.

Eliminating all other differences among treatment groups is the key to asserting causation in an experiment as it minimizes the effect of lurking variables on the results of our study.

Now we address how randomization is used to accomplish this goal.



It should be reasonable that by randomizing subjects to treatments we should end up with groups that are similar to each other – once we apply our treatment to the randomly chosen individuals, the groups should differ only with respect to the treatment under study.

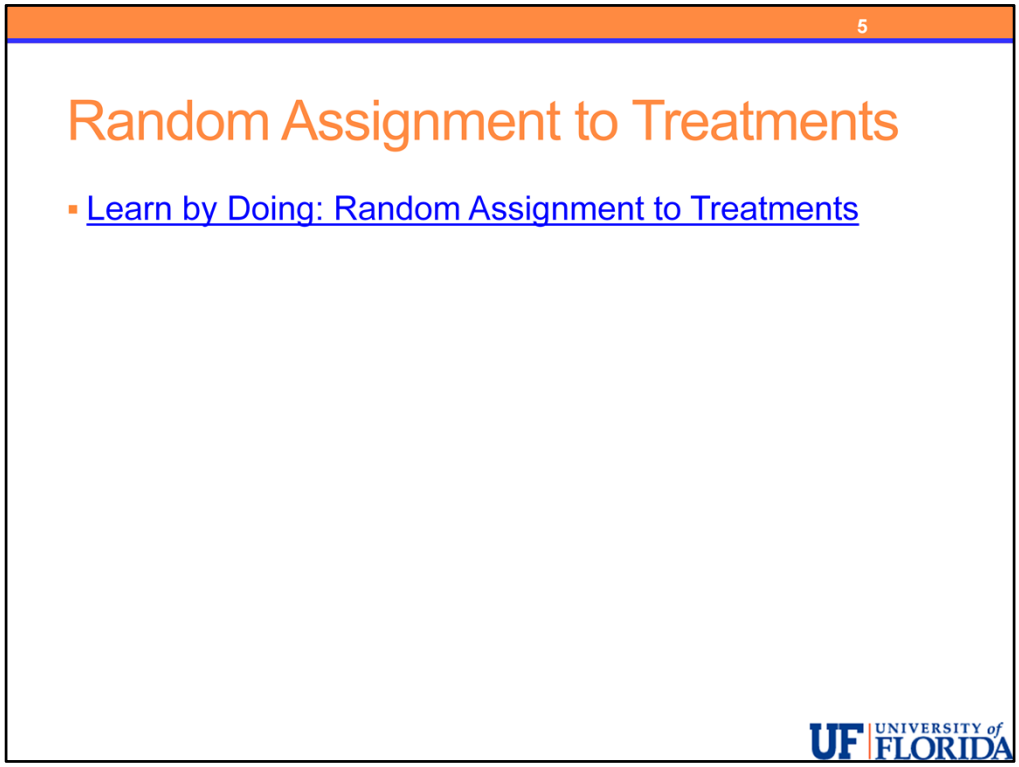
There are two possible ways randomization can enter into an experiment.

First, we may be able to select a simple random sample or other probability sample to determine who will participate. This is not always possible, as in experiments, especially those in the health sciences, we often must use individuals who voluntarily agree to be in our study.

Once we have our sample, subjects are randomly assigned to treatments in order to minimize the impact of lurking variables and to have a greater chance to establish a causal relationship between our treatment and the response of interest to the researcher.

Randomization also helps prevent bias by removing any human element from the assignment process.

In experiments – the most vital stage for randomization is during the assignment of treatments rather than the selection of subjects.



Weblink: {http://bolt.mph.ufl.edu/2012/12/29/learn-by-doing-random-assignment-to-treatment-software/}

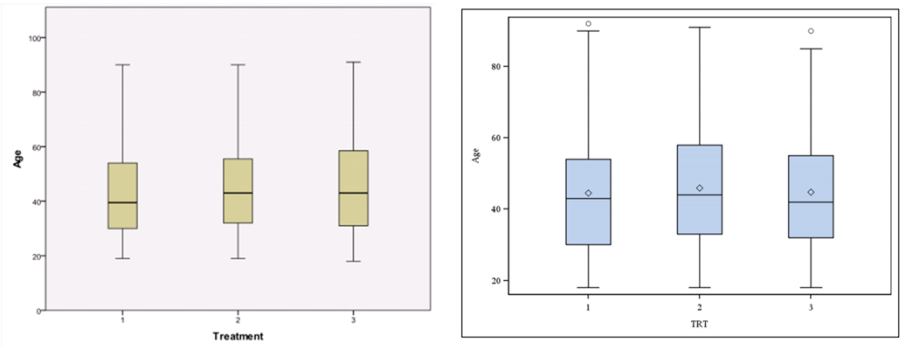
In the materials, there is an activity which illustrates how randomization works to form treatment groups which are similar.

The dataset contains three variables: age, gender, and the number of hours of computer use each week.

We will randomize each person into one of three treatments. What the treatments represent is not important now – you can read more about it online – our goal is to show you that when we randomly create groups, the resulting groups should be similar in age, gender, and the number of hours of computer use each week.

Here are the results of two different randomizations:

Age



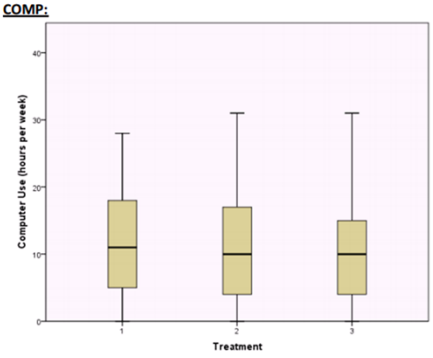
UF UNIVERSITY of FLORIDA

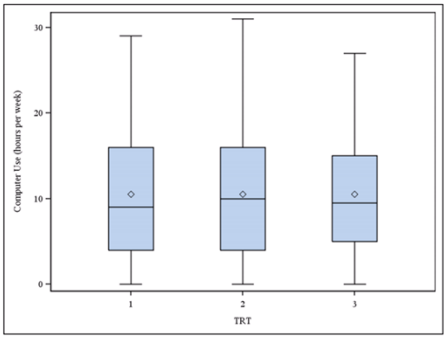
We won't expect EXACTLY the same distribution in each treatment group for our variables however in these two different randomizations, you can see that the ages of individuals in the three treatment groups are very similar. There are no clear difference in age.

It is possible that, even with randomization, groups can be significantly different but it is rare for this to happen with proper randomization.

Hours of Computer Use

COMP:





UF UNIVERSITY of FLORIDA

For computer use, again, a very similar distribution in the three treatment groups. The randomization effectively spreads subjects out evenly into the groups.

Gender

Treatment * Gender Crosstabulation

			Gender		Total
			Female	Male	
Treatment	1	Count	82	78	160
		% within Treatment	51.3%	48.8%	100.0%
	2	Count	79	64	143
		% within Treatment	55.2%	44.8%	100.0%
	3	Count	74	73	147
		% within Treatment	50.3%	49.7%	100.0%
Total		Count	235	215	450
		% within Treatment	52.2%	47.8%	100.0%

Frequency
Percent
Row Pct
Col Pct

Table of GENDER by TRT

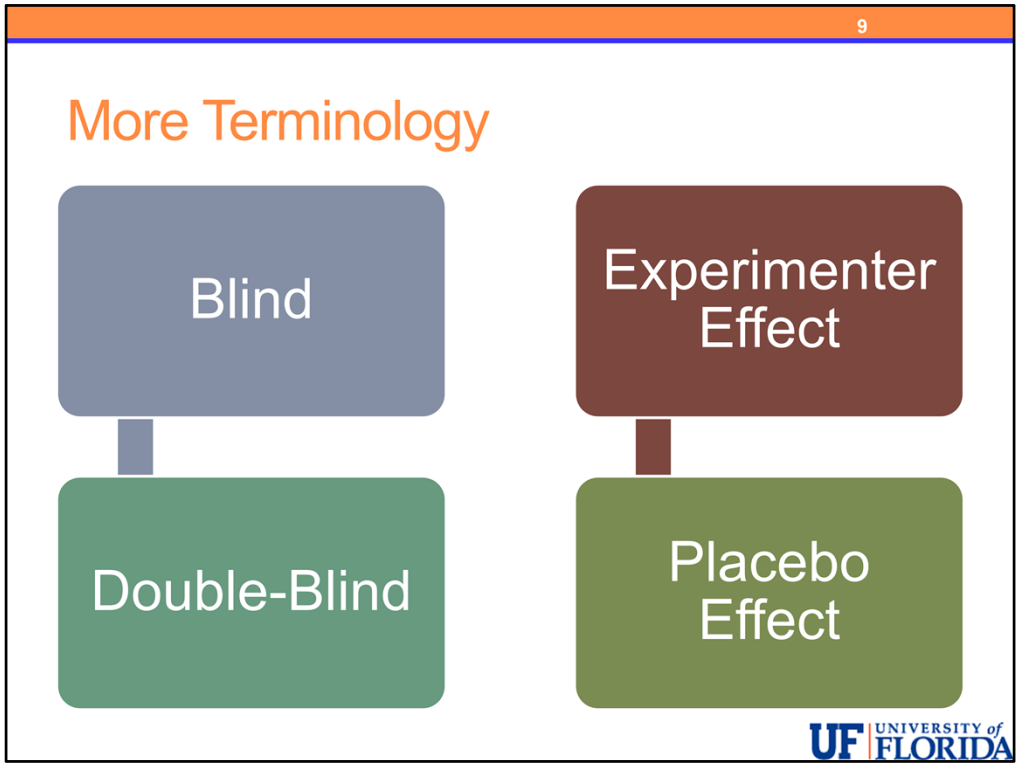
GENDER(Gender)	TRT 1	TRT 2	TRT 3	Total
Female	62 13.78 28.70 42.18	69 15.33 31.94 47.59	85 18.89 39.35 53.80	216 48.00
Male	85 18.89 36.32 57.82	76 16.89 32.48 52.41	73 16.22 31.20 46.20	234 52.00
Total	147 32.67	145 32.22	158 35.11	450 100.00

UF UNIVERSITY of FLORIDA

And finally for gender – we see that we get roughly half men and half women in each treatment group.

In the randomization on the right we do see more variation – however the amount of variation is still within reasonable limits for randomization into treatment groups.

Again, the idea is that by randomizing individuals into treatment groups – we will minimize the effect of any important lurking variables – by evenly distributing subjects into each treatment group – and minimize bias by removing the researcher from the process of assigning subject to treatments directly.



If possible, subjects should be blind to which treatment they receive – this eliminates any bias which might be introduced into the experiment due to the subject's knowledge and/or investigation.

Placebos are often used to help blind subjects (and researchers as we will mention shortly). Subjects are given a treatment which is as similar to the actual treatment under study and yet does not have the same effect. For drugs which are taken orally – this involves creating a pill which has no active ingredients which looks the same as the actual treatment.

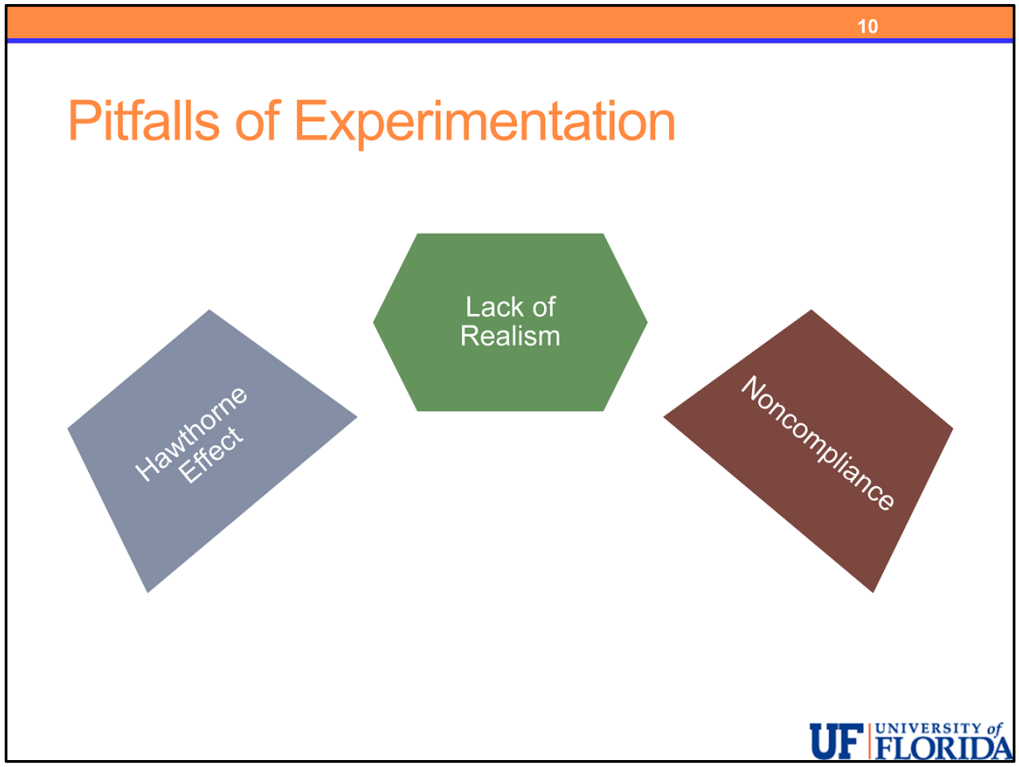
Sometimes – creating a placebo can be difficult since it is obvious to the patient which intervention is being applied.

The placebo effect occurs when patients improve because they are THINK they are receiving treatment, even though they are not.

In order to prevent the experimenter's ideas from influencing the results, the researchers are also often blinded to the treatment applied. Often, researchers CANNOT know which treatment is applied to which patient until after the study is completely finished and the data are about to be analyzed. Possibly they may not be unblinded until after the analysis is complete – to avoid any possible bias by the researcher.

The most reliable way to determine whether the explanatory variable is actually causing changes in the response variable is to carry out a **randomized controlled double-blind**

experiment



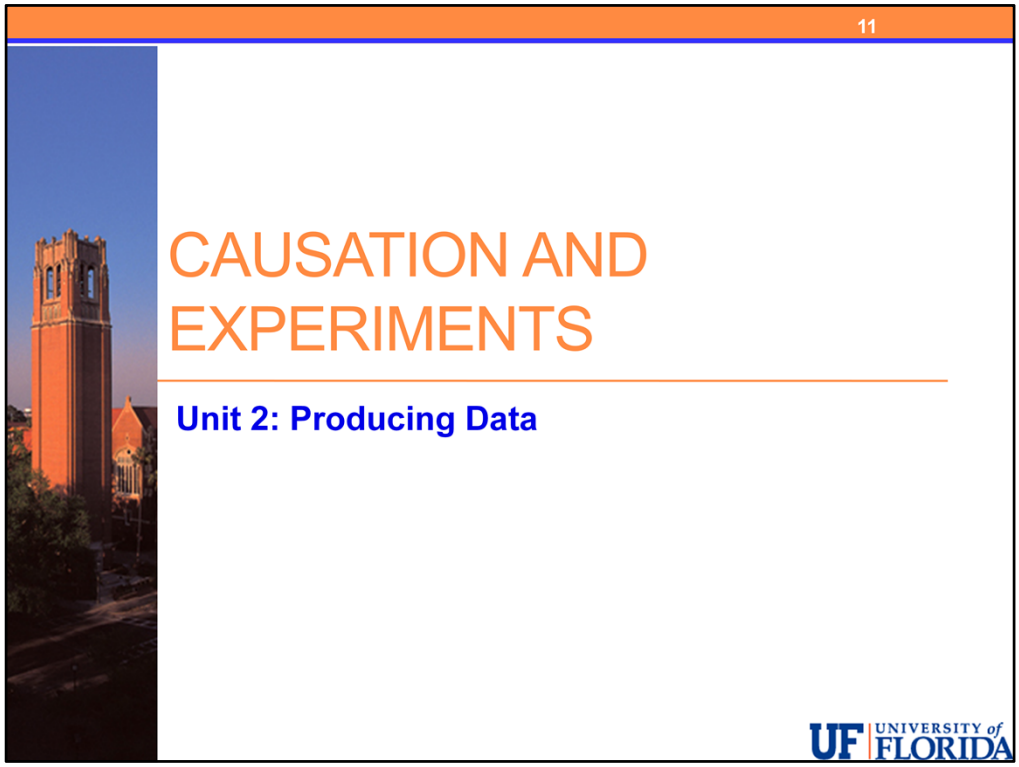
Some problems with experiments relate to human behavior.

The **Hawthorne Effect** results when people in an experiment behave differently from how they would normally behave.

Lack of realism (also called **lack of ecological validity**) – results when the fact that researchers take control of the explanatory variable results in a rather unrealistic setting.

Noncompliance - is in an issue in experiments due to the fact that some subjects will fail to submit to the assigned treatment or fail to follow their treatment precisely.

Although randomized controlled double-blind experiments are the "gold standard" it often may not be possible to study a particular topic in this way due to ethical considerations – and even if you can carry out the experiment – the issues discussed here may still impact the usefulness of the study's results.



There are strengths and limitations associated with both observational studies and designed experiments.

Remember that the main difference is that in observational studies the explanatory variable's values are allowed to occur naturally whereas in experiments, the explanatory variable's values are controlled by the researcher, the treatment is imposed.