Topic	Guiding protocol	Application
Administrative information		
Title	1,2,4	An evidence synthesis of the academic responsive regulation literature: Protocol
Date		Approved by JH and NV on 17 March 2020.
Update/version	1, 4	This is the first version (v1) of the protocol.
Registration	1, 4	No formal registration sought. This protocol was published on 17 March 2020, prior to undertaking the evidence synthesis, on https://jeroenvanderheijden.net/?p=333
Corresponding author(s)	1, 4	Corresponding author: Jeroen van der Heijden, Victoria University of Wellington Mobile +64 (0)22 563 5082 Room 821a, Rutherford House, Pipitea Campus PO Box 600, Wellington 6140, New Zealand jeroenvanderheijden@vuw.ac.nz
Contributors, contributions	1, 4	JH is author of this protocol. The protocol takes inspiration from a series of handbooks on meta-analysis, systematic reviews, and evidence synthesis (including, but not limited to: Card, 2015; Cooper, 2017; Cooper, Hedges, & Valentine, 2019; Eklund Karlson & Takahashi, 2017; Gough, Oliver, & Thomas, 2012; Heyvaert, Hannes, & Onghena, 2017; Howell Major & Savin-Baden, 2010; Ringquist, 2013; Saini & Shlonsky, 2012). The second reviewer (NV) read, provided feedback and approved this protocol.
Amendments	1, 4	If this protocol needs amendments, these will be explained in an updated version of the protocol. Each amendment, description of changes made, and the rational for making changes will be described.
Support	1, 4	This evidence synthesis does not receive targeted funding or financial support. JH is the Chair in Regulatory Practice at VUW. This role is partially funded by the New Zealand Government Regulatory Practice (G-REG) initiative. The evidence review will be used for educational purposes, including the G-REG ongoing professional education program. NV was contracted by the Chair for support with the review.
Sponsor	1, 4	None.
Role of sponsor	1, 4	N/A.
Introduction		
Rationale	1, 2, 3, 4	In 1992, Ayres and Braithwaite published *Responsive Regulation*. The responsive regulation strategy introduced in the book has become one of the most discussed regulatory strategies in the academic literature (Braithwaite, 2011; Parker, 2013). Yet, it remains unknown: - Whether (on average) responsive regulation outperforms the (counterfactual) regulatory strategies it replaces (i.e., traditional government-led command and control regulation, or laissez-faire market competition) - Under what circumstances responsive regulation works best. Synthesizing the empirical knowledge base of the responsive regulation literature may help to fill these knowledge gaps.
Objectives	1, 2, 3, 4	The aim of this evidence synthesis is to evaluate the effectiveness (and lack thereof) of responsive regulation applied to real-world situations. To this end, this evidence synthesis will answer the following questions: 1. What is the breadth, purpose and extent of research activity on responsive regulation? 2. Compared to the (counterfactual) regulatory strategies that responsive regulation replaces (i.e., traditional government-led command and control regulation, or laissez-faire market

		competition), what is the (average) comparative effectiveness of responsive regulation in achieving regulatory goals? 3. What are the advantages and limitations of responsive regulation compared to the strategies it replaces (i.e., traditional government-led command and control regulation, or laissez-faire market competition)? 4. For questions 2 and 3, if heterogeneity is found in studies on responsive regulation: Under what circumstances, in what situations, and for whom does responsive regulation provide better outcomes than the strategies it replaces (i.e., traditional government-led command and control regulation, or laissez-faire market competition)?
Methods		
Eligibility criteria	1, 2, 3, 4	Studies will be selected according to the PICO criteria (participants, interventions, comparators, outcomes) outlined below: *Study designs* We will include any type of empirical study that assesses the performance of an observed situation of responsive regulation that is explicitly framed as meeting the theory and heuristics provided in *Responsive Regulation*. We will only assess unique empirical studies once. If an individual study is reported in multiple publications, we will collate reported research and performance information for that study. *Participants* There will be no restrictions by background, type or number of participants (including, but not limited to, people, firms, regulators, and jurisdictions) of studies. *Interventions* Of interest are studies that empirically observe the application of responsive regulation strategy as introduced by Ayres and Braithwaite (1992). These authors explicitly state that the strategies may result in several regulatory approaches. In *Responsive Regulation*, they introduce Tit-for-Tat regulation (illustrated with regulatory pyramids), tripartism (in which public interest groups are involved in rulemaking and implementation), enforced self-regulation (in which firms write their own self-regulation requirements that are publicly ratified and enforced), and partial-industry regulation (in which regulators seek to leverage off the competitive conduct of an entire industry by regulating some but not other firms). Braithwaite has later introduced restorative justice (a mediation based justice approach that brings together victims and offenders) as another responsive regulation approach (Braithwaite, 2002). Other (clusters of) approaches may be uncovered during the selection and review process. *Comparators* Given the broad perspective of the responsive regulation approaches of interest and the unlikeliness of (a significant number of) studies that compare a pre-responsive regulation situation with the responsive regulation situation, several comparisons will be relevant to include: - Direct observations: studies that compare the current responsive regulation situation with a previous other situation (e.g., traditional government-led command and control regulation, or laissez-faire market competition) - Counterfactual observations: studies that compare a responsive regulation situation with a counterfactual non-responsive regulation

		situation (e.g., traditional government-led command and control regulation, or laissez-faire market competition) - Indirect observations: studies that explicitly seek to explain the effects of the responsive regulation situation, but without explicitly comparing these to an earlier or counterfactual situation. *Outcomes* Endpoints important for theory testing are of primary interest. Endpoints important for decision making are of secondary interest (needless to say, there is overlap between the two). - Endpoints important for theory testing: o Increased levels of compliance o Reduced compliance costs for the regulator o Reduced compliance costs for the regulatee o Reduced time for the regulator to achieve compliance (between observing a violation and compliance) o Reduced time for the regulatee to achieve compliance (between a violation is observed and compliance achieved) - Additional endpoints important for decision making: o Improved relationships with regulatees o Spill-over effects (higher levels of compliance because regulatees become aware of the new approach to regulation) o Improved working conditions for staff *Timing* There will be no restrictions by time, length, or repetitions (including no repetitions) of studies. *Setting* There will be no restrictions by the setting(s) of studies. *Language* We will include articles reported in English. *Academic literature* We will only include published peer-reviewed articles, including 'online first' and 'early access' publications. We will acknowledge the limitations of excluding non-published academic work and academic publications other than peer-reviewed articles when reporting findings from the evidence synthesis (cf., Vevea, Coburn, & Sutton, 2019). *Non-academic literature* There will be no selection of non-academic literature. Our interest is primarily in empirical findings on responsive regulation reported by the academic community. We will acknowledge the limitations of excluding non-academic literature when reporting findings from the evidence synthesis (cf., Mahood, Van Eerd, & Irvin, 2014).
Information sources	1, 4	Both qualitative and quantitative studies will be sought. Documents will be sourced from the following databases: WorldCat, Scopus and Web of Science.
Search strategy	1, 2, 3, 4	Search strategies for each database: - WorldCat search: o all articles with the words "responsive regulation" in their keywords, published in English, since 1992, in the following subject areas: business and economics, law, sociology, political science. - Scopus search:

		○ all articles with the words "responsive regulation" in their titles, abstracts, or keywords, published in English, since 1992 in the following subject areas: social sciences; business, management and accounting; economic, econometrics and finance. - Web of Science search: ○ all articles citing the book *Responsive Regulation* using 'cited reference search' for the combination ayr* (cited author) AND res* (cited work), published in English, since 1992, in the following disciplines: business, criminology, law, economics, management, political science, public administration, public policy, social sciences interdisciplinary, sociology. ○ all articles with the words "responsive regulation" in any searchable field, published in English, since 1992, in the following disciplines: business, criminology, law, economics, management, political science, public administration, public policy, social sciences interdisciplinary, sociology. This search strategy is conventional for the type of evidence synthesis proposed. The main difference with these 'conventional' document searches is that we will add a 'cited reference' search in Web of Science to identify works that have cited the book *Responsive Regulation*. The combination of search terms for the cited reference search (see above) is likely to overcome the most common typographical errors in citations to the book.
Study records and data management	1, 4	Depending on the number of articles included in the evidence synthesis after the selection process (see below), we will decide whether to use an (online) application that facilitates collaboration among reviewers during the data abstraction process such as EPPI-Reviewer or Distiller Systematic Review. If we include fewer than 40 articles, we will not use an (online) application.
Selection process	1, 2, 4	Two reviewers (JH and NV) will independently screen articles against the following inclusion criteria. This will be done in three rounds: - Round 1 ○ Article titles, abstract and keywords will be screened to exclude articles that are unlikely to deal with a responsive regulation approach, that are explicitly not empirical, or both. The reviewers will use the following scores: yes (include), no (exclude), unsure (include). Intercoder reliability scores will be reported (agreement percentage and Cohen's kappa). - Round 2 ○ Article research design sections (or similar) will be screened to exclude articles that are not dealing with a responsive regulation approach, and article method sections (or similar) will be screened to exclude articles that are explicitly not empirical. The reviewers will use the following scores: yes (include), no (exclude), unsure (include). Intercoder reliability scores will be reported (agreement percentage and Cohen's kappa). - Round 3 ○ Articles are screened in full to exclude articles that are not dealing with a responsive regulation approach, that are explicitly not empirical, or both. The reviewers will use the following scores: yes (include), no (exclude), unsure (include). Intercoder reliability scores will be reported (agreement percentage and Cohen's kappa).

		- Round 4: - Articles are screened in full to cluster articles that report on the same study (this to prevent 'double counting' of individual studies). To ensure consistency across the reviewers, we will conduct calibration exercises. We will resolve disagreements by discussion.
Data items (variables and outcomes)		
Data abstraction	1,2, 3, 4	Data will be abstracted from the articles following the PICO criteria discussed above. Data abstracted will be recorded in text (to be coded later). A standardized Excel form will be used to ensure that both reviewers (JH and NV) abstract similar data from the articles. To ensure consistency across the reviewers, we will conduct calibration exercises. We will resolve disagreements by discussion.
Primary variables	1, 2, 3, 4	JH and NV will abstract: - Geographical location lead author - Geographical location(s) responsive regulation approach(es) studied - Calendar year(s) responsive regulation approach(es) implemented - Calendar year(s) responsive regulation approach(es) studied - Policy area(s) responsive regulation approach(es) studied - Type of observation (direct, counterfactual, indirect – see above)
Secondary variables	1, 2, 3	JH will abstract: - Type(s) of responsive regulation approach(es) implemented (i.e., Tit-for-Tat, tripartism, enforced self-regulation, partial industry regulation, restorative justice, other) - Reason(s) responsive regulation approach(es) implemented - Prior regulatory challenge or problem addressed (if applicable) - Regulatory strategy replaced (if applicable) - Other relevant observations about the 'input' or 'throughput' of responsive regulation approach(es) implemented
Primary outcomes	1, 2, 3, 4	JH and NV will abstract (if applicable/reported): - Increased levels of compliance - Reduced compliance costs for regulator - Reduced compliance costs for regulatee - Reduced time for regulator to achieve compliance (between observing violation and compliance) - Reduced time for regulatee to achieve compliance (between a violation is observed and compliance achieved)
Secondary outcomes	1, 2, 3	JH will abstract: - Improved relationships with regulatees - Spill-over effects (higher levels of compliance because regulatees become aware of the new approach to regulation) - Improved working conditions for staff - Other relevant observations about the 'output' or 'outcome' of responsive regulation approach(es) implemented
Risk of bias individual studies		
Risk assessment	1, 4	We expect to predominantly find single-n in-depth, or small-n comparative qualitative studies. This limits the extent to which we can use accepted protocols for assessing potential bias of these studies. To the extent possible, the reviewers (JH and NV) will assess selection bias, performance bias, detection bias, attrition bias and reporting bias (cf., Mayo-Wilson & Grant, 2019). This will be done at the time of round 3 of the selection process (discussed above). The reviewers will use the following scores: low risk of

		bias, unclear risk of bias, high risk of bias. Intercoder reliability scores will be reported (agreement percentage and Cohen's kappa).
Data synthesis		
Quantitative synthesis, methods	1, 2, 4	It is not expected that we will find a large enough number of studies that report an effect-size to allow for a quantitative synthesis (e.g., fixed effects or random effects models).
Additional quantitative analyses	1, 2, 4	If possible, we will provide descriptive statistics when presenting the findings from the evidence synthesis – while keeping in mind the risks of such 'vote counting' (cf., Borenstein, Hedges, Higgins, & Rothstein, 2009).
Qualitative synthesis, methods	3	If the abstracted data allow, we will follow a realist synthesis approach, "a theory-driven synthesis aimed at unpacking mechanisms of how complex programs or interventions work (or why they fail) in particular contexts and settings." (Heyvaert et al., 2017, 237)
Additional qualitative analyses	3	If the abstracted data do not allow for a realist synthesis approach, we will fall back on a more traditional (but systematic) narrative synthesis approach and present findings in a transparent, consistent and comprehensive manner. We will aggregate and integrate data where possible (i.e., qualitative vote counting and qualitative taxonomies), and aim to generate a new inductive understanding of responsive regulation (i.e., an interpretive approach) (cf., Howell Major & Savin-Baden, 2010; Saini & Shlonsky, 2012).
Meta-bias(es)		
Assessment	1, 3, 4	The main publication bias that our evidence synthesis is subject to is the sole focus on articles in peer-reviewed academic journals. There is a risk that we will find a relatively high number of positive experiences with responsive regulation approaches that may not be representative of all the experiences with responsive regulation (i.e., a selective reporting bias). We will be explicit about this possible bias when presenting the findings of the evidence synthesis. Unfortunately, we will not be able to run tests for sample biases (cf., Hardwicke et al., 2020) as we expect to predominantly find single-n in-depth, or small-n comparative qualitative studies.
Confidence or quality assessment		
Method	1, 2, 3, 4	We expect to predominantly find single-n in-depth, or small-n comparative qualitative studies. This limits the extent to which we can use accepted protocols for assessing the quality of these studies. To the extent possible, the reviewers (JH and NV) will assess the quality dimension of the studies using the CASP Checklist for qualitative research (CASP, 2018). This will be done at the time of round 3 of the selection process (discussed above). The reviewers will use the following scores: risk of low quality, unclear risk of low quality, little risk of low quality. Intercoder reliability scores will be reported (agreement percentage and Cohen's kappa). Please note, this quality dimension assessment is not meant to judge the quality of the individual studies, but to assess how much weight we can reasonably assign to findings presented in the evidence synthesis (cf., Heyvaert et al., 2017).

Guides used: (1) AMSTAR 2 = MeaSurement Tool to Assess Systematic Reviews version 2 (Shea et al., 2017); (2) MARS = American Psychological Association (APA) Meta-Analysis Reporting Standards (essentially the MARS protocol is modified from, Cooper, 2017); (3) MMRS = Mixes Methods Research Synthesis protocol (Heyvaert et al., 2017) (4) PRISMA-P = Preferred Reporting Items for Systematic Meta-Analyses (Shamseer et al., 2015).

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